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TITLE: ARTICLE: **Protecting Nursing Home Companies:** Limiting Liability Through Corporate Restructuring

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TEXT:

ABSTRACT: **Nursing homes** face two potential risks: exclusion from the Medicare and Medicaid programs; and financial liability through Medicare and Medicaid overpayments, false claims, and negligence actions. Given the current budget crisis and the scrutiny of **nursing homes**, the magnitude of these risks is only expected to increase. The authors address the increasing risks that **nursing homes** face and propose the creation of single-purpose ownership entities and single-purpose operating entities to minimize risk. In addition, they examine recent cases to show what factors the courts use to allow the United States and private plaintiffs to pierce the corporate veil. The authors conclude by showing how restructuring can reduce the unnecessary risks of exclusion and financial liability.

A corporation is an autonomous entity "separate and distinct from its shareholders, directors and officers, and generally, from other corporations with which it may be affiliated." . . . This autonomy shields parties related to a corporation from the liabilities of that corporation. . . . Indeed, one of the primary purposes of the corporate form is to insulate shareholders from financial liability for a corporation's debts. . . . Equity, however, has created a device called "piercing the corporate veil," which prevents purveyors of fraud and injustice from hiding behind the corporate form of organization. . . . Using this device in appropriate circumstances, courts will disregard the separate identities of corporations controlled by a common parent. n1

n1 Liberty Mutual Ins. Corp. v. M & O Springfield Co., No. 97-4146, 1998 WL 894654, *2 (7th Cir. Dec. 17, 1998) (unpublished opinion) (quoting Van Dorn Co. v. Future Chem. & Oil Corp., 753 F.2d 565, 569 (7th Cir. 1985)) (citations omitted).

In that concise statement, the Seventh Circuit outlined the essential purpose of the corporate form of doing business, and the circumstances in which the protections of that form will be denied to its owners. The creation of the legal concept of a corporation is viewed by many as one of the essential factors that fueled the Industrial Age and permitted the accumulation of resources to advance undertakings beyond the capacity of the wealth of individuals.

Whether it was a corporation formed for the exploration and development of the New World or a corporation formed for the mass production of automobiles, the corporate form allowed the accumulation of wealth from a large number of investors without exposing their personal fortunes to loss if the venture failed. The corporation was invented for the express purpose of limiting the liability of investors to the amount of their investment. Thus, the use of the corporate structure to create insulation from liability is hardly a perversion of the corporate form; rather, it is an application of its primary purpose.

Recently, the principles underlying the corporate form of doing business have expanded to apply to other forms of legal entities, such as limited liability **companies** and limited liability partnerships. Today, business enterprises can select among various legal forms to pool resources and limit the liability of investors.

In the context of **nursing home** ownership and operation, legal entities such as corporations, limited liability **companies**, and limited liability partnerships can be formed to benefit **nursing home companies** by limiting the financial liability and Medicare and Medicaid exclusion exposure of the real-estate investors and business owners. For example, the business entities that result from restructuring can help a **nursing home** operator avoid unnecessary exclusion of all Medicare and Medicaid providers currently owned by the same entity, in the event that any one of them is excluded from the Medicare or Medicaid programs. The business entities can also prevent litigants from obtaining judgments against related **companies**, and the owners personally, in proceedings alleging Medicare or Medicaid overpayments, false claims, or negligence.

In addition to providing a shield to protect against exposure to risk, the creation of multiple asset-holding entities can affirmatively benefit a **nursing home company**. For example, commercial lenders and private investors often are more willing to lend to owners of real estate that are not engaged in the actual operation of **nursing homes**. Further, acquisition and divestiture of individual **nursing homes** often can be more easily accomplished if the assets are held in a single-purpose entity (SPE). The focus of this Article, however, will be limited to the avoidance of risk by use of multiple SPEs.

Due to the risks associated with exclusion from the Medicare and Medicaid programs and being named a defendant or respondent in a lawsuit or administrative proceeding, **nursing home companies** should seek to carefully protect the assets of their owners. One way to accomplish this is to divide the business into real-estate investment and **nursing home** operations. This can be achieved by forming SPEs to own the **nursing home** real estate, and separate SPEs to operate the **nursing home** business. Numerous SPEs may be less attractive as defendants than a single **company** with multiple operating interests and multiple real estate holdings. Moreover, upon the unfortunate occasion of receiving a notice of intent to exclude, a **nursing home** that is operated by a SPE is more easily divested. Further, it is divested without the impending substantial losses often associated with having to divest a number of homes that happen to be owned by the same entity that owns the home to be excluded.

Ultimately, any decision to restructure must be made based on an assessment of the **nursing home company's** business goals. That assessment involves a balancing of acceptable risk with acceptable costs. Fortunately, restructuring need not be an "all or nothing" exercise. Restructuring can be undertaken at a variety of different levels, depending on the individual **company's** balancing of risk and cost.

For example, a **company** could decide to restructure down to the individual facility level by forming real property SPEs to own each piece of real estate that is used as a **nursing home**, and by forming a corresponding number of operating SPEs to lease and operate the **nursing homes**. Alternatively, a **company** could decide to subdivide its operations into subsidiaries that own and operate only a certain number of facilities each, based upon the level of risk the **company** is willing to accept. In addition, a **company** could elect to place all of its real estate in a real property SPE, but operate each facility through an operating SPE. In effect, any restructuring should be customized to the particularized needs of each **company**.

Finally, in order to preserve the integrity of the restructuring, **nursing home companies** must continue to eschew

unnecessary and avoidable risk. The sanctity and independence of the business entity must be preserved because litigants and the government may attempt to disregard the legal structure of a SPE to collect judgments and overpayments against owners and related **companies**. Whatever form they take, **nursing home** business entities must adhere to statutory formalities, preserve the distinction between the business entity and those individuals or entities with ownership or control interests, be adequately capitalized, and avoid even the appearance of siphoning revenues to individuals or entities with common ownership or control.

I. Two Risks Facing **Nursing Homes: Exclusion and Financial Liability**

There are two types of exposure that **nursing homes** seek to avoid: exposure to exclusion from the Medicare and Medicaid programs and exposure to financial liability. The first type of exposure, exclusion exposure, is premised upon federal law that authorizes the Secretary of the United States Department of Health and Human Services (DHHS), acting through the Office of Inspector General (OIG), to exclude a provider from federal healthcare program participation upon the occurrence of certain events.ⁿ² Under this authority, the DHHS Secretary may exclude a provider and its related entities when the provider has violated certain laws.

n2 U.S. Dep't of Health and Human Servs., Office of Inspector Gen., Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs, 64 Fed. Reg. 52,791 (Sept. 30, 1999) (discussion of the OIG's role in exclusions).

The second type of exposure, financial exposure, is that liability which makes the assets of owners vulnerable to claims made upon the business entity. It arises most frequently in the context of tort liability; that is, liability that generally stems from negligence-based actions against **nursing homes**. Financial exposure, however, can also occur in the regulatory context. This refers to liability that stems from Medicare and Medicaid overpayments, fraud, or false claims.

A. Exposure to Exclusion from the Medicare and Medicaid Programs

The Social Security Act vests in the Secretary of DHHS both mandatory and permissive exclusion authority.

Under the mandatory exclusion provisions, the DHHS Secretary must exclude certain individuals and entities from participation in federal healthcare programs for at least five years if, among other things, the individual or entity is convicted of "a criminal offense related to the delivery of an item or service" under the federal Medicare program or under any State healthcare program.ⁿ³

n3 42 U.S.C. § 1320a-7(a) (2003); 42 C.F.R. § 1001.101 (2003). Specifically, under 42 U.S.C. § 1320a-7, Congress requires the Secretary of DHHS to exclude an individual or entity from participation in the federal health care programs where he or it has been convicted of: "(1) a criminal offense related to the delivery of an item or service under subchapter XVIII . . . or under any State health care program;" (2) "a criminal offense relating to neglect or abuse of patients in connection with the delivery of a health care item or service;" (3) certain offenses "in connection with the delivery of a health care item or service or with respect to any act or omission in a health care program . . . consisting of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct;" and (4) an offense "consisting of a felony relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance."

Under the permissive exclusion provisions, the DHHS Secretary may exclude additional individuals or entities from participation in federal healthcare programs.ⁿ⁴ In addition to excluding the individuals or entities that engaged in the prohibited conduct, the DHHS Secretary may exclude entities ownedⁿ⁵ or controlledⁿ⁶ by a sanctioned individual or entity, even if those entities have been convicted of nothing.ⁿ⁷ As such, the DHHS Secretary may exclude an entity from federal healthcare-program participation if a five-percent owner of the stock or assets or an officer, director, partner, agent, or managing employee is sanctioned.ⁿ⁸ Moreover, the exclusion cannot be circumvented by having the excluded individual or entity transfer or sell the interest in the entity to an immediate family member or sibling.ⁿ⁹ To

avoid application of these provisions, the ownership or control interest must be transferred to an unrelated entity or person.

n4 Under the permissive exclusion authority, the Secretary of DHHS may exclude individuals and entities who have committed fraud or other criminal acts, or who have been "otherwise sanctioned" under a federal or state health care program for reasons bearing on the individual's or entity's professional competence, professional performance, or financial integrity. 42 U.S.C. § 1320a-7(b)(5)(B) (2003); 42 C.F.R. § 1001.601(a)(1) (2003).

n5 An ownership interest means a five-percent or greater interest in the capital, stock, or profits of the entity or any mortgage, deed, trust, note, or other obligation secured in whole or in part by the property or assets of the entity. 42 U.S.C. § 1320a-7(b)(8)(A)(i) (2003); 42 C.F.R. § 1001.1001(a)(ii)(A)(2) (2003).

n6 A controlling interest includes officers, directors, agents, partners, and managing employees. 42 U.S.C. § 1320a-7(b)(8)(A)(ii) (2003); 42 C.F.R. § 1001.1001(a)(ii)(A)(3)-(6) (2003).

n7 42 U.S.C. § 1320a-7(b)(8) (2003); 42 C.F.R. § 1001.1001(a)(ii)(A) (2003).

n8 42 U.S.C. § 1320a-7(b)(8)(A)(i) (2003); 42 C.F.R. § 1001.1001(a)(ii)(A) (2003).

n9 42 U.S.C. § 1320a-7(b)(8)(A)(iii) (2003); 42 C.F.R. § 1001.1001(a)(ii)(B) (2003).

Thus, if all of the **company's nursing homes** are owned and operated by a single **company and that company** is excluded from the Medicare and Medicaid programs based on the conduct of just one of the **nursing homes, the company's nursing home** real estate and operations are at unnecessary risk of exclusion. All of the **nursing homes** could be excluded from the Medicare and Medicaid programs. Furthermore, to avoid permissive exclusion attaching to the real estate owned by the **company**, the real estate would have to be transferred out of the **company**. This type of a divestiture can result in substantial loss of value in the asset, especially because many such divestitures must be accomplished on very short notice and under very adverse conditions.

B. Exposure to Financial Liability

Exposure to financial liability has specific meaning in the context of structuring **nursing home** organizations. Certainly every business entity has some form of financial liability exposure based upon contractual obligations, potential negligence actions, employment-related litigation, tax law matters, and other risks that occur in the ordinary course of conducting a business. The financial exposure that a **nursing home** operator is most concerned with, however, is the liability exposure particular to operators of **nursing homes**.

1. Medicare and Medicaid Overpayment Liability

A Medicare fiscal intermediary may suspend payments to or recoup payments from the individual or business entity that enters into an agreement with the Medicare program to provide services to Medicare beneficiaries. This can occur if, for example, it finds fraud, misrepresentation, incorrect payments, payments for unnecessary services, or overpayments related to that Medicare provider. n10 The fiscal intermediary has no authority, however, to suspend payments to or recoup payments from entities *other than* the provider for allegations raised against that provider. n11 Thus, the fiscal intermediary may not recoup overpayments from another entity merely because it is affiliated with the provider by common ownership or control.

n10 See 42 C.F.R. §§ 405.370, 405.371(a), 405.372, 405.373 (2003). See also CENTERS FOR MEDICARE AND MEDICAID SERVICES, CMS-PUB. 13-2, MEDICARE INTERMEDIARY MANUAL, PART 2 §§ 2225, 2229 (2003) (procedures for suspending

interim payments and recovery of overpayment resulting from unnecessary services). A Medicare fiscal intermediary may also suspend Medicare payments to recover Medicaid overpayments owed to a provider. In addition, it may withhold the federal share of Medicaid payments to a Medicaid provider that has Medicare overpayment liability. *See id.* §§ 2226.1, 2226.2.

n11 *See* 42 C.F.R. §§ 405.370, 405.371(a), 405.372, 405.373 (2003).

Under many states' laws, the state Medicaid agency similarly may suspend payments to or recoup payments from a provider if it finds fraud or overpayments related to that provider. n12 Generally, the Medicaid agency's authority is limited to recouping overpayments from the provider only, and the agency cannot recoup from or offset against other entities merely because they are affiliated with the provider by common ownership or control. n13

n12 *See, e.g.*, CONN. AGENCIES REGS. § 17-311-53(b) (2003) ("Whenever the Commissioner . . . renders a rate decision . . . which decision results in the facility being indebted to the Department . . . for past Medicaid overpayments, the department shall recoup said Medicaid overpayments as soon as possible from the department's monthly Medicaid payments to the facility.").

n13 It is worth noting that some states' laws specifically authorize the Medicaid agency to recoup overpayments from another provider that is owned or controlled by the same individual or entity that owns the provider that is subject to the overpayment recoupment. In Connecticut, for example,

if a facility owes money to the department, the department may offset against such indebtedness any liability of the department to another provider which is owned or controlled by the same person or persons who owned or controlled the first facility at the time the indebtedness to the department was incurred. In the case of the same person or persons owning or controlling two or more facilities but separately incorporating them, whether the person or persons own or control such corporations shall be an issue of fact. Where common ownership or control is found, this subsection shall apply notwithstanding the form of business organization utilized by such persons e.g. separate corporations, limited partnerships, etc.

CONN. AGENCIES REGS. § 17-311-53(f) (2003).

Federal and state governments' efforts to aggressively recover overpayments from providers are expected to increase in the future. Recent reports indicate approximately \$ 8 billion is owed to the federal government in Medicare overpayments at a time when Medicare spending is on the rise and budgets are being cut. n14 Both the General Accounting Office and the OIG have noted the Medicare program's lack of progress in collecting debts, such as provider overpayments. n15 States also are facing shortfalls in Medicaid budgets, and the fiscal outlook for states does not appear to be improving. n16 They project worsening budget conditions, and many are looking at new methods of controlling Medicaid deficits, such as increasing fraud and abuse control and increasing third-party liability collections. n17 Given these pressures, it is expected that federal and state governments will aggressively pursue overpayment liability, which has the potential to cause cash-flow problems of enormous magnitude for any **nursing home** that might be targeted, as well as any successor or assignee of such a provider.

n14 *See* U.S. GEN. ACCOUNTING OFFICE, REPORT TO THE CHAIRMAN, SUBCOMMITTEE ON GOVERNMENT EFFICIENCY, FINANCE MANAGEMENT AND INTERGOVERNMENTAL RELATIONS, COMMITTEE ON GOVERNMENT REFORM, HOUSE OF REPRESENTATIVES, DEBT COLLECTION IMPROVEMENT ACT OF 1996, HHS'S CENTERS FOR MEDICARE & MEDICAID SERVICES FACES CHALLENGES TO FULLY IMPLEMENT CERTAIN KEY PROVISIONS, GAO REP. NO. 02-307, at 5 (Feb. 22, 2002).

n15 *See id.* at 1; U.S. DEPT OF HEALTH AND HUMAN SERVS., OFFICE OF INSPECTOR GEN., DELINQUENT MEDICARE DEBT AND COMPLIANCE WITH THE DEBT COLLECTION IMPROVEMENT ACT BY THE CENTERS FOR MEDICARE AND MEDICAID SERVICES, OIG REP. NO. A-17-01-02003, at 3 (2002).

n16 *See* VERNON SMITH ET AL., THE HENRY J. KAISER FAMILY FOUNDATION, KAISER COMMISSION ON MEDICAID AND THE UNINSURED, MEDICAID SPENDING GROWTH: A 50-STATE UPDATE FOR FISCAL YEAR 2003, at 1, 2, 4, 6-7, 13

(2003), available at www.kff.org/content/2003/4082/4082.pdf (last visited Sept. 30, 2003).

n17 See JOHN HOLAHAN ET AL., THE HENRY J. KAISER FAMILY FOUNDATION, KAISER COMMISSION ON MEDICAID AND THE UNINSURED, THE STATE FISCAL CRISIS AND MEDICAID: WILL HEALTH PROGRAMS BE MAJOR BUDGET TARGETS? 12 (2003), available at www.kff.org/content/2003/4073/4073.pdf (last visited Sept. 30, 2003).

2. False Claims Liability

The federal False Claims Act and its whistleblower provisions create liability for Medicare and Medicaid providers who knowingly submit false or fraudulent claims for payment to federal healthcare programs. n18 The False Claims Act also has been used as a mechanism for prosecuting **nursing home** providers that receive Medicare and Medicaid payments, but that allegedly provide substandard quality of care. n19 The government can threaten a **company** with monetary penalties of enormous magnitude because the False Claims Act authorizes penalties of between \$ 5,500 and \$ 11,000 per false claim, as well as treble damages. n20 One **nursing home company** recently paid approximately \$ 176 million to settle criminal and civil false-claims allegations related to its billing practices. n21 Another **nursing home company** recently paid \$ 104.5 million to settle civil false-claims allegations for, among other things, failing to provide care, inadequate staffing, improper care of decubitus ulcers, and failure to meet residents' dietary needs. n22

n18 31 U.S.C. § 3729(a) (2003).

n19 See, e.g., Press Release, U.S. Attorney's Office, U.S. Reaches Settlement with Temple University Health System Affiliates (Mar. 5, 2003) (announcing \$ 500,000 civil settlement involving two **nursing homes** for failing to provide adequate resident assessments and evaluations, nutrition, falls prevention, and pain management, among other care), available at www.usao-edpa.com/Pr/2003/mar/temple.html (last visited Sept. 30, 2003).

n20 31 U.S.C. § 3729(a) (authorizing penalties of \$ 5,000 to \$ 10,000); 64 Fed. Reg. 47,099-104 (Aug. 30, 1999) (In accordance with other legislation, DOJ provides increase of penalty amounts to \$ 5,500 and \$ 11,000 to account for inflation).

n21 See Press Release, Beverly Enterprises, Inc., Beverly Enterprises Finalizes Medicare Settlements (Feb. 3, 2000), available at www.beverlycares.com/beverly_internet/investor/corporate_info/investor_news/february_3_2000_medicare_settlement.html (last visited Sept. 30, 2003).

n22 Press Release, U.S. Dep't of Justice, Vencor and Ventas Paying U.S. \$ 219 Million to Resolve Health Care Claims as Part of Vencor's Bankruptcy Reorganization (Mar. 19, 2001), available at www.usdoj.gov/opa/pr/2001/March/115civ.htm (last visited Sept. 30, 2003).

In addition, many states have false-claims statutes that create additional liability for Medicaid providers who knowingly submit false or fraudulent claims for payment to the state Medicaid program. n23 Moreover, several states have false-claims statutes that contain whistleblower provisions. n24

n23 See, e.g., MICH. COMP. LAWS ANN. § 400.601 (West 2003) (Michigan Medicaid False Claims Act).

n24 See, e.g., CAL. GOV'T CODE § 12650 (West 2003) (California False Claims Act); D.C. CODE ANN. § 2-308.03 (2003) (claims by the District government against contractor).

Nursing homes' exposure to false-claims allegations is not expected to wane in the near future. Recent reports indicate that dollars spent by the federal government for anti-fraud enforcement activities are well-invested. n25 Recent reports also suggest that similar returns could result from investigating and prosecuting Medicaid fraud and enhancing state whistleblower provisions. n26 As a result, it is expected that federal and state governments will aggressively

pursue Medicare and Medicaid false-claims actions, and **nursing homes** will remain ever-popular targets.

n25 *See, e.g.*, JACK A. MEYER, TAXPAYERS AGAINST FRAUD EDUCATION FUND, FIGHTING MEDICARE FRAUD: MORE BANG FOR THE FEDERAL BUCK (2003) (finding benefit to cost ratio of nearly 9 to 1 for federal government funds spent on investigating fraud and prosecuting cases), *available at* www.taf.org/publications%5Cpdf%5Cfightingmedicarefraud.pdf (last visited Sept. 30, 2003).

n26 *See, e.g.*, ANDY SCHNEIDER, TAXPAYERS AGAINST FRAUD EDUCATION FUND, REDUCING MEDICAID FRAUD: THE POTENTIAL OF THE FALSE CLAIMS ACT 33 (2003), *available at* www.taf.org/publications/PDF/reducingmedicaidfraud.pdf (last visited Sept. 30, 2003).

3. Malpractice/Negligence Liability

Plaintiffs may bring lawsuits against **nursing home companies** seeking damages under a variety of tort theories. More than a few judgments against **nursing homes** have been based on specious allegations. Nonetheless, the reality is that **nursing homes** are unsympathetic defendants. **Nursing homes** care for those with little or no potential for improved health outcomes and those with unavoidable negative outcomes, and they rely primarily on public funds from the Medicare and Medicaid programs for payment. **Nursing homes**, however, are often viewed as nothing more than vehicles for mistreating and profiting from the elderly and fragile.

As a result of their image, **nursing homes** are relatively easy targets for plaintiff's attorneys, who can reap extremely high jury verdicts that include punitive-damage awards. For example, one jury recently awarded approximately \$ 2.8 million in actual damages and \$ 310 million in punitive damages to the family of a **nursing home** resident who suffered malnourishment and bed sores while residing at the **nursing home**. n27

n27 *Fuqua v. Horizon/CMS Healthcare Corp.*, No. 4:98-00-CV-1087-Y, 2001 WL 267650, at *1 (N.D. Tex. Feb. 14, 2001) (final judgment).

Recent reports estimate the number and amount of **nursing home** liability claims to be on the rise. Claims against **nursing homes** have tripled from 4.6 claims per 1,000 beds in 1991 to 14.5 claims per 1,000 beds in 2002. n28 Moreover, the average size of a claim has tripled from \$ 63,500 in 1991 to just under \$ 200,000 in 2002. n29

n28 *See* THERESA W. BOURDON & SHARON C. DUBIN, AON RISK CONSULTANTS, INC., LONG TERM CARE GENERAL LIABILITY AND PROFESSIONAL LIABILITY ACTUARIAL ANALYSIS 3, 6, 13 (2003), *available at* www.ahca.org/brief/aon_ltcanalysis2003.pdf (last visited Sept. 30, 2003).

n29 *Id.* at 3, 7, 13.

The financial reality of these claims is a "multi-billion dollar a year cost to the **nursing home** industry." n30 The insurance industry has responded to the increase in the number and amount of claims by raising premiums and restricting the availability of general and professional liability insurance. n31 Recent reports indicate that **nursing home** liability-insurance premiums have sharply increased in recent years--some **nursing home** operators experienced increases of 143% from 2001 to 2002. n32 Furthermore, in those states in which the losses were highest, such as Florida and Texas, **nursing home** liability insurance often is not available. n33

n30 *Id.* at 3.

n31 *See id.* at 31-34.

n32 *Id.* at 31.

n33 *See* NAT'L CONF. OF ST. LEGISLATURES, HEALTH POLICY TRACKING SERVICE SNAPSHOTS: LONG TERM CARE: 2003 MID-YEAR REPORT, **NURSING HOME LIABILITY INSURANCE** (Aug. 2003), available at www.ncsl.org/programs/health/ss3longcare.htm (last visited Sept. 30, 2003).

As a result of the increase in insurance premiums and the unavailability of coverage, many **nursing homes** significantly decreased their coverage and many are without any coverage at all. This phenomenon places the **nursing home's** assets at greater risk: In the event of a malpractice or negligence judgment against the **nursing home**, judgment creditors will pursue all available assets of the **nursing home company** to satisfy the judgment.

If all of the **company's nursing homes** are owned and operated by one **company** and if there is a substantial recoupment action against one of the **nursing homes**, a False Claims Act treble-damages award against another, and a punitive-damages verdict against a third, the assets and operations of all of the **nursing homes** are potentially in jeopardy. The **nursing home company** would bear the responsibility for the liabilities incurred as a result of the conduct of the three facilities, as well as the ongoing operations of all of the facilities. Assuming the liabilities all related to the poorest-performing **nursing homes** in the portfolio it is likely that, unless the **company** has substantial reserves, operating revenues derived from the other **nursing homes** would become necessary to satisfy the creditors.

Furthermore, the creditors would look not only to the operating revenues to satisfy the judgments, but would also aggressively pursue all available assets, including real estate, owned by the **company**. Instead of isolating the risk at the facility level and with the operating entity, the **company** has exposed its real estate and operating assets to the financial liability associated with only a subpart of its **nursing home** operations. Finally, in the event the judgments preclude the **company** from satisfying its monthly mortgage payments, the real estate may be unnecessarily at risk of liens or foreclosure, and the **company** at risk of a foreclosure on a pledge of its stock or membership interests.

II. Structuring to Reduce Risk: Separating the Real-Estate Investment from the **Nursing Home** Operations

These risks--exclusion and financial liability in the form of Medicare or Medicaid overpayments, false-claims settlement or treble-damages awards, and punitive-damages verdicts--arise as a result of the operation of the **nursing home** business. Individually or in the aggregate, they can lead to a crisis for any **nursing home company**. Restructuring can help reduce the overall risk.

Dividing the **nursing home** business into real-estate investment and **nursing home** operations will reduce the **nursing home company's** exposure to risks associated with owning and operating one or more **nursing homes**. The degree to which this reduction of risk can be maximized will be a function of how elaborate a corporate structure the particular **company** is willing to create. The ultimate structure would consist of forming a real property SPE to hold each piece of real estate, as well as a separate operating SPE for each **nursing home** business. Thus, a **nursing home company** currently owning and operating ten **nursing homes** would form twenty entities: ten real property entities that would own and lease the real estate to the ten **nursing home** operating **companies** that would obtain the licenses and Medicare and Medicaid certifications.

While a **company** can modify its particular mix of real property and operating entities to suit its individual needs, the analysis of the structures is identical in all situations. This discussion, therefore, will focus on a structure that employs a maximum division of real estate and operating interests, although lesser groupings will be subject to the same general principles. In all instances, there is an emphasis on separating the ownership of the real estate from the ownership of the operating entity that holds the license and Medicare and Medicaid provider agreements. This is normally achieved by having the operating entity lease the facility from the real-property entity. This can be accomplished even where there is identical ownership and control between and among the real-property entity and the

operating entity.

III. Legal Entities with Limited Liability

The structure discussed earlier is successful due to the protections accorded investors who form legal entities to pool resources and carry out their business endeavors.

Most individuals who own **nursing-home** operating **companies** that participate in the Medicare and Medicaid programs form legal entities, such as corporations, limited liabilities **companies**, or limited liability partnerships, to protect the individual owners from personal liability for the overpayment, malpractice, and false-claims liabilities attributable to the acts or omissions of the operating **company**/provider. Although certain jurisdictions, such as New York, have restrictions on for-profit corporate ownership of healthcare providers, this is the prevailing method of **nursing home** ownership in the United States. n34

n34 See, e.g., N.Y. PUB. HEALTH LAW § 2801-a(9) (McKinney 2003) (with limited exceptions, authorizing only a "natural person, a partnership or limited liability **company**" to engage in the business of operating a hospital for profit); *id.* § 2801 (including **nursing home** in the definition of hospital).

A. The Corporation

As a general rule, under the law in every state, a corporation is a legal entity separate from its shareholders. Thus, individuals who own the stock of a corporation are not personally liable for acts or omissions of the corporation, and parent corporations that own the stock of a subsidiary are not liable for acts of the subsidiary. n35 The policy served by creating a separate corporate identity to insulate shareholders and parent corporations from liability is the promotion of commerce and industrial growth. n36

n35 See RESTATEMENT (SECOND) OF AGENCY: CORPORATE SUBSIDIARIES § 14M (1983) [hereinafter RESTATEMENT].

n36 See generally 18 AM. JUR. 2D, *Corporations* § 43 (1985).

B. The Limited Liability Company

Recently, the limited liability **company** has become an increasingly popular vehicle for business owners. n37 Limited liability **company** statutes generally are flexible and allow the business owners, or members, substantial freedom to operate their business pursuant to the limited liability **company** operating agreement. n38 The **company** is managed either by the members directly or by a board of managers, thereby allowing the separation of ownership and control in a manner similar to a corporation. n39 Furthermore, the limited liability **company** form of doing business offers its members tax benefits akin to a partnership, and offers its members and managers limited liability akin to a corporation. n40

n37 See LARRY E. RIBSTEIN & ROBERT R. KEATINGE, RIBSTEIN AND KEATINGE ON LIMITED LIABILITY **COMPANIES** 1 n.1 (2002) (limited liability **companies** growing by more than 30% per year).

n38 *Elf Atochem North America, Inc. v. Jaffari*, 727 A.2d 286, 290-91 (Del. 1999) (noting that Delaware's Limited Liability **Company** Act provides "substantial freedom of contract").

n39 RIBSTEIN & KEATINGE, *supra* note 37, § 8.02 at 2.

n40 *Id.*

As with the corporate form of doing business, limited liability **company** formation statutes provide that the members and managers of a limited liability **company** are not personally liable for the liabilities of the **company**. n41 Under Delaware's Limited Liability **Company** Act, for example, except as otherwise set forth in the statute,

the debts, obligations and liabilities of a limited liability **company**, whether arising in contract, tort or otherwise, shall be solely the debts, obligations and liabilities of the limited liability **company**, and no member or manager of a limited liability **company** shall be obligated personally for any such debt, obligation or liability of the limited liability **company** solely by reason of being a member or acting as a manager of the limited liability **company**. n42

n41 *See, e.g.*, CONN. GEN. STAT. ANN. §§ 34-133(a), 34-133(b), 34-134 (West 2003); DEL. CODE ANN. tit. 6, § 18-303(a) (2003).

n42 DEL. CODE ANN. tit. 6, § 18-303(a).

The limited liability principles applicable to corporations and limited liability **companies** exist whether the owners, members, or shareholders are individuals or other legal entities, such as corporations or limited liability **companies**.

IV. Holding Owners Liable

Notwithstanding these legal protections, in matters involving lawsuits against **companies** with few assets, injured parties may attempt to "pierce the veil" and hold the principals, owners, or related **companies** personally liable for the obligations, acts, or omissions of the **company**.

A. Piercing the Corporate Veil

Generally, the corporate veil may be pierced and liability may attach if a shareholder or parent corporation so controls the operation of the corporation or subsidiary corporation as to make it a mere adjunct, instrumentality, or alter ego of the shareholder or parent corporation--and fraud or injustice would result if the corporate form were upheld. n43 Despite this general rule, however, corporate veil-piercing is subject to different standards, depending on whether federal law or state law is applied.

n43 *See generally* RESTATEMENT, *supra* note 35, at § 14M cmt. a.

B. Liability of Limited Liability **Company** Members and Managers

In the limited liability **company** context, notwithstanding the protections accorded members and managers under formation statutes, courts may hold members and managers responsible for **company** liabilities on other grounds. A member or manager may be personally liable to the limited liability **company** for the member's or manager's failure to comply with statutory requirements or pursuant to the **company** operating agreement. n44 For example, under Delaware's Limited Liability **Company** Act, a limited liability **company** "shall not make a distribution to a member to the extent that at the time of the distribution, . . . all liabilities of the limited liability **company** . . . exceed the fair value of the assets of the limited liability **company**." n45 A member who receives a distribution knowing that it was made in violation of the statute is liable to the limited liability **company** for the amount of the distribution. n46

n44 *See, e.g.*, CAL. CORP. CODE § 17101(e) (West 2003) ("a member . . . may agree to be obligated personally . . . as long as the

agreement . . . is set forth in the articles of organization or in a written operating agreement"); CONN. GEN. STAT. ANN. § 34-134 (West 2003) ("[a] member or manager of a limited liability **company** is not a proper party to a proceeding by or against a limited liability **company** . . . , except where the object of the proceeding is to enforce a member's or manager's right against or liability to the limited liability **company** or as otherwise provided in an operating agreement"); *id.* § 34-141 (a member or manager is required to discharge his duties in good faith and shall not be liable to the limited liability **company** if he acts in good faith); DEL. CODE ANN. tit. 6, § 18-303(b) (2003) ("under a limited liability **company** agreement . . . , a member or manager may agree to be obligated personally for any or all of the debts, obligations and liabilities of the limited liability **company**"); 805 ILL. COMP. STAT. 180/10-10 (West 2003) (members are liable if a provision to that effect is in the articles of organization and a member has consented in writing to the adoption of the provision).

n45 DEL. CODE ANN. tit. 6, § 18-607(a) (2003).

n46 *Id.* § 18-607(b).

In addition, courts may hold members and managers personally liable by applying the "piercing the corporate veil" doctrine to the limited liability **company** form of doing business. Some states' limited liability **company** acts specifically authorize the application of the corporate veil-piercing doctrine in the limited liability **company** context. n47 Even in those states with limited liability **company** statutes that do not specially authorize the application of the corporate veil-piercing doctrine, some courts are willing to pierce the veil of the limited liability **company**. n48

n47 *See, e.g.*, CAL. CORP. CODE § 17101(b) (West 2003) (member may be liable "under the same or similar circumstances and to the same extent as a shareholder of a corporation"); GA. CODE ANN. § 14-11-314 (2003) ("this chapter does not alter any law with respect to disregarding legal entities"); MINN. STAT. § 322B.303, subd. 2 (West 2003) ("case law that states the conditions and circumstances under which the corporate veil of a corporation may be pierced under Minnesota law also applies to limited liability **companies**"); N.D. CENT. CODE § 10-32-29, 3 (2003) ("case law that states the conditions and circumstances under which the corporate veil of a corporation may be pierced under North Dakota law also applies to limited liability **companies**"); WASH. REV. CODE § 25.15.060 (2003) (members "shall be personally liable for any act, debt, obligation, or liability of the limited liability **company** to the extent that shareholders of a Washington business corporation would be liable in analogous circumstances"); WIS. STAT. ANN. § 183.0304(2) (West 2003) ("nothing in this chapter shall preclude a court from ignoring the limited liability **company** entity under principles of common law of this state that are similar to those applicable to business corporations and shareholders in this state"). Some states have limited the application of the corporate veil-piercing doctrine to specifically exclude the failure to follow formalities applicable to corporations. *See also* CAL. CORP. CODE § 17101(b) (West 2003); COLO. REV. STAT. ANN. § 7-80-107(2) (West 2003); WASH. REV. CODE § 25.15.060 (2003).

n48 *See, e.g.*, STEPHEN B. PRESSER, PIERCING THE CORPORATE VEIL § 401 [2] (West 2002); KLM Indus., Inc. v. Tylutki, 815 A.2d 688, 689 n.2 (Conn. App. Ct. 2003) ("the determination of whether to pierce the corporate veil of a stock corporation or to disregard the protections afforded a limited liability **company** requires the same analysis"); Curole v. Ochsner Clinic, L.L.C., 811 So. 2d 92, 96 (La. Ct. App. 2002) (limited liability **company** veil may be pierced based on a "totality of the circumstances" review, but finding insufficient allegations to support veil-piercing claim for venue purposes) (citing Hollowell v. Orleans Reg. Hosp., LLC, 217 F.3d 379, 387 (5th Cir. 2000)); J.C. Compton Co. v. Brewster, 59 P.3d 1288, 1293 (Or. Ct. App. 2002) (reversing judgment in favor of plaintiff on LLC veil-piercing claim where plaintiff failed to show a relationship between the misconduct and the plaintiff's injury); Bonner v. Brunson, No. A03A1514, 2003 WL 21730686, at *1 (Ga. Ct. App. July 28, 2003) (a Georgia court may pierce the veil of the limited liability **company** if the member, "in order to defeat justice or perpetrate fraud, conducts his personal and limited liability **company** business as if they were one by commingling the two on an interchangeable or joint basis or confusing otherwise separate properties, records, or control"); Kaycee Land & Livestock v. Flahive, 46 P.3d 323, 328-29 (Wyo. 2002) (holding that the doctrine of piercing the veil should apply to limited liability **companies**, although the factors that would justify piercing an limited liability **company** veil might differ).

Despite the willingness of many courts to pierce, there are arguments against applying corporate veil-piercing principles to limited liability **companies**. n49 One rationale is that the limited liability **company** statutes expressly define circumstances in which the member or manager will be held liable. For example, limited liability **company** statutes impose liability on members and managers for withdrawing funds and making distributions from struggling **companies**, particularly where the distributions would exceed the fair value of the assets of the **company**. n50 It is unnecessary, therefore, to pierce the veil of the limited liability **company** based on undercapitalization, a factor commonly applied in corporate veil-piercing cases. n51 The same result can be reached against members of limited liability **companies** by applying the statute. n52

n49 *See, e.g.*, *New Horizons Supply Co-op. v. Haack*, No. 98-1865, 1999 WL 33499, at *3 (Wis. Ct. App. Jan. 28, 1999) (rejecting trial court's theory of piercing limited liability **company** veil, but upholding trial court's decision based on failure to follow statutory formation requirements). *See also* Warren H. Johnson, *Limited Liability Companies (LLCs): Is the LLC Liability Shield Holding Up Under Judicial Scrutiny?*, 35 NEW ENG. L. REV. 177, 209-214 (2000) (arguing in favor of a "juridical personality" for limited liabilities **companies** and rejecting the treatment of limited liability **companies** "like a partnership" or "like a corporation").

n50 *See, e.g.*, DEL. CODE ANN. tit. 6, § 18-607(a) (2003).

n51 *See, e.g.*, *Autrey v. 22 Tex. Servs., Inc.*, 79 F. Supp. 2d 735, 745 (S.D. Tex. 2000); *Cnty. Care Ctrs., Inc. v. Hamilton*, 774 N.E.2d 559, 565-66 (Ind. Ct. App. 2002). *Cf.*, RIBSTEIN & KEATINGE, *supra* note 37, § 12.03 at 6 (noting that inadequate capitalization is rare, even in corporations).

n52 The converse also applies. For example, in *Pepsi-Cola Bottling Co. v. Handy*, No. 1973-S, 2000 WL 364199, at *3-*6 (Del. Ch. Mar. 15, 2000), the court looked to the Delaware Limited Liability **Company** Act and found that the defendants were not entitled to statutory protections as members of a limited liability **company** because the allegations were "based on conduct [that] occurred before the LLC was formed." Thus, defendants could not use the Delaware Limited Liability **Company** Act to shield them from liability under other theories.

A second rationale for not applying corporate veil-piercing standards to limited liability **companies** is that "many of the organizational formalities applicable to corporations do not apply to [limited liability **companies**]." n53 Thus, while failure to follow formalities is a frequent factor in corporate veil-piercing cases, n54 it is inappropriate to pierce the veil of a limited liability **company** on this basis. Furthermore, some limited liability **company** statutes specifically preclude liability of members and managers for failure to adhere to management formalities. n55

n53 *Kaycee Land & Livestock v. Flahive*, 46 P.3d 323, 328 (Wyo. 2002). *See also*, RIBSTEIN & KEATINGE, *supra* note 37, § 12.03 at 5-7 (discussing distinctions between corporations and limited liability **companies** in the context of veil-piercing).

n54 *See* *United States v. Pisani*, 646 F.2d 83, 88 (3rd Cir. 1981); *Cnty. Care Ctrs., Inc.*, 774 N.E.2d at 565. *See also* *Kaycee Land & Livestock*, 46 P.3d at 328 (holding that "the doctrine of piercing the veil should apply to limited liability **companies**," although the factors that would justify piercing an limited liability **company** veil might differ because, for example, "many of the organizational formalities applicable to corporations do not apply to LLCs").

n55 *See, e.g.*, CAL. CORP. CODE § 17101(b) (West 2003); COLO. REV. STAT. ANN. § 7-80-107(2) (West 2003); MONT. CODE ANN. § 35-8-304(2) (2002); WASH. REV. CODE ANN. § 25.15.060 (West 2003).

At least one state legislature appears outwardly to have recognized that veil-piercing in the context of corporations and veil-piercing in the context of limited liabilities **companies** may not completely overlap. Four years after it was enacted, Illinois' Limited Liability **Company** Act was amended to remove language from the original act that held a member of a limited liability **company** "personally liable . . . to the extent that a shareholder of an Illinois business corporation is liable in analogous circumstances under Illinois law." n56 As amended, the act now provides that "the debts, obligations, and liabilities of a limited liability **company**, whether arising in contract, tort, or otherwise, are solely the debts, obligations, and liabilities of the **company**." n57 Moreover, members are now liable if "(1) a provision to that effect is contained in the articles of organization; and (2) a member so liable has consented in writing to the adoption of the provision or to be bound by the provision." n58

n56 *See* 805 ILL. COMP. STAT. § 180/10-10 (West 2003), amended by P.A. 90-424, § 10, effective Jan. 1, 1998.

n57 *Id.* § 180/10-10(a).

n58 *Id.* § 180/10-10(d).

Limited liability **companies** are relatively new structures n59 and, as a result, jurisprudence in this area is unsettled. n60 If statutory requirements are satisfied, therefore, defendant members or managers of limited liability **companies** may benefit by arguing that the statute controls on the particular issue and common law piercing principles are inapplicable to the analysis.

n59 RIBSTEIN & KEATINGE, *supra* note 37, § 1.02 at 2 n.2. The first limited liability **company** act was enacted in Wyoming in 1977. *Id.* at 6. See *Kaycee Land & Livestock v. Flahive*, 46 P.3d 323, 326 (Wyo. 2002). By the mid-1990s, all fifty states and the District of Columbia had enacted limited liability **company** statutes. RIBSTEIN & KEATINGE, *supra* note 37, at 8.

n60 RIBSTEIN & KEATINGE, *supra* note 37, § 12.03 at 3-5 (noting uncertainty in how courts have treated and will treat veil-piercing in the limited liability **company** context).

V. The Standards and Factors Applied in Veil-Piercing Cases

The arguments asserted in support of veil-piercing are identical, whether made against corporate shareholders, parent corporations, or members or managers of limited liability **companies**. As such, this Article draws no further distinction between limited liability **companies** and corporations.

A. The Federal Standard in Medicare Overpayment and False Claims Veil-Piercing Cases

More and more frequently, the United States attempts to pierce the corporate veil and recover from owners and related **companies** for Medicare overpayments and violations of the False Claims Act. n61 When addressing Medicare veil-piercing cases, federal courts generally apply a federal common law standard fashioned by the Third Circuit in *United States v. Pisani*. n62 The *Pisani* court concluded that "a uniform federal rule" was needed because application of state law could "frustrate specific objectives of the Medicare program." n63 The specific objectives identified by the court were "prompt reimbursements to providers," paying providers no more than their "reasonable costs," and "uniformity in the Medicare program." n64 The court found that application of state common law, which required proof of fraud, n65 would frustrate the goals of the Medicare program. This conclusion was reached because a provider could circumvent the objectives of the Medicare act by implementing ploys to obtain overpayments, avoid repaying them, and keep few or no records for the Medicare program to audit, making it difficult for the Medicare program to prove fraud. n66

n61 For a sampling of cases involving attempts to pierce the veil of Medicare provider **companies**, see *United States v. Pisani*, 646 F.2d 83, 87 (3d Cir. 1981); *United States v. Bridle Path Enters., Inc.*, No. CIV.A.99-11051-GAO, 2001 WL 1688911, at *2 (D. Mass. Dec. 4, 2001) (piercing the corporate veil to recover Medicare overpayments); *United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F. Supp. 2d 35, 39-41 (D. Mass. 2000) (dismissing a parent corporation from a Medicare false-claims action); *Healthcare Tech. Servs., Inc. v. Shalala*, No. CIV.A.99-4467, 2000 WL 537448, at * 3--4 (E.D. Pa. Apr. 25, 2000) (declining to dismiss related **companies** from action seeking to recover Medicare overpayments on allegations that one individual was President and CEO of four **companies**, all four **companies** were located in the same city, and four **companies** "shifted patients between them to increase payments flowing to one **company**, and avoid or bypass various actions . . . that reduced payments to another related **company**"); *United States ex rel. Piacentile v. Wolk*, No. CIV.A.93-5773, 1995 WL 20833, at *4 (E.D. Pa. 1995) (holding shareholder not liable for corporation's violation of the False Claims Act where there was no basis for piercing the corporate veil); *United States v. Lorenzo*, 768 F. Supp. 1127, 1132-33 (E.D. Pa. 1991) (piercing the corporate veil in false-claims action against dentist and related **companies**); *United States v. Arrow Med. Equip. Co.*, No. CIV.A.90-5701, 1990 WL 210601, at *8 (E.D. Pa. Dec. 18, 1990) (declining to dismiss officers and related **companies** from action seeking to recover Medicare overpayments because defendants "cannot be permitted to use the corporate form as a defensive shield to ward off . . . overpayment claim[s] and to escape the reach of the Medicare regulations from which they previously benefited"); *United States v. Thomas*, 515 F. Supp. 1351, 1357 (W.D. Tex. 1981) (piercing the corporate veil to recover Medicare payments where assets were dissipated to sole shareholder's benefit at time that corporation was failing).

n62 *Pisani*, 646 F.2d at 86, 88.

n63 *Id.* at 86.

n64 *Id.* at 86-87.

n65 *See Id.* at 87. Notwithstanding the fraud factor applied in many federal (and state) cases, the Court of Appeals for the District of Columbia Circuit recently noted: "The difference between being a fraud and conducting one is important. Even a fully-capitalized, Fortune 500 corporation can embark on a fraud, but that would not make its corporate form a sham or its shareholders personally liable." *United States v. Jamieson Sci. and Eng'g, Inc.*, 322 F.3d 738, 741 (D.C. Cir. 2003) (citations omitted) (holding President and CEO of corporation not personally liable under False Claims Act based on the **company's** alleged fraudulent conduct).

n66 *Pisani*, 646 F.2d at 88-89.

The *Pisani* court identified the following factors to consider when determining whether to hold an owner or related **company** liable for Medicare overpayments to or false claims of a provider **company**:

First is whether the corporation is grossly undercapitalized for its purposes. Other factors are "failure to observe corporate formalities, non-payment of dividends, the insolvency of the debtor corporation at the time, siphoning of funds of the corporation by the dominant stockholder, non-functioning of other officers or directors, absence of corporate records, and the fact that the corporation is merely a facade for the operations of the dominant stockholder or stockholders." . . . Also, the situation "must present an element of injustice or fundamental unfairness," but a number of these factors can be sufficient to show such unfairness. n67

n67 *Id.* at 88 (citations omitted) (quoting *DeWitt Truck Brokers v. W. Ray Flemming Fruit Co.*, 540 F.2d 681, 686-87 (4th Cir. 1976). *See also* *United States v. Jon-T Chem., Inc.*, 768 F.2d 686, 691-93 (5th Cir. 1985) (applying "a laundry list of factors" and concluding that government's claims for fraudulent misrepresentation and conversion sounded in tort rather than contract and, thus, indicia of fraud were unnecessary to uphold ruling piercing the corporate veil); *Healthcare Tech. Servs., Inc. v. Shalala*, No. CIV.A.99-4467, 2000 WL 537448, at * 3 (E.D. Pa. Apr. 25, 2000); *United States v. Lorenzo*, 768 F. Supp. 1127, 1132-33 (E.D. Pa. 1991); *United States v. Golden Acres, Inc.*, 702 F. Supp. 1097, 1104-07 (D. Del. 1988) (applying these factors, court held related **companies** and individuals liable for HUD judgment against defendant **company** for **company's** failure to make mortgage payments to HUD).

Applying these factors, the court concluded that *Pisani*, the sole shareholder, president, and registered agent of Eaton Park **Nursing Home**, was personally liable for Medicare overpayments made to the **nursing home**. n68 The court found that *Pisani* "followed no corporate formalities, operated the corporation with his personal funds, loaned large sums to the corporation and then repaid the loans to himself with corporate funds while the corporation was failing, and kept the corporation undercapitalized by loaning it money instead of investing equity in it." n69

n68 *Pisani*, 646 F.2d at 84, 89-90.

n69 *Id.* at 88.

Although most federal courts apply the laundry list of factors identified by the *Pisani* court in determining whether to pierce the corporate veil, some federal courts apply the following three-factor test: "The veil may be pierced only if the parent and subsidiary lacked independence, the principals conducted their affairs with a requisite degree of 'fraudulent intent,' and failure to pierce the veil would work substantial injustice." n70 This test seems to require proof of fraud, which the *Pisani* court found would frustrate the goals of the Medicare program by allowing a defendant to encourage overpayments and circumvent the repayment procedures. The cases, however, reveal that courts will infer fraud or intentional wrongful conduct from the facts of the case. n71

n70 United States ex rel. Kneepkins v. Gambro Healthcare, Inc., 115 F. Supp. 2d 35, 39-40 (D. Mass 2000) (applying three-factor test in Medicare false-claims action). *See also* United States v. Bridle Path Enters., Inc., No. CIV.A.99-11051-GAO, 2001 WL 1688911, at *3 (D. Mass. Dec. 4, 2001) (applying three-factor test in Medicare overpayment-recoupment action).

n71 *See, e.g., Bridle Path Enters.*, 2001 WL 1688911, at *3 (noting a "strong inference of intentional fraud" based on payments made to owners and related **companies** while Medicare provider was operating at a net loss).

Notwithstanding federal courts' routine application of federal common law in Medicare veil-piercing cases, "when there is little need for a nationally uniform body of law, state law may be incorporated as the federal rule of decision." n72 As will be addressed, some states have more-stringent requirements for piercing the corporate veil--such as a showing of fraud--that benefit defendants. Thus, in every case the choice of law should be considered carefully, even if the plaintiff is the United States and the allegations relate to Medicare overpayments or false claims. This is particularly true when the defendant is not a corporation, but a limited liability **company**, because limited liability **company** members can argue that veil-piercing is inapplicable and the liability of members should be determined based on the state law under which the limited liability **company** is formed.

n72 United States v. Kimbell Foods, Inc., 440 U.S. 715, 728 (1979).

B. State Standards

State Medicaid agencies often attempt to pierce the corporate veil and recover from owners and related entities for Medicaid overpayments. n73 In addition, private plaintiffs frequently attempt to pierce the corporate veil and recover in tort from owners and related **companies**. n74

n73 Cmty. Care Ctrs., Inc. v. Hamilton, 774 N.E.2d 559, 562 (Ind. Ct. App. 2002).

n74 *See, e.g., Autrey v. 22 Tex. Servs., Inc.*, 79 F. Supp. 2d 735, 746-47 (S.D. Tex. 2000) (plaintiffs' allegations against **nursing home** and related **companies** created triable issue of fact as to veil-piercing that survived defendants' motion for summary judgment); *House v. 22 Tex. Servs., Inc.*, 60 F. Supp. 2d 602, 610, 614 (S.D. Tex. 1999) (court pierces corporate veil to obtain personal jurisdiction over individual defendants).

In veil-piercing cases, depending on state choice of law rules or agreements between the parties as to choice of law, a court may apply the law of the state in which the facility is located or the law of the state in which the defendant **company** is formed. n75 Once again, choice of law should be carefully considered, due to the differences in states' application of veil-piercing standards.

n75 *See, e.g., Wausau Bus. Ins. Co. v. Turner Const. Co.*, 141 F. Supp. 2d 412, 416-17 (S.D.N.Y. 2001) (court applied New York law by agreement of the parties, although New York choice of law principles would apply the law of the state of incorporation [Delaware] to determine whether to pierce the corporate veil); *Autrey*, 79 F. Supp. 2d at 740 (in **nursing home** malpractice action, court applied the law of the state of incorporation of the corporate defendants to determine whether to pierce the corporate veil); *Downing v. Jameson*, No. CV 96-0323910S, 1998 WL 811876, at *3-*4 (Conn. Super. Ct. Nov. 13, 1998) (court applied Connecticut law to assess whether veil-piercing allegations against foreign **company** survived a motion for summary judgment).

No common standard exists among the various jurisdictions, and the factors that courts apply differ from state to state and case to case. n76 Nonetheless, factors commonly applied by state courts include the following: failure to observe corporate formalities; inadequate capitalization; commingling of assets; siphoning of funds; nonpayment of dividends; unjust loss or injury; and improper conduct, fraud, or illegality. n77 These factors often boil down to two

categories: (1) unity of interest or no separate personality, and (2) fraud or injustice. n78

n76 See PRESSER, *supra* note 48, § 1.03[4] at I-27 to 31 (West 1991) (citing FREDERICK J. POWELL, PARENT AND SUBSIDIARY CORPORATIONS: LIABILITY OF A PARENT CORPORATION FOR THE OBLIGATIONS OF ITS SUBSIDIARY (1931) (the seminal treatise on piercing the corporate veil); WILLIAM MEADE FLETCHER, FLETCHER CYCLOPEDIA OF THE LAW OF PRIVATE CORPORATIONS §§ 41 at 557-61, 41.30 at 617-18 (West 1999)).

n77 See PRESSER, *supra* note 48, § 1.03[4] at I-29; FLETCHER, *supra* note 76, § 41.30 at 625-31. See also *Messick v. Moring*, 514 So. 2d 892, 894 (Al. 1987); *Angelo Tomasso, Inc. v. Armor Constr. & Paving, Inc.*, 187 Conn. 544, 557 (1982); *SFA Folio Collections, Inc. v. Bannon*, 217 Conn. 220, 232 (1991) (citing H. HENN & J. ALEXANDER, LAWS OF CORPORATIONS, § 149 at 355 (3d ed. 1983)); *Dania Jai-Alai Palace, Inc. v. Sykes*, 450 So. 2d 1114, 1118 (Fla. 1984) (quoting *Riesen v. Maryland Cas. Co.*, 14 So. 2d 197, 199 (Fla. 1943)); *Solomon v. Betras Plastics, Inc.*, 550 So. 2d 1182, 1184 (Fla. Dist. Ct. App. 1989); *Hanson v. Bradley*, 10 N.E.2d 259, 264 (Mass. 1937); *RLI Ins. Co. v. Martin Ginden Ins. Agency, Inc.*, No. 917614F, 1994 WL 879678, at *2 (Mass. Super. Ct. June 22, 1994); *My Bread Baking Co. v. Cumberland Farms, Inc.*, 233 N.E.2d 748, 751-52 (Mass. 1968), *cited in* *Markham v. Fay*, 884 F. Supp. 594, 603 (D. Mass. 1995) (referring to *My Bread Making Co.* as a "seminal decision"); *Glenn v. Wagner*, 329 S.E.2d 326, 330 (N.C. 1985) (quoting *B-W Acceptance Corp. v. Spencer*, 149 S.E.2d 570, 576 (N.C. 1966)); *Castleberry v. Branscum*, 721 S.W.2d 270, 271-272 (Tex. 1986).

n78 PRESSER, *supra* note 76, 1.03[4] at I-28 (noting Powell's test requiring (i) that the subsidiary is an "alter ego," or "mere instrumentality" of the parent; (ii) that a "fraud or wrong" occurred; and (iii) that "unjust loss or injury" resulted); FLETCHER, *supra* note 76, § 41.32 at 637 ("fraud, illegal activity or fundamental unfairness are required in many jurisdictions"). See also *id.* § 41.25 at 605-06.

Courts vary in the number of factors considered and the weight assigned to those factors in determining whether or not to pierce the corporate veil. The courts' discretion is reflected in the large, murky body of case law. n79 For example, some jurisdictions require a finding of fraud before piercing the corporate veil. n80 Other courts will infer the indicia of fraud from the facts of the case. n81 Finally, some courts do not require fraud or indicia of fraud, but simply a showing of injustice. n82

n79 RIBSTEIN & KEATINGE, *supra* note 37, § 12.03 at 4-5.

n80 See *e.g.*, *Gen. Ins. Servs., Inc. v. Marcola*, 497 S.E.2d 679, 683-84 (Ga. Ct. App. 1998) (lack of intentional misrepresentation by president supported refusal to pierce the veil); TEX. BUS. CORP. ACT ANN. art. 2.21(A)(2) (2003) (in contract actions, Texas requires actual fraud: the liability of shareholders for contractual obligations of a corporation is limited to instances where the shareholder "caused the corporation to be used for the purpose of perpetrating and did perpetrate an actual fraud . . . primarily for the direct personal benefit of the" shareholder).

n81 See, *e.g.*, *United States v. Bridle Path Enters., Inc.*, No. CIV.A.99-11051-GAO, 2001 WL 1688911, at *3 (D. Mass. Dec. 4, 2001).

n82 *Messick*, 514 So. 2d at 894-95; *Castleberry*, 721 S.W.2d at 271.

C. Discussion of Veil-Piercing Cases

The following cases demonstrate under what circumstances the United States and private plaintiffs will attempt to pierce the corporate veil to recover Medicare overpayments, false claims, and malpractice judgments.

1. Owners Personally Liable for Medicare Overpayments

In *United States v. Bridle Path Enterprises, Inc.*, a Massachusetts federal district court held the owners of a home health agency personally liable for the Medicare overpayment debt of the provider, Bridal Path. n83 For cost year 1993, the Medicare fiscal intermediary determined that Bridal Path had received an overpayment of \$ 231,568. n84 Bridal Path never requested an administrative hearing to challenge that determination. n85 Bridal Path made payments toward the overpayment until July 1997, when it sold all of its assets to Prism Home Care, Inc. (Prism), and notified the

Medicare program that it was terminating its Medicare participation. n86 At the time of the sale and voluntary termination, \$ 64,807.84 was outstanding on the overpayment liability. n87

n83 *Bridle Path Enters., Inc.*, 2001 WL 1688911, at *1.

n84 *Id.*

n85 *Id.*

n86 *Id.*

n87 *Id.*

The United States sought to hold Bridle Path's owners personally liable for the Medicare overpayment, on the grounds that Bridle Path was defunct and had little or no assets to satisfy the debt. n88 Noting there was "no single 'litmus' test" for determining whether to pierce the veil, the court looked at three factors: (1) the corporate identity; (2) the injustice that would result from not piercing the veil; and (3) the fraudulent intent of the defendants. n89

n88 *Id.* at *2.

n89 *Bridle Path Enters., Inc.*, 2001 WL 1688911, at *3.

Due to the number of checks Bridle Path wrote in 1996 and 1997 to its owners, their home health agency, and their real-estate holding **company**, the court found that the owners did not treat Bridle Path as a separate corporate entity. n90

n90 *Id.* at *2.

n91 *Id.* at *3.

During 1997, [the owners] made numerous sizeable payments to themselves from [Bridle Path]'s operations and payroll accounts, either directly or through one of their other **companies**. There is no evident rational business purpose to these payments, especially since [Bridle Path] was operating at a severe net loss at the time. In July 1997, when [Bridle Path] received an infusion of cash from its asset sale to Prism, the defendants used \$ 68,573.36 of this income to pay for renovations to their personal residences. The defendants also funneled a generous portion of the proceeds into their own pockets in the months immediately following the sale. In contrast, the defendants did not apply any of the \$ 750,000 Prism paid for [Bridle Path]'s assets to the Medicare debt. Such wrongful diversion of corporate assets at a time when the corporation was failing, and in fact dissolving, justifies piercing the corporate veil. n91

Unfortunately, there is little discussion of why Bridle Path made payments to the owners. Bridle Path paid \$ 40,000 to one owner, \$ 56,000 to a home health agency owned by the owners, \$ 6,800 to a real-estate holding **company** owned by the owners, \$ 17,600 to an individual from whom the owners acquired a physical therapy **company**, and \$ 68,000 to a contractor who testified that the payment was for work at the owners' private residence. n92 Bridal Path also increased payments to the owners out of Bridle Path's payroll accounts. n93 The owners did "not dispute or explain any of these

payments." n94 Thus, the inference is that all the payments, even those arguably to legitimate service providers or landlords, were not made in the ordinary course of business.

n92 *Id.* at *2.

n93 *Id.*

n94 *Id.*

The owners made two arguments to support their claim that they did not intend to defraud the government. First, they argued that the Internal Revenue Service (IRS) instructed them not to pay creditors prior to paying tax liabilities. Second, they claimed that they anticipated an additional \$ 750,000 payment from Prism if, as stated in the purchase agreement, Prism achieved certain net revenues within the first year of operation. n95 The court disagreed. According to the court, "[a] strong inference of intentional fraud arises from these facts" and the owners offered "no facts to defeat the inference--only their flat assertion." n96

n95 *Bridle Path Enters., Inc.*, 2001 WL 1688911, at *3.

n96 *Id.*

In addition to piercing the corporate veil, the court held the owners personally liable under the federal priority statute, which prohibits a person indebted to the government from making a voluntary assignment of property to themselves or another entity instead of paying the government debt. n97 The owners made several payments to themselves out of Bridle Path's corporate accounts after they stopped making payment toward the Medicare overpayment. n98 The court found "no reason not to conclude that the defendants are personally liable for the [Bridle Path] Medicare debt." n99

n97 *Id.* at *4.

n98 *Id.*

n99 *Id.*

2. Owner and Related **Companies** Liable for False Claims Act Judgment

In *United States v. Lorenzo*, a Pennsylvania district court pierced the corporate veil to reach a shareholder and related **companies** in a Medicare false-claims action. n100 There, the government pursued a false-claims action against a dentist and his related **companies** for Medicare claims filed for oral cancer examinations of **nursing home** residents. n101 After concluding that the claims submitted by U.S. Mobile, a **company** owned and controlled by the dentist, constituted false claims, the court addressed the liability of the dentist and his related **companies**. n102

n100 *United States v. Lorenzo*, 768 F. Supp. 1127, 1133 (E.D. Pa. 1991).

n101 *Id.* at 1128.

n102 *Id.* at 1132.

The court held the dentist and his related **companies** jointly and severally liable for U.S. Mobile's false claims. n103 The dentist placed the Medicare revenues into the accounts of U.S. Mobile and his own professional bank account. n104 U.S. Mobile transferred undocumented funds to related **companies**, including suspicious rental transactions with related **companies** where the rental amount nearly doubled from the previous lease and documentation failed to show any other related party paying similar rents. n105 In addition, U.S. Mobile entered into contracts for services and equipment with the dentist and other related **companies**. n106 Further, the dentist transferred the services of another dentist to his private practice, but continued to pay the dentist from U.S. Mobile funds. n107 The court found:

There can be no question that corporate formalities were not observed; that significant inter-entity transactions were not documented; and that the corporations and partnerships were treated as a single unit and the alter ego of [the dentist].

Finally, it is clear that U.S. Mobile was undercapitalized and that revenues were siphoned off from other ventures. n108

n103 *Id.* at 1133.

n104 *Id.* at 1132.

n105 *Id.* The court describes the "undocumented" transactions as: a ten-year lease entered into in 1985 that required U.S. Mobile to pay twice the rent it paid under a 1984 ten-year lease, with the dentist and his wife as signatories to the leases; and loans made with undocumented terms between U.S. Mobile and the related **companies** and the dentist and his wife. *Id.*

n106 *Lorenzo*, 768 F. Supp. at 1132-33. The court described the contracts for services and space as rental by U.S. Mobile of space and services from a related **company** that resulted in U.S. Mobile owing in excess of \$ 200,000 over a three-year period; contracts between U.S. Mobile and a related **company** for services, staff, and the use of a computer; and the purchase of a photocopier by U.S. Mobile to benefit the dentist's private office.

n107 *Id.* at 1133.

n108 *Id.*

Consequently, the court pierced the veil and held the dentist and related **companies** liable for U.S. Mobile's false claims. n109

n109 *Id.*

3. Parent Corporation Dismissed from a False-Claims Action Against Subsidiary

In *United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*, the Massachusetts district court dismissed a parent corporation from the government's false-claims action because the government's allegation that the parent was the sole owner of the subsidiary corporation was insufficient to pierce the corporate veil. n110 There, the government brought a false-claims action against, among others, Dialysis Holdings, a successor in interest to a Medicare lab, and its sole owner, Gambro Healthcare, for allegedly performing unnecessary and wasteful blood tests at a medical testing lab. n111 Dialysis Holdings, Gambro's wholly-owned subsidiary, was the only link between Gambro Healthcare and the alleged wrongdoers. n112

n110 United States ex rel. Kneepkins v. Gambro Healthcare, Inc., 115 F. Supp. 2d 35, 39-40 (D. Mass 2000).

n111 *Id.* at 37, 39.

n112 *Id.* at 39.

The court applied a three-factor standard to determine whether to pierce the veil: (1) the corporate identity; (2) the injustice that would result from not piercing the veil; and (3) the fraudulent intent of the defendants. n113 It concluded that the government's pleadings were insufficient as to Gambro because "the only fact alleged is Gambro's sole ownership of Dialysis Holdings" and "that alone is plainly not enough." n114

n113 *Id.*

n114 *Id.* at 40.

The government raised three arguments in opposition to Gambro's motion to dismiss. First, the government argued that the court should disregard the corporate form, "in the interests of 'public convenience, fairness and equity'" and, furthermore, "that the corporate form garners less respect in matters involving the enforcement of federal statutes." n115 The court rejected the argument, finding that the government did not allege that Gambro filed a false claim itself and did not allege that Gambro had stripped Dialysis Holdings of its assets. n116

n115 *Id.* (quoting *Town of Brookline v. Gorsuch*, 667 F.2d 215, 221 (1st Cir. 1981)).

n116 *Kneepkins*, 115 F. Supp. 2d at 40.

Second, the government argued that "Gambro, a privately-held corporation whose affairs are not open to scrutiny, must be kept in the case because the information concerning its relationship with Dialysis Holdings and Vivra is within its control, unavailable to the government for pleading purposes, and may only be unearthed through discovery." n117 The court rejected the argument, because the government had not alleged facts supporting that belief. n118

n117 *Id.*

n118 *Id.*

Finally, the government argued that the pleadings were sufficient to put Gambro on notice of the claims. n119 The court rejected the argument, concluding that the government "may not require a defendant to guess at what the contours of the claims against it may be when they take shape at some uncertain future time." n120

n119 *Id.* at 41.

n120 *Id.*

4. Owners and Related Companies Not Liable for Medicaid Overpayment Judgment

In *State v. Woodvale Management Services, Inc.*, a Minnesota appellate court refused to find shareholders, officers, directors, and related **companies** liable for Medicaid overpayments made to an intermediate care facility for the mentally retarded (ICF/MR). n121 There, two individuals were the sole officers, directors, and shareholders of a corporation that operated an ICF/MR. n122 The individuals formed a management corporation and transferred all of the ICF/MR corporation's stock to the management corporation. n123 The individuals also owned a sole proprietorship that leased property to the ICF/MR corporation. n124 Eventually, the state closed the ICF/MR, which was in poor financial condition at the time. n125 The State of Minnesota subsequently attempted to pierce the corporate veil and recover the Medicaid payments owed by the ICF/MR from the individuals and the parent management **company**. n126

n121 *State v. Woodvale Mgmt. Servs., Inc.*, No. C2-98-584, 1998 WL 811554, *1 (Minn. Ct. App. Nov. 24, 1998).

n122 *Id.*

n123 *Id.*

n124 *Id.*

n125 *Id.*

n126 *Id.*

Absent a showing of improper conduct, the court refused to find the individuals and related corporation liable for the debt of the ICF/MR. n127 It found the corporate entities "were, in fact, operated as separate corporations, observing all of the requisite and statutory corporate formalities." n128 It noted that "corporate dividends were not paid but reinvested in the corporation and . . . there was no evidence that [the parent] siphoned funds from [the ICF/MR]." n129 The court also found that it was "undisputed" that the ICF/MR was adequately capitalized. n130 Although the ICF/MR was insolvent at the time the judgment became due, it was solvent during the period that gave rise to the judgment. n131 The court noted that "it is the State that directly caused the insolvency of [the ICF/MR] by closing the facility." n132

n127 *Woodvale Mgmt. Servs., Inc.*, 1998 WL 811554, at *2.

n128 *Id.* at *3.

n129 *Id.*

n130 *Id.*

n131 *Id.*

n132 *Id.*

Furthermore, the court found no indicia of fraud. Rather, it found that the management **company** provided management services to the ICF/MR, which in turn provided services to residents. n133 Although the state argued that the \$ 3,000 initial capitalization of the ICF/MR corporation was inadequate, the court found that at the time it was

capitalized, "there was no indication that the amount would prove insufficient." n134

n133 *Woodvale Mgmt. Servs., Inc.*, 1998 WL 811554, at *3.

n134 *Id.* at *4.

5. Jury to Hear Question of Whether **Nursing Home** Corporation was Adequately Capitalized

In *Autrey v. 22 Texas Services, Inc.*, plaintiffs filed a malpractice action against a **nursing home** operator and its general and limited partners, as well as the operator's management **company** and its general and limited partners. n135 The defendant general and limited partners moved for summary judgment on the grounds that plaintiffs failed to produce any evidence to justify piercing the corporate veil. n136 Applying Pennsylvania law, under which "there is a strong presumption against piercing the corporate veil," the Texas district court concluded that plaintiffs raised a genuine issue of fact as to the liability of the general and limited partners. n137

n135 *Autrey v. 22 Tex. Servs., Inc.*, 79 F. Supp. 2d 735, 738 (S.D. Tex. 2000).

n136 *Id.* at 740.

n137 *Id.* at 740, 741.

With respect to the management **company**, the court found that the general partner of the management **company**, which was responsible for 100% of the operations of forty-nine **nursing homes** in Texas, as well as others in other states, had \$ 42,000 in assets and virtually no liquid assets. n138 It noted that the "financial condition raises disturbing questions," especially where "undercapitalization" is a basis for piercing the corporate veil. n139 In addition to undercapitalization, the court looked to the corporate structure of the general partner. n140 It found that "at the time of incorporation, [the **company**] had no employees, office space, or expenses; consequently, the **company** paid no rent and spent no money on advertising." n141 Furthermore, the court found it "suspicious" that the general partner "had nonfunctioning corporate officers." n142 The court concluded that if plaintiffs could prove at trial that defendants "asserted control over the management and ownership of the Texas **nursing homes** owned by [the general partner], it would add credence to their claim that [the general partner] represents nothing more than a corporate sham benefitting Defendants, all of whom serve as the sole shareholders of [the general partner]." n143

n138 *Id.* at 740.

n139 *Id.* at 740-41.

n140 *Id.* at 741.

n141 *Autrey*, 79 F. Supp. 2d at 741.

n142 *Id.*

n143 *Id.*

With regard to the operating **company**, the court found that six months after its formation, it had more than \$ 54,000 in liabilities with no accompanying net assets. n144 "Based on the nature and risk of the **nursing home** business, the Court notes that engaging in the ownership of forty-nine **nursing homes** while also maintaining no net assets appears to amount to nothing less than a disputable issue regarding undercapitalization." n145

n144 *Id.*

n145 *Id.* at 742.

These factual issues were sufficient to survive defendants' motion for summary judgment. The court held that "given the dispute surrounding whether [the entities] were adequately capitalized, the Court finds it reasonable to allow a jury to decide the issue." n146

n146 *Id.* at 746-47.

6. Veil-Piercing Inappropriate on Summary Judgment in Medicaid Overpayment Liability Action

In *Community Care Centers, Inc. v. Hamilton*, a **nursing home** corporation appealed an Indiana trial court decision in favor of the state Medicaid agency, rendering the **nursing home** shareholders personally liable for over \$ 6 million in Medicaid overpayments. n147 The trial court had granted the Medicaid agency's motion for summary judgment on the grounds that the shareholders "through the manipulation of the corporate form, were the wrongful recipients of [over \$ 6 million] in taxpayer-derived Medicaid funds," which was "enhanced by the absence . . . of corporate budgetary records, payment by the corporation of individual obligations and vice versa, commingling assets and affairs, together with the transfer of assets by salaries which were on their face fundamentally, unreasonably disparate to any value received." n148

n147 *Cnty. Care Ctrs., Inc. v. Hamilton*, 774 N.E.2d 559, 562 (Ind. Ct. App. 2002).

n148 *Id.* at 564.

Applying Indiana law, under which courts are "reluctant to disregard corporate identity and do so only to protect third parties from fraud or injustice," n149 the court examined the evidence as it related to the following eight factors: (1) undercapitalization; (2) absence of corporate records; (3) fraudulent representation by shareholders; (4) use of the corporation to promote fraud, injustice, or illegal activities; (5) payment by the corporation of individual obligations; (6) commingling of assets and affairs; (7) failure to observe required corporate formalities; and (8) other shareholder acts or conduct ignoring the corporate form. n150 The appellate court reversed the trial court's grant of summary judgment:

While it may be that [the **company's**] corporate veil should be pierced, it should not have been pierced on summary judgment. Piercing the corporate veil should only be accomplished on summary judgment in extraordinary circumstances such as when it is patently obvious that the sole purpose for a corporation's existence is to perpetrate a fraud or injustice. n151

n149 *Id.*

n150 *Id.* at 564-70.

n151 *Id.* at 570.

VI. Conclusion

A. Restructuring to Reduce Unnecessary Risk of Exclusion

Forming operating SPEs, such as limited liability **companies**, to operate each **nursing home** will avoid unnecessary exclusion of all other **nursing homes** under common ownership or control in the event of exclusion of any one of the **nursing homes**.

The benefit of having the **company's nursing homes** owned and operated by SPEs is further demonstrated by the following example. In this example, **Company X** is neither the licensed operator nor the certified provider of any of the **nursing homes**. Instead, **Company X** forms three single-purpose operating **company** subsidiaries--**Company A**, **Company B**, and **Company C**, each wholly owned by **Company X**--to be the licensed operators and certified providers of the **nursing homes**. **Company A** operates the Friendly **Nursing Home**, **Company B** operates the Caring **Nursing Home**, and **Company C** operates the Loving **Nursing Home**. **Company A** enters into a plea agreement with the United States to settle civil and criminal claims arising under the False Claims Act for allegedly providing substandard quality of care to the residents of the Friendly **Nursing Home**, and for billing and receiving payment from the Medicare and Medicaid programs for that substandard care. The DHHS Secretary excludes **Company A** from the Medicare and Medicaid programs.

Under this scenario, the DHHS Secretary does not exclude the Caring **Nursing Home** and the Loving **Nursing Home** for the conduct attributable to the Friendly **Nursing Home**, because the former are neither owned nor controlled by **Company A**. In addition, under this scenario, entities participating in the Medicare and Medicaid programs that provided items or services to all three **nursing homes** would be precluded from billing for items or services related to business conducted only with the Friendly **Nursing Home**. They could continue to seek reimbursement from any federal program for any business done with the Caring **Nursing Home** and the Loving **Nursing Home**.

In this example, **Company A's nursing home** operations will have the maximum protection against exclusion if each **nursing home** is operated by an operating SPE. If a **nursing home** must be excluded, it will mandate neither the exclusion nor the divestiture to avoid exclusion of any other **nursing home** provider.

Moreover, **Company A's** real estate holdings will have the maximum protection in the event of exclusion if the operating interests are held separate and apart from the real estate. Placing the real-estate interests in a real-property SPE and the operating interests in an operating SPE will avoid from the outset the possibility of restructuring on short notice to avoid a permissive exclusion attaching to the real estate.

Forming operating SPEs with ownership identical to other operating SPEs does not present unreasonable exposure to the owners or related **companies**. The DHHS Secretary may exclude any individual who has a direct or indirect ownership or control interest in, or is an officer or managing employee of, a sanctioned entity. n152 There is, however, no requirement or authority for the DHHS Secretary to exclude an individual who *had* a direct or indirect ownership or control interest in, or who *was* an officer or managing employee of a sanctioned entity. n153 The owners, shareholders, members, directors, or officers of the soon-to-be excluded operating entity could divest their interest in the **company** without having to divest their interests in any other **nursing home** operations, because the DHHS Secretary must give notice of intent to exclude. n154 This approach is commonly employed in divestiture situations with the knowledge and consent of the OIG.

n152 42 C.F.R. § 1001.1051(a)(1) (2003).

n153 *See id.* § 1001.1051(a)(1), (2).

n154 42 C.F.R. §§ 1001.2002(a), 2003 (2003).

B. Restructuring to Reduce Exposure to Financial Liability

Forming operating SPEs for each **nursing home** can prevent third-party and government litigants from obtaining and enforcing judgments against related operating **companies**, the real estate, and investors in the event that the operating **company** is sued to recoup Medicare or Medicaid overpayments, for False Claims Act violations, or for **nursing-home** malpractice.

Furthermore, holding the real estate in a separate real-property entity that leases the **nursing home** to the operating entity protects the assets by making the real estate unavailable for collection by judgment creditors of the operating entity. This, in turn, can serve to make the real estate more attractive to potential lenders because the most problematic risks of **nursing home** operations do not reach the real estate. Indeed, many current investors and lenders are requiring that the real property owner not engage in the operation of the facility. The model for such an approach is the Real Estate Investment Trust (REIT), which prohibits owners from engaging in the operations of the real estate they own. There are other legitimate corollary benefits and uses for a separate real-property SPE. For example, the real estate could be placed in a trust for estate-planning purposes while the current operators directly own the operating entity. In addition, the real-property entity could attract investors who are leery of operating risks, thereby altering the ownership composition between the real-property entity and the operating entity.

Forming operating SPEs with ownership identical to other operating SPEs, or ownership identical to the real property entities, does not present unreasonable exposure to the owners or related **companies**. Although there is no single litmus test for determining when courts will pierce the corporate veil, the following factors alone are insufficient: wholly owned, sole shareholder, or sole member **companies**; n155 insolvency; n156 and failure to pay corporate dividends. n157 Due to the variation among courts in applying veil-piercing analyses, defendants should carefully evaluate choice-of-law provisions when faced with a veil-piercing claim. Some jurisdictions require a showing of fraud, or indicia of fraud, an element favorable to defendants. Finally, defendant limited liability **companies** should assert that the corporate veil-piercing doctrine is inapplicable to the **company**, which instead should be held to the statutory standards in the state where it was formed.

n155 *United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F. Supp. 2d 35, 39 (D.Mass 2000).

n156 *State v. Woodvale Mgmt. Servs., Inc.*, No. C2-98-584, 1998 WL 811554, *2 (Minn. Ct. App. Nov. 24, 1998).

n157 *Id.*

APPENDIX: Practice Guide

I. Avoiding Veil-Piercing

Mere ownership of a **nursing home** operating **company** is insufficient to hold the shareholders, members, or parent **company** liable for the acts and omissions of the **company**, even if the related **companies** have identical directors and officers. That said, there are steps that **nursing home companies** should take to minimize the risk of veil-piercing exposure.

A. Adhere to Formalities. The following are formalities that courts have found significant:

- o Adopt bylaws;

- o Conduct meetings of the shareholders/directors/officers/ members;
- o Maintain meeting minutes that reflect business decisions made by the officers; and
- o Maintain separate banking and accounting records that account for the cash and assets of the **company** separate and distinct from the cash and assets of shareholders, directors, officers, members, and affiliates.

B. Preserve the distinction among the operating entity and its shareholders, directors, officers, members, and affiliates. Conduct business in the **company** name, not in the name of an affiliate, shareholder, director, officer, or member of the **company**. Relevant measures include the following:

- o Hold out to the public only the operating entity, not its shareholders/members or affiliates, as operating the **nursing home**;
- o Have the operating entity, not related/affiliate **companies**, rent the property;
- o Enter into product and service agreements on behalf of the operating entity;
- o Market the services of the **nursing home**, not those of its affiliates;
- o Use admissions agreements that identify the **nursing home** operating entity only, not its "chain" affiliates; and
- o Employ and pay **nursing home** personnel at the **company** level, not at the chain level.

C. Adequately Capitalize the Operating Entity. There is little guidance concerning what constitutes adequate capitalization of a **nursing home**. In one case, \$ 3,000 was deemed to be sufficient capitalization of an ICF/MR at the time of incorporation. In another case, \$ 500 was viewed as "thin capitalization," but the court did not decide whether that amount of capitalization was too thin. In the recent *Autrey* case discussed in the Article, the court questioned the adequacy of a **nursing home** management **company's** capitalization where the management was responsible for the operations of forty-nine **nursing homes**, had \$ 42,000 in assets, and virtually no liquid assets. 158 The following are indicia of capitalization that courts will consider.

1. Initial Capitalization

- o Capitalize to meet state minimum statutory requirements.
- o Capitalize to meet industry standards. Some states require Medicaid providers upon enrollment to show financial statements and demonstrate minimum working capital capacity.
- o The lack of some amount of operating capital will be found to be inadequate capitalization.

2. Solvency

- o Maintain capital necessary to pay immediate and foreseeable obligations.

3. Insurance

- o Maintain adequate insurance according to state-law and industry standards.
- o Maintain capital necessary to pay out insurance deductibles as foreseeable

obligations of the **company**.

n158 Autrey v. 22 Tex. Servs., Inc., 79 F. Supp. 2d 735, 738-39 (S.D. Tex. 2000).

D. Avoid even the appearance of siphoning revenues to related entities or shareholders/members. Indicia of siphoning include the following:

- o Repayment of loans from shareholders at a time when other creditors are not being paid;
- o Payment of rent to related **companies** for greater than fair market value; and
- o Payment of management fees to related **companies** for greater than fair market value.

II. Deciding Whether to Restructure

Ultimately, the decision to restructure is made based on an assessment of the organization's business goals, which involves a balancing of acceptable risk with acceptable costs. If the business goal is minimizing liability and exclusion exposure, the costs associated with creating SPEs to hold the real estate and operate the **nursing home** may outweigh the risks of losing several **nursing homes** to exclusion or malpractice judgments. On the other hand, if the business goal is administrative simplicity, the balance likely would not tip in favor of creating a real-property SPE and an operating SPE for each **nursing home**. There is a point at which the goals of administrative simplicity and minimizing liability and exclusion exposure converge, coupled with the costs associated with restructuring, no longer outweigh the risk of losing several **nursing homes**.

The costs of restructuring can be high. For each entity, there are costs associated with:

- o Deciding upon the legal structure to form and in which state to form it;
- o Forming the legal structure;
- o Preparing the articles of incorporation or limited liability **company** operating agreements;
- o Qualifying the entities to do business in the state in which the **nursing home** is located;
- o Annual **company** and business registration fees;
- o Maintaining corporate formalities;
- o Maintaining adequate capitalization;
- o Locally managing day-to-day operations and financials; and
- o Locally establishing facility policy.

Moreover, restructuring has financing, tax, and employment implications that go beyond the scope of this Article.

Nevertheless, the benefits of restructuring can be great. Establishing real property SPEs and operating SPEs benefits the organization by:

- o Making real estate unavailable for collection by judgment creditors;
- o Shielding from exclusion affiliate **nursing homes** operated by separate entities with the same

ownership and control;

- o Shielding from judgment creditors the operating cash and assets of affiliate **nursing homes;**
- o Precluding the poor-performing **nursing home** from depleting the cash and assets of more successful operations, and driving into bankruptcy the business operation of all of the commonly-owned **nursing homes;** and
- o Increasing opportunities for commercial and government financing.

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SUMMARY: ABSTRACT: Every year, the American Health Lawyers Association assembles a Year in Review summary of the leading developments in case law, legislation, and administrative actions affecting healthcare. This article provides a comprehensive overview of these developments, with an emphasis on healthcare reform. Keywords: Healthcare Reform, Antitrust, State and Local Healthcare Legislation, False Claims Act, Fraud Enforcement and Recovery Act, Anti-Kickback Statute, Stark, Medicaid, Medicare, Health Insurance Portability and Accountability Act, American Recovery and Reinvestment Act, Health Information Technology for Economic and Clinical Health Act, Red Flag Rules, Health Care Quality Improvement Act, Tax

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TEXT:

Introduction

The latter half of 2008 and 2009, to date, have painted a rich tableau of events for healthcare law. With a new administration in the White House and a shift in the congressional balance of power, health-care has risen to the top of the political agenda for the first time in fifteen years. The American Health Lawyers Association (AHLA) and its members are watching developments in this area closely to evaluate the impact of legislation and to help their clients prepare for significant changes in the way they deliver healthcare. Health reform may have massive implications for health lawyers. New statutes and mechanisms for delivering care will increase the importance of health lawyers and their craft as the new system is rolled out. Providers, plans, and the government will be subject to new rules and

expectations, and this will affect the practice of health law for years to come.

Sharing the canvas with the elections and the enhanced focus on healthcare reform this year is the recession and how it has affected both providers and the industry overall. The headlines spelled out the impact of the downturn in the economy on the healthcare industry: "Hospitals Feel Effects of Economic Crisis, AHA Survey Finds," n1 "Chicago Hospital Hangs For Sale Sign, Citing Credit Crunch," n2 "Financial Crisis Hits Health-Care **Companies**." n3 Contrary to traditional wisdom, healthcare is not recession proof, and in the current economy, appears to be neither recession delayed nor moderated.

n1 Health Lawyers Weekly, Vol. 6, No. 45 (Nov. 21, 2008), www.healthlawyers.org/News/Health%20Lawyers%20Weekly/Pages/default.aspx. This publication is an AHLA member benefit, and is available to non-members by subscription.

n2 Wall St. J. (Oct. 9, 2008), *available at* <http://blogs.wsj.com/health/2008/10/09/chicago-hospital-hangs-for-sale-sign-citing-credit-crunch/> (last visited July 8, 2009).

n3 Bus. Wk. (Nov. 28, 2008) *available at* www.businessweek.com/investor/content/nov2008/pi20081126_889656.htm (last visited July 8, 2009).

This Year in Review 2008-2009 will review important cases and regulatory actions in many of the traditional areas of health law, which are still the mainstay of practitioners. However, the principal thread that ties this year's key health law events together will reflect the more general environment in which they occurred. In particular, the content and analysis will attempt to emphasize and illustrate the issues critical to achieving comprehensive healthcare reform. It also will present some of the novel and emerging issues to illustrate possible directions for health law in the future.

Healthcare Reform

Healthcare reform became one of the top items on the political agenda early on in the Obama administration, and it is expected to remain at the forefront of media coverage and congressional attention in the year ahead. The following discussion summarizes the key developments in 2009 and highlights some of the early legislative initiatives that have begun to define the cornerstones of the healthcare reform effort. Specifically, several topics already have emerged as a key focus of regulatory attention, including:

- . health information technology and electronic health records (EHRs);
- . quality of care;
- . universal access and coverage;
- . prescription drug pricing; and
- . relationships between pharmaceutical and device **companies** and healthcare professionals.

Because these topics will likely drive the healthcare reform debate and be the target of legislative proposals in the year ahead, this review presents them as part of the more general subject of health-care reform.

Health information technology and EHRs

Most of the players in the healthcare industry agree that EHRs are essential to the practice of modern medicine. But the expenses and potential dangers associated with new technology are a major obstacle to widespread implementation.

Only 1.5% of U.S. hospitals have an EHR system present in all clinical units, according to a recent study published online in the *New England Journal of Medicine*.ⁿ⁴ The study found that an additional 7.6% of acute care hospitals have a basic system in place that includes functionalities for physicians' notes and nursing assessments in at least one clinical unit. This percentage went up to 10.9% without the requirement for clinical notes. More than 75% of hospitals, however, reported adopting electronic laboratory and radiologic reporting systems.

n4 Ashish K. Jha, M.D., M.P.H. et al., *Use of Electronic Health Records in U.S. Hospitals*, 360 *New Eng. J. Med* 1628 (2009), available at <http://content.nejm.org/cgi/content/full/360/16/1628> (last visited July 8, 2009).

According to another study published June 18, 2008, in the *New England Journal of Medicine*, only 4% of 2,758 physicians responding to a recent survey reported having an extensive, fully functional EHR system, and 13% reported having a basic system.ⁿ⁵ Among the 83% of respondents who did not have an EHR, 16% reported that their practice had purchased but not yet implemented such a system at the time of the survey. According to the study, its findings "suggest that the U.S. health care system faces major challenges in taking full advantage of electronic health records to realize its health care goals."ⁿ⁶ The study was supported by the Department of Health and Human Services (HHS) Office of the National Coordinator for Health Information Technology.

n5 Catherine M. DesRoches, Dr.P.H. et al., *Electronic Health Records in Ambulatory Care--A National Survey of Physicians*, 359 *New Eng. J. Med* 50 (2008), abstract available at <http://content.nejm.org/cgi/content/abstract/359/1/50> (last visited July 8, 2009).

n6 *Id.* at 57.

Hospitals also have been slow to help physicians purchase EHRs, despite regulatory exceptions allowing them to do so without running afoul of federal fraud and abuse laws, according to a study issued September 18, 2008 by the Center for Studying Health System Change.ⁿ⁷ In August 2006, HHS issued exceptions to the federal physician self-referral and anti-kickback laws that opened the door for hospitals to subsidize up to eighty-five percent of the upfront and ongoing costs of EHR software and related information technology support services for physicians. The regulatory exceptions/safe harbors are set to sunset on December 31, 2013. The study, funded by the Robert Wood Johnson Foundation, was based on site visits to twelve nationally representative metropolitan communities in 2007.

n7 Joy M. Grossman & Genna Cohen, *Despite Regulatory Changes, Hospitals Cautious in Helping Physicians Purchase Electronic Medical Records*, Center for Studying Health System Change, Issue Brief No. 123, Sept. 2008, available at www.hschange.com/CONTENT/1015/1015.pdf (last visited July 8, 2009).

However, significant progress in the adoption and use of electronic prescribing has been accomplished over the last two years, according to a report issued by Surescripts, which operates the country's largest e-prescribing network.ⁿ⁸ "In the past two years, the U.S. has gone from 19,000 to 103,000 prescribers routing prescriptions electronically--punctuated by 39 percent sequential growth in prescriber adoption in the first quarter of this year," said Harry Totonis, president and CEO of Surescripts.ⁿ⁹ According to the *National Progress Report on E-Prescribing*, total e-prescribing message volume doubled between 2007 and 2008 to more than 240 million, while electronic requests for prescription benefit information grew from 37 million to 78 million during that time period. The report also found that prescription histories delivered to prescribers grew from more than 6 million in 2007 to more than 16 million in 2008. Prescriptions routed electronically grew from 29 million in 2007 to 68 million in 2008.ⁿ¹⁰

n8 Press Release, Surescripts, U.S. Achieves Major Milestones in E-Prescribing (Apr. 22, 2009), available at www.surescripts.net/downloads/NPR_Announcement_Final.pdf (last visited July 6, 2009).

n9 *Id.*

n10 *See id.* (citing the National Progress Report on E-Prescribing, *available at* www.surescripts.net/downloads/NPR/national-progress-report.pdf (last visited July 6, 2009)).

American Recovery and Reinvestment Act of 2009 and EHR technology

In an effort to nail down some of the pieces of healthcare reform and lay the groundwork for more sweeping legislation on the topic, President Obama signed into law on February 17, 2009, a massive \$ 787 billion economic recovery package that included a number of significant healthcare-related provisions. n11 Citing spiraling healthcare costs that are "crushing families and businesses," President Obama presented this initiative as a "meaningful step . . . towards modernizing our healthcare system." n12 The House passed the *American Recovery and Reinvestment Act of 2009* (H.R. 1) on February 13, 2009, by a 246-183 margin; the Senate followed suit on the same day in a 60-38 vote.

n11 *See* American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5 [hereinafter *ARRA*].

n12 President Barack Obama, Remarks at Signing of Economic Stimulus Bill (Feb. 17, 2009) (transcript *available at* www.america.gov/st/texttrans-english/2009/February/20090217171300eafas0.5613825.html) (last visited July 6, 2009).

As referenced above, the *American Recovery and Reinvestment Act of 2009* (the Act) includes among its provisions incentives for the adoption and use of EHR technology by Medicare and Medicaid professionals and hospitals. n13 Medicare offers incentive payments for a period of up to five years. Medicare will begin penalizing professionals and hospitals by reducing payments to professionals and hospitals that fail to adopt EHR technology by 2015. Medicaid professionals and hospitals also are eligible for incentive payments under the Act, with first-year payments available until 2016 and subsequent payments available no later than 2021.

n13 *ARRA* § 4102.

Under the Act, eligible professionals may apply to receive Medicare incentive payments between the years 2011 and 2016. In addition, the Act calls for a reduction in payments to eligible professionals if they do not adopt certified EHR technology by 2015. EHR technology includes an electronic record of health-related information on an individual that includes patient demographic and clinical health information and has the capacity to:

- . provide clinical decision support;
- . support physician order entry;
- . capture and query information relevant to healthcare quality; and
- . exchange electronic health information with and integrate such information from other sources.

EHR technology is "certified" when it meets standards and implementation specifications for health information technology as adopted by the HHS Secretary.

Eligible hospitals will receive incentive payments for being EHR users starting in 2011 until 2015. The Act also provides for the reduction in Medicare and Medicaid payments in the event the eligible hospital does not implement and use EHR after 2015. A hospital is eligible for incentive payments if it is either a subsection (d) hospital or a critical access hospital and uses EHR technology. n14 A subsection (d) hospital does not include:

1. rehabilitation hospitals;
2. hospitals where the patients are predominantly under age eighteen;
3. hospitals having average inpatient stays of greater than twentyfive days; or
4. hospitals involved extensively in the treatment of or research on cancer. n15

n14 See Social Security Act, 42 U.S.C. § 1395ww(d)(1)(B) (2007).

n15 See *id.*

If a hospital qualifies as an eligible hospital as set forth above, the hospital can receive incentive payments if it uses EHR technology. If a hospital does not become a meaningful user of a certified EHR technology on or after 2015, the hospital may be subject to reductions in its annual market basket adjustment.

State legislatures and health information technology

Driven by the view that health information technology (HIT) plays an integral part in healthcare reform and cost containment efforts, states also have dramatically increased the pace of enacting legislation to spur the adoption of HIT by the healthcare sector, according to a report released by the National Conference of State Legislatures. n16 The report found that lawmakers in state legislatures around the country introduced more than 370 bills related to HIT during an 18-month period between 2007 and 2008. During that timeframe, 44 states and the District of Columbia enacted 132 bills containing HIT provisions--three times as many bills that passed in the same period from 2005 to 2006.

n16 National Conference of State Legislatures, *Health Information Technology 2007 and 2008 Legislation (2008)*, available at www.ncsl.org/print/health/forum/HIT_Enacted.pdf (last visited July 6, 2009).

Patient safety and quality

Another topic that received attention in 2008 and 2009 and that likely will garner additional importance in the healthcare reform debate is patient safety and the overall quality of care. The performance of the U.S. health system continues to lose ground, despite the investment of more resources than any other industrialized nation, according to a *2008 National Scorecard on U.S. Health System Performance* issued by the Commonwealth Fund. n17 The 2008 Scorecard found little overall improvement since the Commonwealth Fund Commission on a High Performance Health System issued the first National Scorecard in 2006. Most notably, said the report, is a marked decline in U.S. scores on access, as well as lackluster performance on key indicators of health outcomes, quality, and efficiency.

n17 The Commonwealth Fund Commission on a High Performance Health System, *The Commonwealth Fund, Why Not the Best? Results from the National Scorecard on U.S. Health System Performance, 2008 (July 2008)*, available at www.commonwealthfund.org/Content/Publications/Fund-Reports/2008/Jul/Why-Not-the-Best-Results-from-the-National-Scorecard-on-U-S-Health-System-Per-# citation (last visited July 6, 2009).

According to the report, the United States had an overall score of 65 out of a possible 100 across 37 core indicators of healthy lives, quality, access, efficiency, and equity when compared to national and international top performing benchmarks. The report highlighted several areas of particular concern--including low scores on efficiency measures (53 out of 100). The United States also fell to last place among 19 industrialized nations on preventable mortality (i.e.,

deaths that might have been prevented with timely and effective care). Although United States rates improved somewhat from earlier measurements, the nation lagged behind big gains in other countries, the report said.

Medical errors that occur during or after surgery and that are potentially preventable may cost employers nearly \$ 1.5 billion annually, according to a study released July 28, 2008 by the HHS Agency for Healthcare Research and Quality (AHRQ).ⁿ¹⁸ The study found that one of every 10 patients who died within 90 days of surgery did so because of a preventable error, and that one-third of these deaths occurred after the initial hospital discharge. The study, which was conducted by researchers at AHRQ, was based on a nationwide sample of more than 161,000 patients ages 18 to 64 in employer-based health plans who underwent surgery between 2001 and 2002. The authors of the study concluded that the effects of medical errors continue long after the patient leaves the hospital, and that "medical error studies that focus only on the [hospital] inpatient stay" may underestimate the financial impact of patient safety events by "up to 30 percent."ⁿ¹⁹

ⁿ¹⁸ William E. Encinosa & Fred J. Hellinger, *The Impact of Medical Errors on Ninety-Day Costs and Outcomes: An Examination of Surgical Patients*, 43 *Health Services Research* 2067 (2008), available at www3.interscience.wiley.com/cgi-bin/fulltext/120855828/PDFSTART (last visited July 6, 2009).

ⁿ¹⁹ *Id.* at 2067.

Never events

In an effort to reduce the occurrence of certain surgical errors and ensure that government reimbursement is not available for these events, on January 15, 2009, the Centers for Medicare and Medicaid Services (CMS) finalized three national coverage determinations (NCDs) to establish uniform national policies that will prevent Medicare from paying for three so-called "never events."ⁿ²⁰ Never events, identified in the National Quality Forum's (NQF's) list of Serious Reportable Events, are adverse events that ideally should never happen. The three NCDs bar Medicare payment for:

1. wrong surgical or other invasive procedures performed on a patient;
2. surgical or other invasive procedures performed on the wrong body part; and
3. surgical or other invasive procedures performed on the wrong patient.

ⁿ²⁰ In January 2009, CMS announced three national coverage determinations (NCDs) to establish uniform national policies that will prevent Medicare from paying for certain serious, preventable errors in medical care. Decision memos are available at www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=223; www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=221; and www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=222 (last visited July 6, 2009).

Several states adopted similar regulatory changes. In June 2008, Massachusetts health officials announced that the state will no longer pay for costs associated with 28 serious reportable healthcare events identified by NQF.ⁿ²¹ In addition, the state Medicaid program in New York will no longer reimburse providers for 14 never events, including wrong-site or wrong-patient surgeries, serious medication errors, and unintentionally leaving a foreign object in a patient.ⁿ²² The list will be continually reviewed and revised as needed, according to the state Department of Health. Hospitals will be required to provide information that will designate which complications were present on admission and which ones occurred during or as a result of hospital care.

ⁿ²¹ See Press Release, Patrick Administration Announces Non-Payment Policy for 28 Serious Reportable Events (June 18, 2008),

available at

www.mass.gov/?pageID=eohhs2pressrelease&L=4&L0=Home&L1=Government&L2=Special+Commissions+and+Initiatives&L3=The+HealthyMass+Initiative
(last visited July 6, 2009).

n22 See Press Release, Medicaid to Cease Reimbursement to Hospitals for 'Never Events' and Avoidable Errors (June 5, 2008), available at www.health.state.ny.us/press/releases/2008/2008-06-05_medicaid_cease_paying_never_events.htm (last visited July 6, 2009).

Medical error reporting

In a key patient safety development in November 2008, HHS published a final rule implementing patient safety legislation enacted in 2005 to promote medical error reporting. n23 The *Patient Safety and Quality Improvement Act of 2005* set forth privilege and confidentiality protections in civil and criminal proceedings for patient safety work product (PSWP) reported by providers to new patient safety organizations (PSOs). n24 The PSOs will collect, aggregate, and analyze the data to identify ways to prevent medical errors. The final rule, effective January 19, 2009, details the framework for confidential error reporting and specifies the requirements and procedures for entities to become PSOs.

n23 73 Fed. Reg. 70732.

n24 See Patient Safety and Quality Improvement Act of 2005 (Pub. L. No. 109-41).

According to HHS, the final PSO rule, although generally consistent with the February 2008 proposal, n25 includes a number of changes or new requirements. For example, the final rule requires PSOs to notify providers if PSWP it submits is inappropriately disclosed or if its security is breached. The final rule also adds flexibility to requirements for how a component PSO maintains separation between itself and its parent organizations. In addition, the final rule includes changes from the proposed rule regarding the listing and delisting of PSOs and the ways PSOs must comply with statutory requirements. The final rule expands the types of entities and organizations excluded from listing as PSOs and increases flexibility in how PSOs can store PSWP. PSOs' listings automatically expire after three years, unless specifically continued by the Secretary. The final rule provides an expedited delisting process for PSOs in certain serious circumstances.

n25 73 Fed. Reg. 8112.

Behavior of healthcare professionals

According to a *Sentinel Event Alert* (the Alert) issued July 9, 2008, by the Joint Commission, rude language and hostile behavior among healthcare professionals pose a serious threat to patient safety and overall quality of care. n26 "Verbal outbursts, condescending attitudes, refusing to take part in assigned duties, and physical threats all create breakdowns in teamwork, communication, and collaboration necessary to deliver patient care." n27

n26 The Joint Commission, Joint Commission Alert: Stop Bad Behavior among Health Care Professionals (July 9, 2008), available at www.jointcommission.org/NewsRoom/NewsReleases/nr_07_09_08.htm (last visited July 6, 2009).

n27 *Id.*

The Alert recommends that healthcare organizations take a number of specific steps to address bad behavior among healthcare workers, including:

- . educating all healthcare team members about professional behavior;

- . enforcing a code of conduct consistently and equitably;
- . establishing a comprehensive approach to addressing intimidating and disruptive behaviors, including a zero-tolerance policy and strong support from physician leadership; and
- . developing a system to detect and receive reports on unprofessional behavior.

The Commission also has introduced new standards for 2009, "requiring more than 15,000 accredited healthcare organizations to create a code of conduct that defines acceptable and unacceptable behaviors and to establish a formal process for managing unacceptable behavior." n28

n28 *Id.*

Rating **nursing homes**

In another quality and safety initiative launched in December 2008, CMS posted ratings of the nation's 15,800 **nursing homes on its Nursing Home Compare** website. n29 Consumers are able to compare **nursing homes** based on a new five-star rating system. According to CMS, in the first round of quality ratings, about 12 percent of **nursing homes** received a five-star rating, while 22 percent were assessed one star.

n29 www.medicare.gov/nhcompare.

Access and coverage issues

A number of key health law developments over the past year relate to the broader issue of consumer access to healthcare coverage and illustrate growing public and governmental concern about this issue.

Shortly before the elections last fall, the House and Senate passed mental health parity legislation as part of the massive economic stabilization bill that was signed into law on October 3, 2008 by President Bush. n30 The mental health parity legislation requires insurance **companies** and employers offering mental health coverage to provide it on par with the coverage offered for other physical illnesses.

n30 *See* Emergency Economic Stabilization Act of 2008, H.R. 1424, 110th Cong. (2007-2008).

In February 2009, President Obama signed into law legislation that reauthorizes the popular State Children's Health Insurance Program (SCHIP) for four-and-a-half years. n31 The legislation includes several provisions that extend coverage to legal immigrant children and pregnant women who have been in the country fewer than five years. On the same day he signed the reauthorization legislation into law, President Obama issued a memorandum withdrawing a controversial directive issued by CMS on August 17, 2007, that set forth stricter requirements for states to expand SCHIP eligibility to children in families with higher incomes. n32

n31 Children's Health Insurance Program Reauthorization Act of 2009, H.R. 2, 111th Cong. (1st Sess. 2009).

n32 *See* 74 Fed. Reg. 6347, www.whitehouse.gov/the_press_office/PresidentialMemorandumStateChildrensHealthInsuranceProgram/ (last visited July 6, 2009).

A San Francisco ordinance that imposed employer-spending mandates to cover certain healthcare expenses of employees was challenged on Employee Retirement Income Security

A San Francisco ordinance that imposed employer-spending mandates to cover certain healthcare expenses of employees was challenged on Employee Retirement Income Security Act (ERISA) pre-emption grounds. n33 In a closely watched decision, the Ninth Circuit ruled that ERISA does not preempt the ordinance. The San Francisco Health Care Security Ordinance (the Ordinance), n34 passed in 2006, requires medium and large employers (those with more than twenty employees) and nonprofits with more than fifty employees to make certain levels of healthcare expenditures for individuals employed for more than ninety days who work more than ten hours per week. Qualifying healthcare expenditures include:

- . contributions to health savings accounts;
- . direct reimbursement to employees for healthcare expenses;
- . payments to third parties for healthcare services;
- . costs incurred in the direct delivery of healthcare services; or
- . payments to the city "to be used on behalf of covered employees." n35

n33 *Golden Gate Restaurant Ass'n v. City and County of San Francisco*, 546 F.3d 639 (9th Cir. 2008).

n34 Healthcare Security Ordinance, San Francisco Administrative Code, Chapter 14 (S.F. Admin. Code § 14).

n35 *Golden Gate Restaurant v. San Francisco*, 546 F.3d at 644.

First, the appeals court held that the city-payment option did not create an ERISA plan. According to the appeals court, an employer's administrative responsibilities under the Ordinance to make the required payments for covered employees and retain adequate records did not make the city-payment option an ERISA plan.

Next, the appeals court rejected the argument that Section 514(a) of ERISA preempted the Ordinance because it "relates to" employers' ERISA plans. The appeals court stressed that the Ordinance did not require any employer to adopt an ERISA plan or other health plan. Nor did it require any employer to provide specific benefits through an existing ERISA plan or other health plan:

Any employer covered by the Ordinance may fully discharge its expenditure obligations by making the required level of employee healthcare expenditures, whether those expenditures are made in whole or in part to an ERISA plan or in whole or in part to the city. The Ordinance thus preserves ERISA's "uniform regulatory regime." n36

n36 *Id.* at 655-56.

The plaintiffs in the case have petitioned the U.S. Supreme Court to review the Ninth Circuit's decision.

Coverage issues under private health plans also were prominent over the past year in California. In August 2008,

amid growing scrutiny by courts and regulators of post-claims underwriting--in other words, rescinding health policies without proving that applicants willfully misrepresented themselves on their health applications--the California legislature passed legislation aimed at addressing the practice. n37 Under the bill, healthcare service plans licensed by the Department of Managed Health Care (DMHC) and health insurers regulated by the California Department of Insurance (CDI) would have been required to complete medical underwriting *prior to* issuing a contract or policy. The bill also would have prohibited plans and insurers from canceling or rescinding an individual plan contract or policy unless specified conditions were met.

n37 California Assembly Bill No. 1945 (2008).

A month later, California Governor Arnold Schwarzenegger vetoed AB 1945, citing concerns about the "fragile" individual insurance market. n38 The Legislature reintroduced a similar bill in December 2008. n39 Over the last year, however, most of California's major health plans reached settlement agreements with the DMHC or CDI concerning certain rescinded policies. In addition, on June 3 of this year, CDI unveiled new regulations extending requirements related to rescission practices to the state's remaining insurers that had not reached settlements with regulators. n40

n38 See correspondence available at http://gov.ca.gov/pdf/press/AB1945_DeLaTorre_Veto_Message.pdf.

n39 California Assembly Bill No. 2 (2008).

n40 See California Code of Regulations, Title 10, Chapter 5, Subchapter 2: Policy Forms and Other Documents, Article 11: Standards for Health History Questionnaires in Health Insurance Applications, Pre-Issuance Medical Underwriting and Rescission of Health Insurance Policies.

Prescription drug pricing

One of the most significant issues for any comprehensive healthcare reform proposal involves the cost of prescription drugs and the percentage that this expense represents in the nation's overall healthcare bill. An important component of this issue is the high cost of biotechnology drugs, which are produced from living cell cultures rather than synthesized chemically, and which are among the fastest growing and most expensive components of the nation's drug bill. Without a statutory pathway, lawmakers have raised concerns that manufacturers of biotech drugs, which are often prohibitively expensive and include medications used to treat cancer, diabetes, and AIDS, can charge monopoly prices indefinitely. The past year saw a number of legislative initiatives seeking to correct this situation.

The Promoting Innovation and Access to Life-Saving Medicines Act, introduced this past year by Representatives Henry A. Waxman (D-CA), Frank Pallone, Jr. (D-NJ), Nathan Deal (R-GA), and Jo Ann Emerson (R-MO), would grant the original product five years of exclusive marketing, while a modification of a previously approved product would be entitled to three years of exclusivity. n41 The exclusivity periods could be extended by up to one year if the applicant establishes that the product can be used for new disease indications or if it conducts pediatric studies, according to a summary of the bill. Senators Charles E. Schumer (D-NY), Susan Collins (R-ME), Sherrod Brown (D-OH), Mel Martinez (R-FL), Debbie Stabenow (D-MI), and David Vitter (R-LA) introduced a similar bill in the Senate, which also contemplates a five-year period of exclusivity. n42 Other bills introduced in the House and Senate differ on the length of the exclusivity period.

n41 Promoting Innovation and Access to Life-Saving Medicines Act, H.R. 1427, 111th Cong. (1st Sess. 2009).

n42 Promoting Innovation and Access to Life-Saving Medicine Act, S.B. 726, 111th Cong. (1st Sess. 2009).

The Obama administration said in its fiscal year (FY) 2010 budget proposal that it supports efforts to create a clear regulatory pathway for approving follow-on generics of biotechnology products. According to budget documents, brand name manufacturers would still have a guaranteed period of exclusivity but would be prohibited from reformulating existing products to restart the exclusivity process. The budget outline further signaled the administration's support for new efforts by the Food and Drug Administration (FDA) "to allow Americans to buy safe and effective drugs from other countries" as a way to help lower costs. n43

n43 See Department of Health and Human Services, Budget Funding Highlights, *available at* www.whitehouse.gov/omb/assets/fy2010_new_era/Department_of_Health_and_Human_Services1.pdf (last visited July 6, 2009).

Given the focus on drug pricing in healthcare reform proposals, it was not surprising that a significant number of fraud and abuse enforcement efforts over the past year involved allegations of improper pricing and marketing practices by drug manufacturers. These practices include misrepresenting and inflating the average wholesale price (AWP) of prescription drugs and the improper marketing of off-label uses of prescription drugs. For example:

. In Alabama, a jury found GlaxoSmithKline and Novartis liable for more than \$ 100 million for misreporting and inflating the AWP and thereby overcharging the state Medicaid agency. n44

. Eli Lilly and **Company** agreed to a multi-state settlement of \$ 62 million to resolve off-label marketing charges. n45

. Biopharmaceutical **company** Cephalon entered into a criminal plea and agreed to pay \$ 425 million to settle allegations that it unlawfully promoted three of its drugs for off-label uses. n46

. Eli Lilly and **Company** agreed to pay \$ 1.415 billion to settle criminal and civil allegations that the drug maker illegally marketed its antipsychotic drug Zyprexa (olanzapine) for unapproved uses. n47

. A federal district court in Massachusetts approved a \$ 352.7 million settlement of class actions alleging drug wholesalers First DataBank and Medi-Span engaged in a scheme with drug pricing publisher McKesson Corporation to fraudulently "mark up" the average wholesale price for numerous prescription drugs. n48

n44 Health Lawyers Weekly, Vol. 6, No. 26 (July 11, 2008), www.healthlawyers.org/News/Health%20Lawyers%20Weekly/Pages/default.aspx.

n45 Press Release, Oregon Department of Justice, AG Reaches \$ 62 Million Settlement with Eli Lilly Pharmaceutical (Oct. 7, 2008) *available at* www.doj.state.or.us/releases/2008/re1100708.shtml (last visited July 16, 2009); Press Release, Illinois Attorney General, Madigan Reaches Landmark \$ 62 Million Settlement with Eli Lilly (Oct. 7, 2008) *available at* www.illinoisattorneygeneral.gov/pressroom/2008_10/20081007.html (last visited July 16, 2009).

n46 Press Release, U.S. Department of Justice, Biopharmaceutical **Company**, Cephalon, to Pay \$ 425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008), *available at* www.usdoj.gov/opa/pr/2008/September/08-civ-860.html (last visited July 6, 2009).

n47 Press Release, U.S. Department of Justice, Eli Lilly and **Company** Agrees to Pay \$ 1.415 Billion to Resolve Allegations of Off-label Promotion of Zyprexa (Jan. 15, 2009), *available at* www.usdoj.gov/opa/pr/2009/January/09-civ-038.html (last visited July 6, 2009).

n48 *New England Carpenters Health Benefits Fund v. First DataBank*, 602 F. Supp. 2d 277 (D. Mass. 2009).

Vendor-healthcare professional relationships

Closely related to controlling the cost of prescription drugs in the national healthcare budget is the intense scrutiny of relationships between pharmaceutical and device **companies** and healthcare professionals. Fueled by concerns about conflicts of interest and the potential for illegal kickbacks, enforcement agencies, lawmakers, and the media have directed significant attention to these relationships over the past year. Professional associations, state legislatures, and pharmaceutical manufacturers have responded by enunciating vigorous standards and policies to control potential conflicts of interest and allow for more transparency in the way healthcare providers are compensated for their role in the drug development process.

Federal action

At the federal level, Senators Charles Grassley (R-IA) and Herb Kohl (D-WI) introduced the *Physician Payments Sunshine Act of 2009*.ⁿ⁴⁹ The legislation would establish a national registry of payments to physicians by medical device, medical supply, and pharmaceutical **companies**, and would require manufacturers of pharmaceuticals, medical devices, and biologics to publicly report money given to physicians if more than \$ 100 every year.

n49 *Physician Payments Sunshine Act of 2009*, H.R. 5605, 111th Cong. (1st Sess. 2009).

State legislatures

A number of state legislatures also were active in the area. For example, on March 11, 2009, the Massachusetts Public Health Council (PHC) passed final regulations to implement a state law enacted in 2008 governing gift-giving and other sales and marketing practices of pharmaceutical and medical device firms.ⁿ⁵⁰ According to Massachusetts officials, the new rules, which mandate broad public disclosure of fees, payments, and other compensation by **companies** to healthcare providers, will be some of the toughest in the nation.

n50 105 MASS. CODE REGS. § 970.000 (2009).

Vermont Governor Jim Douglas signed a bill on June 8 imposing sweeping new restrictions and disclosure requirements related to vendor gift-giving and marketing activities.ⁿ⁵¹ The bill, passed by the state legislature in May 2009, expands the ban on gifts to healthcare professionals to include "anything of value," including meals, entertainment, and travel expenses. The measure applies to manufacturers of drugs, devices, and biological products.ⁿ⁵²

n51 Press Release, Vermont Association for Mental Health, Vermont Governor Jim Douglas signs S.48 into Law (June 8, 2009), available at www.vamh.org/node/44 (last visited July 6, 2009).

n52 The text of the bill, numbered S.48, is available at www.leg.state.vt.us/docs/2010/bills/Passed/S-048.pdf (last visited July 16, 2008).

A call to reduce conflicts of interest

The Institute of Medicine (IOM) added its voice to the growing number of policymakers, lawmakers, and groups calling on the medical community to strengthen conflict-of-interest policies and broaden their disclosure of financial dealings with pharmaceutical, biotechnology, and medical device firms. The IOM released a report on April 28, 2009,

arguing that voluntary and, if necessary, regulatory measures should be taken to reduce conflicts of interest in medical research, education, and practice. n53 In its report, the IOM acknowledges that collaborations between physicians or medical researchers and pharmaceutical, device, and biotechnology **companies** do help achieve scientific advancements that benefit the public. At the same time, IOM notes that financial ties between medicine and industry may create conflicts that improperly interfere with professional judgment and ultimately negatively impact patient care.

n53 A summary of the report, entitled Institute of Medicine of the National Academies, *Conflict of Interest in Medical Research, Education, and Practice, A Focus on Medical Research, Report Brief* (Apr. 2009), is available at www.iom.edu/Object.File/Master/65/984/COI%20research%20report%20brief%20for%20web%20.pdf (last visited July 6, 2009). The report is available for purchase on the IOM website.

IOM recommends, as a first step, disclosure of financial relationships with the industry in a standardized format to help "assess the severity of conflicts and to determine whether the relationship needs to be eliminated or actively managed." Congress also should create a national reporting program that requires the industry to disclose financial dealings with the medical community on a public website as a means of deterring inappropriate interactions and undue influence. The report also calls on researchers, medical school faculty, and physicians in private practice to forgo any vendor gifts, to decline to publish or present "ghostwritten" materials, and to limit consulting arrangements to "legitimate expert services" formalized in contracts and paid for at a fair market rate. In addition, physicians should limit the use of free drug samples except for patients who cannot otherwise afford the medications, the report says. n54

n54 *Id.*

Codes of ethics

The Pharmaceutical Research and Manufacturers of American (PhRMA) Board of Directors announced July 10, 2008, that it has adopted a revised PhRMA Code on Interactions with Healthcare Professionals (Code) to ensure that pharmaceutical marketing practices comply with the highest ethical standards, according to a press release issued by PhRMA. n55 The voluntary Code, which became effective January 2009, "reaffirms that interactions between **company** representatives and healthcare professionals should be focused on informing the healthcare professionals about products, providing scientific and educational information, and supporting medical research and education." n56

n55 PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA), CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS (Jan. 2009), available at www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf (last visited July 6, 2009).

n56 Press Release, PhRMA, PhRMA Revised Marketing Code Reinforces Commitment to Responsible Interactions with Healthcare Professionals (July 10, 2008), available at www.phrma.org/news_room/press_releases/phrma_code_reinforces_commitment_to_responsible_interactions_with_healthcare_professionals/ (last visited July 6, 2009).

Among several changes in the revised Code are new provisions prohibiting the distribution of non-educational items (such as pens, mugs, and other "reminder" objects adorned with a **company** or product logo) to healthcare providers and their staff. The revised Code notes that such items are often "of minimal value," but nonetheless recognizes they "may foster misperceptions that **company** interactions with healthcare professionals are not based on informing them about medical and scientific issues," the release said. n57 Another new provision prohibits **company** sales representatives from providing restaurant meals to healthcare professionals. Sales representatives are allowed, however, to provide occasional meals in healthcare professionals' offices in conjunction with informational presentations. In addition, the revised Code reaffirms PhRMA's position that **companies** should not provide any

entertainment or recreational benefits to healthcare professionals. The revised Code also includes new provisions that require **companies** to ensure that their sales representatives are sufficiently trained about applicable laws, regulations, and industry codes of practice that govern interactions with healthcare professionals.

n57 *Id.*

Six months later, the Advanced Medical Technology Association (AdvaMed)--the national trade association of medical technology manufacturers--undertook a similar initiative and issued a revised Code of Ethics on Interactions with Health Care Professionals (HCPs) (the AdvaMed Code or Code). n58 The revised AdvaMed Code, effective July 1, 2009, contains several changes that will significantly impact the medical device industry. These changes include:

- . the addition of guidelines for the payment of royalties to HCPs;
- . the inclusion of a new section on the provision of evaluation and demonstration products to customers at no charge;
- . more comprehensive guidelines for furnishing reimbursement and health economics information to HCPs;
- . a prohibition on the provision of entertainment and recreation;
- . a prohibition on the provision of non-educational branded promotional items, such as pens, notepads, mugs, and similar items; and
- . increased restrictions on the provision of restaurant meals or meals at other off-site venues.

n58 Press Release, AdvaMed, AdvaMed's Compliance Leadership Expands with Updated Code of Ethics (Dec. 18, 2008), *available at* www.advamed.org/NR/rdonlyres/C855A560-81B7-41CA-A056-366C5EDC9C52/0/PressRelease121808CODERRevisionapprovedbyAdvaMedBoard.pdf (last visited July 6, 2009). The AdvaMed code is online at <http://66.111.110.250/NR/rdonlyres/61D30455-F7E9-4081-B219-12D6CE347585/0/AdvaMedCodeofEthicsRevisedandRestatedEffective20090701.pdf>.

More generally, the revisions to the AdvaMed Code seek to strike the appropriate balance between encouraging beneficial, productive interactions between device manufacturers and HCPs and establishing safeguards to ensure that such arrangements meet high ethical standards and are conducted in a manner that is consistent with fraud and abuse authorities. The revised AdvaMed Code applies to all medical device "**Companies**;" the prior version, by its plain terms, applied only to AdvaMed "Members." Thus, although each device manufacturer must make its own decision regarding whether to comply with the AdvaMed Code, irrespective of that decision, the revised Code's provisions extend to all medical device manufacturers, and, as such, arguably establish industry standards. n59

n59 This item is an excerpt of an article written by Elizabeth Carder-Thompson, Gina M. Cavalier, and Matthew E. Wetzel, Reed Smith LLP, *AdvaMed Issues Revised Code of Ethics on Interactions with Healthcare Professionals*, for HEALTH LAWYERS WEEKLY, Vol. 7, No. 1 (Jan. 9, 2009), www.healthlawyers.org/News/Health%20Lawyers%20Weekly/Pages/default.aspx.

A positive industry response

In response to professional codes and new legislation, the pharmaceutical industry astutely recognized the importance of proactively addressing the concerns raised by their relationships with healthcare providers. Eli Lilly and

Company (Lilly) will become the first pharmaceutical research **company** to disclose its payments to physicians in an online registry. Under Lilly's plan, the public will have access to an internet database listing its payments to physicians, including 2009 payments to physicians who serve the **company** as speakers and advisers. By 2011, Lilly plans to expand the reporting capabilities of the registry to resemble the Sunshine Act legislation. n60

n60 Press Release, Eli Lilly and **Company**, Lilly Set to Become First Pharmaceutical Research **Company** to Disclose Physician Payments (Sept. 24, 2008), available at <http://newsroom.lilly.com/releasedetail.cfm?ReleaseID=336444> (last visited July 6, 2009).

Merck announced that it will enhance transparency by publishing its grants to patient organizations, medical professional societies, and other organizations on its website. The **company** said that it is "committed to begin disclosure in 2009 of payments to physicians who speak on behalf of our **company** or our products." n61

n61 Press Release, Merck & **Company**, Merck Takes Important Steps to Enhance Transparency (2008), available at www.merck.com/newsroom/press_releases/corporate/2008_0925a.html (last visited July 6, 2009).

Following suit, in February 2009 Pfizer announced that it will publicly disclose payments made to U.S. physicians for consulting services, speaking engagements, and conducting clinical trials. n62

n62 Press Release, Pfizer Inc., Pfizer to Publicly Disclose Payments to U.S. Physicians, Healthcare Professionals and Clinical Investigators (Feb. 9, 2009), available at http://mediaroom.pfizer.com/portal/site/pfizer/?ndmViewId=news_view&newsId=20090209006347&newsLang=en (last visited July 6, 2009).

Antitrust

The significance of containing the costs of healthcare in any reform initiative and the connection between costs and the availability of generic drugs were illustrated in several key antitrust developments. Specifically, Bristol-Myers Squibb (BMS) agreed to pay \$ 1.1 million for failing to comply with court-ordered reporting obligations that arose from prior settlements of charges that the **company** unlawfully deprived consumers of cheaper generic versions of its drugs Buspar and Taxol. n63 In addition, BMS will pay a \$ 2.1 million civil penalty to resolve a Federal Trade Commission (FTC) complaint that BMS failed to disclose certain critical statements it made to the generic manufacturer Apotex as part of a patent settlement involving BMS' blockbuster blood thinner Plavix. n64

n63 HEALTH LAWYERS WEEKLY, Vol. 7, No. 1 (Jan. 9, 2009), www.healthlawyers.org/News/Health%20Lawyers%20Weekly/Pages/default.aspx.

n64 HEALTH LAWYERS WEEKLY, Vol. 7, No. 13 (Apr. 3, 2009), www.healthlawyers.org/News/Health%20Lawyers%20Weekly/Pages/default.aspx.

Not surprisingly, in March 2009 the FTC gave its resounding support to legislation that would ban so-called "pay to delay" payments as part of patent settlements between brand and generic drug **companies**. n65 The bill would ban the practice of "exclusion" or "reverse" payments in which a brand-name **company** pays or provides value to the generic **company** to abandon a patent challenge if the generic **company** agrees to delay marketing its generic drug. These types of deals have increased in prevalence after various court decisions made it more difficult for FTC to bring antitrust suits to stop exclusion payments. For example, in March 2005 the Eleventh Circuit vacated the FTC's decision that settlement agreements between Schering-Plough Corporation and two generic drug manufacturers were anticompetitive. n66

n65 See **Protecting** Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 111th Cong. (1st Sess. 2009).

n66 See *Schering-Plough Corp. v. Fed. Trade Comm'n.*, 402 F.3d 1056 (11th Cir. 2005).

More recently, the Ninth Circuit affirmed on January 13, 2009 a jury verdict finding Kaiser Foundation Health Plan could not maintain a restraint-of-trade claim under Section 1 of the *Sherman Act* against Abbott Laboratories and Geneva Pharmaceuticals Technology for entering into an agreement that allegedly delayed the market entry of a generic version of Abbott's brand-name drug Hydrin (terazosin hydrochloride). n67 The appeals court, however, reversed summary judgment to Abbott on Kaiser's monopolization claim under Section 2 of the Sherman Act. According to the appeals court, Kaiser raised a genuine issue of material fact as to whether the brand-name drug maker obtained one of its patents on terazosin hydrochloride by fraudulently omitting certain relevant information in its patent application.

n67 *Kaiser Found. Health Plan, Inc. v. Abbott Labs., Inc.*, 552 F.3d 1033 (9th Cir. 2009).

In other antitrust developments this year, two health systems reached preliminary settlements of respective class actions alleging they conspired with hospitals in their areas to keep nurses' wages at artificially low levels. n68 According to the lawsuits, which sought treble damages for class members as well as fees and costs, absent such conspiracy, hospitals in the areas where the suits were filed would have substantially increased registered nurse compensation to attract a sufficient number of nurses to their facilities. Instead, a nationwide nursing shortage remains, the complaints said.

n68 *Cason-Merenda v. Detroit Med. Ctr.*, No. 06-15601 (E.D. Mich. Mar. 24, 2009). The settlement agreement is *available at* [www.healthlawyers.org/News/Health%20Lawyers%20Weekly/Documents/HLW_04_03_09/Detroit_Medical_settlement\[1\].pdf](http://www.healthlawyers.org/News/Health%20Lawyers%20Weekly/Documents/HLW_04_03_09/Detroit_Medical_settlement[1].pdf).

Challenges to State and Local Healthcare Legislation

Innovative state laws and the intersection of state law with federal healthcare laws were the subject of a number of key court rulings over the past year. In the much-anticipated *Wyeth v. Levine* case, the Supreme Court held that federal law does not preempt state failure-to-warn claims involving the labeling of prescription drugs regulated by the FDA. n69 The 6-3 opinion, authored by Justice Stevens, rejected drug maker Wyeth's argument that state tort claims like those at issue obstruct the federal regulation of drug labeling. According to the majority, Congress has repeatedly declined to preempt state law in this area. The majority also gave no weight to the FDA's position in recently promulgated regulations that state tort suits interfere with its statutory mandate, saying this stance represents a dramatic shift from the agency's long-standing view that state actions complement the FDA's role in **protecting** consumers.

n69 *Wyeth v. Levine*, 129 S. Ct. 1187 (2009).

In its opinion affirming a Vermont Supreme Court decision, the Court majority rejected Wyeth's argument that it would be impossible for it to comply with both the state law duties underlying the negligence claims and its duties under federal labeling regulations. The majority also affirmed the judgment of the Vermont Supreme Court, finding Levine's common law claims did not stand as an obstacle to the statutory purposes of the Food, Drug, and Cosmetic Act.

Regulation of prescription data

Several challenges to state laws this year involved the regulation of prescription data. In November 2008, the First Circuit held that a New Hampshire law regulating the use of prescription data did not amount to an unconstitutional restriction on commercial speech. n70 Plaintiffs IMS Health and Verispan acquire prescription data from billions of

prescription transactions per year throughout the United States. They then de-identify patient information and sell the data to their clients--mostly pharmaceutical **companies**. The pharmaceutical **companies** use the information to market to specific prescribers. On June 30, 2006, the Prescription Information Law became effective in New Hampshire. n71 The law expressly prohibits the transmission or use of both patient-identifiable data and prescriber-identifiable data for certain commercial purposes.

n70 *IMS Health Inc. v. Ayotte*, 550 F.3d 42 (1st Cir. 2008).

n71 N.H. REV. STAT. ANN. §§ 318:47-f, 318:47-g, 318-B:12(IV) (2009).

Describing the New Hampshire law as an "innovative" approach to address the "spiraling cost of brand-name prescription drugs," the First Circuit found that the law regulates conduct, not speech. Even if the law amounted to a regulation of protected speech, the appeals court said it still passed constitutional muster. "In combating this novel threat to the cost-effective delivery of healthcare, New Hampshire has acted with as much forethought and precision as the circumstances permit and the Constitution demands," the appeals court said. n72

n72 *IMS v. Ayotte*, 550 F.3d at 45.

In April 2009, the U.S. District Court for the District of Vermont refused to strike down as unconstitutional a law that regulates the collection and use of data identifying healthcare providers' prescribing patterns. n73 The court found that the law did regulate protected commercial speech, but held that it withstood scrutiny under the First Amendment.

n73 *IMS Health Inc. v. Sorrell*, No. 1:07-CV-188 (D. Vt. Apr. 23, 2009).

The Vermont law prohibits pharmacies and other regulated entities from selling or using prescriber-identifiable data for marketing or promoting prescription drugs unless the prescriber consents--or in other words, "opts-in." The law also creates an evidence-based education program for healthcare professionals about the cost-effective utilization of prescription drugs that is funded by fees paid by drug manufacturers. The court found that the legislature's stated purposes of containing healthcare costs and **protecting** the public interest were substantial government interests.

The court also concluded that the legislature's determination that prescription data are "an effective marketing tool that enables detailers to increase sales of new drugs" was supported in the record and therefore the law could help curb prescription drug costs. n74 Likewise, the court said evidence supported the legislature's finding that new drugs often provide little or no benefit over older drugs and unrestricted use of prescription data in marketing may contribute to over-prescription of new drugs. Thus, the legislature's decision to restrict the use of prescription data in marketing to further their substantial interest in **protecting** public health was sufficiently direct and material, the court concluded. Finally, the court held the law was narrowly tailored because it did not prohibit the practice of detailing altogether; it just restricted the use of prescriber-identifiable data.

n74 *IMS v. Sorrell*, No. 1:07-CV-188 at 36.

In addition to Vermont and New Hampshire, Maine has enacted laws aimed at regulating so-called "data mining" of physicians' and other providers' prescribing habits, which is then used by pharmaceutical manufacturers for their marketing activities, known as "detailing." In December 2007, a federal district court agreed to preliminarily enjoin the enforcement of the Maine statute that restricts the collection and disclosure of physician prescribing information for marketing purposes that was set to go into effect January 1, 2008. n75

n75 *IMS Health Corp. v. Rowe*, No. CV-07-127-B-W (D. Me. Dec. 21, 2007), amended by *IMS Health Corp. v. Rowe*, 532 F. Supp. 2d 153 (D. Me. 2008).

Medical device amendments

The issue of whether the Medical Device Amendments of 1976 (MDA) pre-empts state tort claims challenging the safety and effectiveness of a medical device was also at the forefront of healthcare law developments this year. In 2008, in *Riegel v. Medtronic*, the U.S. Supreme Court held that the MDA preempts state common law claims challenging the safety and effectiveness of a medical device that received FDA premarket approval. n76

n76 *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008).

In a closely related decision by the Wisconsin Supreme Court in February 2009, the court held that the MDA preempts state tort claims against the device manufacturer Medtronic, even though the device giving rise to the negligence and strict liability allegations was implanted after the FDA gave supplemental premarket approval to correct a problem with the original device. n77 According to the high court, the *Riegel* framework applied because the original premarket approval was ongoing despite the FDA's subsequent approval of changes to the device to correct a faulty battery.

n77 *Blunt v. Medtronic, Inc.*, 760 N.W.2d 396 (Wis. 2009).

A unanimous Wisconsin Supreme Court relied specifically on *Riegel* to conclude the MDA preempted the plaintiff's state law tort claims. In *Riegel*, the majority of the Court held that the premarket approval process imposes device-specific requirements under the MDA and that state "tort duties" constitute "requirements" pursuant to the statute that are "different from, or in addition to, federal requirements." n78 The Wisconsin high court found that the plaintiff's claims fit squarely within the parameters outlined in *Riegel* and therefore were preempted by the MDA. Most notably, the high court said the preemption analysis was not altered by the FDA's supplemental premarket approval of the defibrillator in 2003.

n78 *Riegel v. Medtronic*, 128 S. Ct. at 1003-11.

In March 2009, House lawmakers Frank Pallone Jr. (D-NJ) and Henry A. Waxman (D-CA) introduced legislation to reverse the *Riegel* decision. House Energy and Commerce Committee Chairman Waxman and Subcommittee on Health Chairman Pallone said in a joint statement that the Court's decision "ignores both congressional intent and thirty years of experience in which federal regulation, through the U.S. Food and Drug Administration, and tort liability played complementary roles in **protecting** consumers from device risks." n79 The *Medical Device Safety Act of 2009* would explicitly clarify that federal law does not preempt state product liability lawsuits. n80 According to Pallone and Waxman, the *Riegel* decision "has left consumers without any ability to seek compensation for their injuries" and "removed one of the industry's most important incentives to maintain product safety after approval and disclose newly-discovered risks to patients and physicians." n81

n79 See Press Release, Representative Henry A. Waxman, 30th District of California, Health Leaders Introduce Legislation Reversing Supreme Court's Medical Device Decision (Mar. 5, 2009), available at <http://waxman.house.gov/News/DocumentSingle.aspx?DocumentID=115178> (last visited July 7, 2009).

n80 Medical Device Safety Act of 2009, H.R. 1346, 111th Cong. (1st Sess. 2009).

n81 Press Release, Representative Henry A. Waxman, 30th District of California, Health Leaders Introduce Legislation Reversing Supreme Court's Medical Device Decision (Mar. 5, 2009), *available at* <http://waxman.house.gov/News/DocumentSingle.aspx?DocumentID=115178> (last visited July 7, 2009).

False Claims Act

A potent enforcement tool in previous years and again this year, the Civil False Claims Act (FCA) was the subject of several significant court rulings. In June 2008, the U.S. Supreme Court unanimously ruled that the FCA requires proof the defendant "intended that the false statement be material to the Government's decision to pay or approve the false claim." n82 The opinion in *Allison Engine v. United States*, authored by Justice Samuel Alito, reversed a Sixth Circuit decision that held it was sufficient under the FCA for a plaintiff to prove that a false statement resulted in payment from the government.

n82 *Allison Engine Co. v. United States ex rel. Sanders*, 128 S. Ct. 2123, 2125 (2008).

According to the Court, "the Sixth Circuit's interpretation of § 3729(a)(2) [of the FCA] impermissibly deviates from the statute's language, which requires the defendant to make a false statement 'to get' a false or fraudulent claim 'paid or approved by the Government.'" Thus, a defendant must intend for the government to pay the claim, the Court held. "Eliminating this element of intent would expand the FCA well beyond its intended role of combating 'fraud against the Government,'" Alito wrote. n83 Congress later overturned the *Allison Engine* case, however, with the recent enactment of the *Fraud Enforcement and Recovery Act* (FERA). n84

n83 *Id.* (emphasis in original internal quotations omitted).

n84 *See* Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21 [hereinafter FERA]; *see also infra* for a discussion of FERA, beginning on page 35.

Also in 2008, the Tenth Circuit upheld the dismissal of a physician's FCA qui tam action against a hospital, finding that the hospital's alleged false certifications in Medicare cost reports as to its compliance with all applicable Medicare statutes and regulations did not constitute false claims for payment under the FCA. n85 The appeals court agreed with the district court that the FCA "cannot be stretched" so far as to allow a plaintiff to maintain a cause of action against a Medicare provider based on an allegation that the provider's certification of compliance with Medicare statutes and regulations, contained in the annual cost report, rendered all claims submitted for reimbursement false within the meaning of the FCA. n86

n85 *United States ex rel. Conner v. Salina Reg'l Health Ctr.*, 543 F.3d 1211 (10th Cir. 2008).

n86 *Id.* at 1214.

The Tenth Circuit rejected the physician's assertion that the certifications contained in the hospital's annual Medicare cost reports, standing alone, explicitly conditioned Medicare payments on compliance with all applicable Medicare statutes and regulations. "Although [the] certification [in the annual report] represents compliance with underlying laws and regulations, it contains only general sweeping language and does not contain language stating that payment is conditioned on perfect compliance with any particular law or regulation," the appeals court said. "Nor does any underlying Medicare statute or regulation provide that payment is so conditioned." n87

n87 *Id.* at 1219.

In early 2009, the Third Circuit held that an FCA action against a hospital based on allegations that the hospital's arrangement with an anesthesiology practice group for pain-management services violated the Stark Law and the Anti-Kickback Statute should proceed. n88 The appeals court rejected the lower court's conclusion that the defendant hospital had satisfied the personal services exception under Stark, finding that an earlier agreement between the parties did not cover pain-management services provided by the practice at a subsequently opened hospital clinic, nor did the agreement "by definition" reflect fair market value for compensation that included free office space, supplies, and support personnel. The Third Circuit said it was specifically addressing the Stark Law exception in its opinion because the Anti-Kickback Act's safe harbor provision was substantially identical.

n88 *United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88 (3d Cir. 2009).

In *United States ex rel. Eisenstein v. City of New York*, the Supreme Court ruled that if the government declines to intervene in a qui tam action, it is not a "party" to that action and, as a result, a relator must file a notice of appeal within thirty days of the entry of judgment under Rule 4(a)(1)(A) of the Federal Rules of Appellate Procedure. n89 The Court reasoned that if the United States were automatically a "party," intervention would be a meaningless act: "There would be no reason for the United States to intervene in an action in which it is already a party." n90 The Court further reasoned that "the United States' status as a 'real party in interest' in a qui tam action does not automatically convert it into a 'party.'" n91 The Court also rejected the relator's argument that a qui tam action is one that is brought in the name of the government by stating that a "person or entity can be named in the caption of a complaint without necessarily becoming a party to the action." n92

n89 *United States ex rel. Eisenstein v. City of New York*, 129 S. Ct. 2230 (2009).

n90 *Id.* at 2230.

n91 *Id.*

n92 *Id.*

This decision resolves a split in the courts as to whether the relator in a qui tam action in which the government has declined to intervene had to appeal within thirty days or received the benefit of the extended sixty-day period provided by Rule 4(a) in cases in which the United States is a party. Although it always has been prudent for the losing party in an unintervened qui tam action to file a notice of appeal within thirty days, the Supreme Court has finally eliminated this trap for the unwary.

Fraud Enforcement and Recovery Act of 2009

On May 20, 2009, President Obama signed FERA into law. n93 FERA contains amendments to the FCA. The amendments expand the scope of liability under the FCA and give the government enhanced investigative powers. FERA specifies that an entity violates the FCA if it "knowingly and improperly avoids or decreases an obligation" to pay money to the United States--including an obligation based on an "established duty . . . arising from . . . the retention of any overpayment." n94

n93 See Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21.

n94 *Id.*

Most notably, FERA overturns the 2008 Supreme Court decision in *Allison Engine* by removing certain language in Sections 3729(a)(2) and (a)(3) of the FCA. n95 Specifically, prior to the 2009 amendments, liability existed under section 3729(a)(2) when a person "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government." FERA removes the words "to get" and "by the Government" from the language of section 3729(a)(2)--essentially eliminating the requirement that a claim be presented to a representative of the federal government. Instead, FCA liability now extends to include any false or fraudulent claim for government money or property, whether or not the claim is presented to a government official or employee, whether or not the government has physical custody of the money, and whether or not the defendant specifically intended to defraud the government. The 2009 amendment to the FCA also expands the bar on retaliation against "employees" and now includes retaliatory actions taken against any "contractor, or agent."

n95 *Allison Engine v. United States*, 128 S. Ct. 2123, regarding 31 U.S.C. §§ 3729(a)(2-3).

Under the 2009 amendments to the FCA, when the government files a complaint, or files a complaint in intervention amending, clarifying, or adding claims to a relator's complaint, the government's complaint is treated as being filed on the date of the relator's original complaint for statute of limitations purposes. As a result, the time the government spends investigating a case or negotiating with a defendant does not count toward the statute of limitations.

The amendments also expand the Attorney General's authority to issue Civil Investigative Demands and broaden the government's authority to share documents obtained through subpoena with qui tam relators and other parties. n96

n96 This discussion is an excerpt from an article by Joshua T. Buchman, Ankur J. Goel, and Russell Hayman, McDermott Will & Emery, LLP, *Congress Amends Civil False Claims Act*, for HEALTH LAWYERS WEEKLY, Vol. 7, No. 20 (May 22, 2009), www.healthlawyers.org/News/Health%20Lawyers%20Weekly/Pages/default.aspx.

Anti-Kickback Statute and Stark

In other fraud and abuse developments, the HHS Office of Inspector General (OIG) issued on March 24, 2009, an open letter to healthcare providers indicating that OIG will no longer accept into the Self-Disclosure Protocol (SDP) issues that involve only liability under the physician self-referral (Stark) Law in the absence of a colorable Anti-Kickback Statute (AKS) violation. n97 On April 24, 2006, the OIG had issued an open letter promoting the use of the SDP to resolve civil monetary penalty (CMP) liability under Stark and the AKS for financial arrangements between hospitals and physicians. n98 The letter issued in March 2009 cautions that while OIG is narrowing the SDP's scope for "resource purposes," providers should not "draw any inferences about the Government's approach to enforcement of the physician self-referral law." n99 The recent letter also establishes a minimum \$ 50,000 settlement amount for kickback issues, effective March 24, 2009, to be accepted into the SDP.

n97 Department of Health and Human Services, Office of Inspector General, An Open Letter to Health Care Providers (Mar. 24, 2009) [hereinafter *DHHS March 24, 2009 Open Letter*], available at <http://oig.hhs.gov/fraud/docs/openletters/OpenLetter3-24-09.pdf> (last visited July 7, 2009).

n98 Letter from Department of Health and Human Services, Office of Inspector General, An Open Letter to Health Care Providers (Apr. 24, 2006), available at <http://oig.hhs.gov/fraud/docs/openletters/Open%20Letter%20to%20Providers%202006.pdf> (last visited July 7, 2009).

n99 *DHHS March 24, 2009 Open Letter*.

The U.S. District Court for the District of Colorado said it lacked subject matter jurisdiction to consider whether CMS' broadened definition of when an "entity" furnishes designated health services (DHS) was an impermissible construction of the Stark Law. n100 The court found that the plaintiffs in the case--physicians and physician-owned entities--could have their claim heard administratively, albeit indirectly, through the hospitals with which they contract "under arrangement." Thus, federal question jurisdiction was barred under 42 U.S.C. § 405(h) because administrative channels were available to consider the plaintiffs' claim.

n100 *Colorado Heart Inst., LLC v. Johnson*, 609 F. Supp. 2d 30 (D.D.C. 2009).

Medicaid

California state laws enacted to implement cuts in reimbursement rates for the state's Medicaid program (known as Medi-Cal) have been the subject of judicial review in several recent cases alleging violation of federal Medicaid law. In July 2008, the Ninth Circuit reviewed AB 5, which cut Medi-Cal reimbursement rates by 10 percent for certain providers. n101 Plaintiff medical providers and beneficiaries sought an injunction on the grounds that AB 5 was preempted by federal Medicaid law, specifically 42 U.S.C. § 1396a(a)(30)(A).

n101 *Independent Living Ctr. of S. Cal., Inc. v. Shewry*, 543 F.3d 1050 (9th Cir. 2008).

Under this provision, a state Medicaid program must provide payments "sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the general geographical area." n102 The court ruled that the plaintiffs' allegations of direct economic injury, directly traceable to the implementation of AB 5, were sufficient to temporarily enjoin the California Department of Health Care Services (DHCS) from implementing the 10 percent rate cut.

n102 *Id.* at 1053.

Not long afterward, California enacted AB 1183, which mandated a 5 percent reduction in reimbursement rates for pharmacies and which also was reviewed by the Ninth Circuit. n103 The court held that the reduction in Medi-Cal rates under AB 1183 would "drastically impair payments" and "create [] significant gaps in access" for the state's most vulnerable patients. DHCS was temporarily enjoined from "continu[ing] to violate the requirements of federal law . . ." where plaintiffs had demonstrated irreparable harm in the form of reduction of their Medi-Cal revenue payments--harm that could not be addressed in a subsequent action against the state because of sovereign immunity under the Eleventh Amendment. n104

n103 *California Pharmacists Ass'n v. Maxwell-Jolly*, 563 F.3d 847 (9th Cir. 2009).

n104 *Id.* at 852-53.

Medicare

The Recovery Audit Contractor (RAC) program is back and will be rolled out nationally. n105 The program, which searches for improperly billed Medicare claims, was placed under a stop order in November 2008 due to protests from potential contractors over the award process. The RAC program was made permanent under the Tax Relief and Health

Care Act of 2006, which requires HHS to expand the program to all fifty states by no later than 2010. n106 The protest has been resolved and the program will be underway in 2009, as scheduled. CMS awarded RAC contracts last October and plans to roll out the RAC program in phases through 2009 in four regions. Additional states will be added to each region in 2009.

n105 See Tax Relief and Health Care Act of 2006 § 302, H.R. 611, 109th Cong. (2006).

n106 *Id.*

In a January 2009 update report on the RAC pilot program, conducted from 2005 to 2008, CMS said that RACs corrected more than \$ 1.03 billion in Medicare improper payments. n107 Approximately 96 percent of the improper payments were overpayments collected from providers, and 4 percent were underpayments repaid to providers, the report said. The new report includes updated appeals statistics through August 31, 2008.

n107 See CENTERS FOR MEDICARE & MEDICAID SERVICES, THE MEDICARE RECOVERY AUDIT CONTRACTOR (RAC) PROGRAM: UPDATE TO THE EVALUATION OF THE 3-YEAR DEMONSTRATION (Jan. 2009), available at www.cms.hhs.gov/RAC/Downloads/AppealUpdatethrough83108ofRACEvalReport.pdf (last visited July 8, 2009).

Some lawmakers have challenged the program, saying that RACs are paid to find overpayments, which could affect their impartiality. These challenges find support in the more recent statistics on the number of successful appeals of RAC determinations. According to the January 2009 report, 22.5 percent of RAC determinations were appealed, with 7.6 percent being overturned on appeal. In an earlier report on the RAC pilot program, issued in July 2008, CMS had reported that only 4.6 percent of the RACs' overpayment determinations were overturned on appeal.

Private plan marketing

Medicare private plan marketing activities came under increasing scrutiny last year, with reports of "hard sell" tactics and concerns about the adequacy of federal oversight. In an effort to step up its oversight activities, CMS issued two rules on marketing practices of Medicare Advantage (MA) and Part D plans in September 2008. n108 The two rules, one a final rule and one an interim final rule with comment period, implement new prohibitions on door-to-door marketing and cold-calling and add requirements related to broker/agent commissions. The new marketing requirements were effective October 1, 2008.

n108 73 Fed. Reg. 54208; 73 Fed. Reg. 54226.

CMS also issued an interim final rule revising compensation requirements for agents and brokers selling MA and prescription drug plans to Medicare beneficiaries. n109 The revisions modify the September rules. In addition to new marketing restrictions, those rules established a six-year compensation structure that limited first-year compensation for an agent or broker to no more than 200 percent of the total compensation for each of the next five renewal years.

n109 73 Fed. Reg. 67406.

Privacy/Security/Health Insurance Portability and Accountability Act

In what was undoubtedly one of the most noteworthy developments in health law over the past year, the Health Information Technology for Economic and Clinical Health Act (HITECH Act), n110 adopted as part of the American

Recovery and Reinvestment Act of 2009 (ARRA), n111 delivered a sweeping expansion of Health Insurance Portability and Accountability Act (HIPAA) and data breach notification requirements. Virtually every healthcare provider and third-party service provider that stores or accesses individuals' medical information will be affected by this new federal law. A brief listing of the key provisions in the HITECH Act follows.

n110 Health Information Technology for Economic and Clinical Health Act of 2009, S.350, 111th Cong. (1st Sess. 2009).

n111 American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5.

Business associates will be subject to HIPAA security provisions and to sanctions for violation of business associate requirements. The HIPAA requirements for administrative, physical, and technical information safeguards and written policies and procedures will apply directly to business associates, as will civil and criminal penalties for violations. The HHS Secretary will publish annual guidance on the most effective and appropriate technical safeguards for this purpose. The HITECH Act also provides that a business associate that obtains or creates Protected Health Information (PHI) pursuant to a written contract or arrangement may use or disclose PHI *only* "in compliance with each applicable requirement of [45 C.F.R.] 164.504 (e)." The cited section contains the detailed implementation requirements for a Business Associate Agreement as well as the requirement for action in the event of knowledge of a "pattern of activity or practice" that is a material breach of the Business Associate Agreement. In other words, whatever the Business Associate Agreement provides, business associates will be directly responsible for full compliance with the relevant requirements of the Privacy Rule itself, and subject to civil and criminal penalties if they fail to comply.

Federal law now requires consumer notification of data breaches involving unsecured PHI. Covered entities and business associates must comply. The breach notification provisions are effective for breaches that occur thirty days after the Secretary of HHS publishes implementing interim final regulations. These regulations are due within 180 days after enactment. Vendors of personal health records and their service providers are subject to the same security breach notification requirement.

Individuals may require covered entities not to disclose certain self-pay services to health plans. Under the Privacy Rule pre-HITECH Act, an individual has a right to request restrictions on disclosure of the individual's PHI, but a covered entity is not required to grant that request, although the individual's request is retained in the record. Under the HITECH Act, a covered entity is *required* to agree to an individual's request for privacy protections as to the disclosure of PHI for payment or healthcare operations *if* the information pertains *only* to a healthcare item or service that the individual has paid for out of pocket in full, *unless* disclosure is otherwise required by law or is for treatment purposes.

The limited data set becomes a default minimum necessary standard. HIPAA regulates a covered entity's uses and a covered entity's disclosures of PHI. For non-treatment and most other disclosures, covered entities are required to use, disclose, and request only the minimum necessary PHI. The HITECH Act provides that, to be treated as in compliance with the HIPAA minimum necessary requirements, a covered entity must limit its requests for and use of disclosures of PHI to (1) a "Limited Data Set" "*to the extent practicable,*" or (2) "*if needed by such entity,*" (i.e., apparently, the Limited Data Set is not "practicable") to the minimum necessary to accomplish the intended purpose of such use, disclosure, or request. The Secretary of HHS is directed to issue guidance on what constitutes the minimum necessary within eighteen months of enactment. This provision sunsets after those regulations are issued.

Covered entities using EHRs are required to provide accounting of disclosures of PHI for treatment, payment, and healthcare operations. HIPAA, pre-HITECH Act, exempted a covered entity from an obligation to provide individuals with an accounting of disclosures of their PHI if, among other things, the disclosure was for treatment, payment, or healthcare operations. Under the HITECH Act, this exception is eliminated as to covered entities that use EHRs. In recognition of the burden that this is likely to impose, the period for which an accounting is required is limited to three years, not the six-year period otherwise required.

A covered entity or a business associate cannot "directly or indirectly" receive remuneration in exchange for PHI of an individual except pursuant to a valid HIPAA authorization that includes specifics on any further exchanges of the PHI by its recipient. The HITECH Act provides a number of exceptions to this prohibition, including transfers for public health activities, as defined by HIPAA; transfers for research purposes, subject to the limitations on the remuneration; and transfers for treatment, unless the Secretary of HHS determines otherwise.

The HIPAA healthcare operations exception for marketing communications is narrowed significantly if direct or indirect remuneration is received. Before the HITECH Act, a covered entity or business associate could provide communications that might otherwise be considered marketing without individual authorization *if* the communication was to describe a healthcare item or service or third-party payment for the item or service, for treatment, or for case management or counseling about alternative treatments. These activities were considered health-care operations. Under the HITECH Act, such communications are not healthcare operations *if* the covered entity or business associate making the communication receives "direct or indirect remuneration" for making the communication. The relatively broad federal fraud and abuse definition of remuneration is likely to apply. Payment for treatment, however, is specifically not remuneration for this purpose.

The Act amends the Social Security Act to add a provision requiring the Secretary to formally investigate any complaint where a preliminary investigation of the facts indicates "a possible violation due to willful neglect." In addition, under ARRA, state attorneys general are authorized to bring a civil action on behalf of any resident in connection with an alleged HIPAA violation. The attorney general is authorized to seek an injunction, statutory damages, and attorneys' fees in the lawsuit. n112

n112 This discussion of HITECH is an excerpt from: James B. Wieland, *The HITECH Act: Congress Includes Sweeping Expansion of HIPAA and Data Breach Notification Requirements in Stimulus Bill* (2009), HEALTH LAWYERS WEEKLY, Vol. 7, No. 7 (Feb. 20, 2009), www.healthlawyers.org/News/Health%20Lawyers%20Weekly/Pages/default.aspx.

Resolution Agreement

In other HIPAA-related developments, this past year witnessed the first-ever Resolution Agreement imposed by HHS on a covered entity. n113 The agreement stems from potential privacy and security breaches that arose when unencrypted electronic backup media and laptop computers were removed from the Providence Health & Services premises and left unattended on several occasions between September 2005 and March 2006. The media and laptops were subsequently lost or stolen, compromising the protected health information of more than 386,000 patients, HHS said. As part of the agreement, Providence must revise its policies and procedures regarding physical and technical safeguards (e.g., encryption) governing off-site transport and storage of electronic media containing patient information, subject to agency approval; train workforce members on the safeguards; conduct audits and site visits of facilities; and submit compliance reports to HHS for three years.

n113 See Press Release, Department of Health and Human Services Press Release, HHS, Providence Health & Services Agree on Corrective Action Plan to Protect Health Information (July 17, 2008), *available at* www.hhs.gov/ocr/privacy/hipaa/enforcement/examples/providenceresolutionagreement.html (last visited July 8, 2009).

Protection of a patient's medical information in litigation

In HIPAA-related litigation, the Georgia Supreme Court held that a defendant's attorneys in a medical malpractice action could not informally interview the plaintiff's prior treating physicians unless HIPAA privacy rule requirements were satisfied. n114 Reversing an October 2007 appeals court decision, the high court said HIPAA, not Georgia law, governed such ex parte communications because the federal statute "affords patients more control over their medical records when it comes to informal contacts between litigants and physicians." Thus, defense counsel may informally

interview plaintiff's treating physicians only after obtaining a valid authorization or a protective order or ensuring the patient was given notice and an opportunity to object to the ex parte contact in accordance with HIPAA. n115

n114 *Moreland v. Austin*, 670 S.E.2d 68 (Ga. 2008).

n115 *See* 45 C.F.R. § 164.512(e).

The Georgia Supreme Court said the appeals court's analysis failed to recognize that HIPAA preempts Georgia law with regard to ex parte communications between defense counsel and a plaintiff's prior treating physicians. Under Georgia law, a plaintiff waives his right to privacy with regard to medical records that are relevant to a medical condition the plaintiff placed at issue in court proceedings. "HIPAA, on the other hand, prevents a medical provider from disseminating a patient's medical information in litigation, whether orally or in writing, without obtaining a court order or the patient's express consent," the high court said. n116

n116 *Moreland v. Austin*, 670 S.E.2d at 71.

Enforcement of Red Flag Rules

Healthcare attorneys also were focused on the Red Flag Rules enforcement calendar this year. The rules were promulgated under authority of the Fair and Accurate Credit Transactions Act of 2003 (FACTA) n117 and contain a number of specific guidelines designed to assist in detecting, preventing, and mitigating identity theft. n118 On October 22, 2008, the FTC announced that it was delaying enforcement of key elements of its identity theft detection, prevention, and mitigation rules to allow creditors and financial institutions additional time to fully implement policies and procedures designed to thwart identity theft. n119 On April 30, 2009, the FTC decided to further delay enforcement of the Red Flag Rules for three months until August 1, 2009. n120 The Red Flag Rules will be applicable, in many circumstances, to both for-profit and not-for-profit healthcare providers.

n117 Fair and Accurate Credit Transactions Act of 2003, Pub. L. 108-159, 117 Stat. 1980.

n118 Identity Theft Red Flags and Address Discrepancies Under the Fair and Accurate Credit Transactions Act of 2003; Final Rules, 72 Fed. Reg. 63718 (Nov. 9, 2007); *see* Interagency Guidelines on Identity Theft Detection, Prevention, and Mitigation, 16 C.F.R. Part 681, App. A.

n119 The FTC's Enforcement Policy Statement is *available at* www.ftc.gov/os/2008/10/081022idtheftredflagrule.pdf (last visited July 17, 2009).

n120 The FTC's Extended Enforcement Policy is *available at* www.ftc.gov/os/2009/04/P095406redflagextendedenforcement.pdf (last visited July 17, 2009).

Peer Review/Health Care Quality Improvement Act Immunity

In a closely watched hospital peer review case, the Fifth Circuit reversed a judgment awarding \$ 33 million to a cardiologist who alleged that the hospital's temporary restriction of his catheterization lab privileges was improper and caused injury to his reputation and career. n121 The appeals court found the hospital immune under the Health Care Quality Improvement Act (HCQIA) from money damages for the abeyance of the physician's privileges while it investigated concerns involving his handling of several patients.

n121 *Poliner v. Texas Health Sys.*, 537 F.3d 368 (5th Cir. 2008).

In Colorado, an appeals court ruled that a hospital that revoked a surgeon's provisional staff privileges without providing him notice and a hearing was not entitled to immunity under HCQIA. n122 In so doing, the appeals court rejected the defendants' arguments that HCQIA's notice and hearing requirements were waived voluntarily by the surgeon when he applied for provisional status and agreed to be bound by medical staff bylaws that did not give rise to hearing and appeal rights for provisional staff. The bylaw provision at issue could be read, at most, to have waived a right to hearing and appeal under the medical staff bylaws, the appeals court concluded. However, "[t]here is a legally significant distinction between rights under a hospital's or medical staff's own bylaws and those under the HCQIA," the appeals court said. n123 The appeals court found that the surgeon's HCQIA rights to notice and hearing were not waived by his alleged acknowledgment that medical staff bylaws did not afford him hearing and appeals rights.

n122 *Peper v. St. Mary's Hosp. and Med. Ctr.*, 207 P.3d 881 (Col. Ct. App. 2008).

n123 *Id.* at 888-89.

A hospital was entitled to qualified immunity under HCQIA even though it did not hold a formal hearing before suspending a physician's privileges because it provided "other procedures" that were "fair and reasonable . . . under the circumstances," the Fourth Circuit held on April 10, 2009. n124 Affirming a district court decision granting the hospital's motion to dismiss the action, the Fourth Circuit said the hospital's path to immunity was "not a recommended model," but the failures in its process, viewed in light of the totality of circumstances "against a measuring stick of objective reasonableness," did not rebut the presumption of immunity under HCQIA.

n124 *Wahi v. Charleston Area Med. Ctr., Inc.*, 562 F.3d 599 (4th Cir. 2009).

The appeals court also affirmed the district court's dismissal of the physician's contract and civil rights claims, to which immunity under HCQIA did not apply, finding that no contract existed between the parties and that the hospital did not become a state actor by reporting him to the National Practitioner Data Bank (NPDB). The appeals court said the physician was not entitled to an injunction requiring the hospital to provide him a hearing and remove his name from the NPDB because he did not present a viable claim that the hospital committed a wrong.

In a case of first impression for the federal appellate courts, the First Circuit declined on January 14, 2009, to overturn the HHS Secretary's interpretation of "under an investigation" for purposes of a hospital's reporting obligations pursuant to the HCQIA. n125 The Secretary had upheld a hospital's decision to report a physician's resignation to the NPDB after a hospital committee had completed the fact-gathering process, but before it had taken a final action or formally closed the investigation. The appeals court found the Secretary's interpretation that the investigation was still ongoing at the time of the physician's resignation for HCQIA reporting purposes "eminently sensible" in light of the statute's legislative history and underlying purpose.

n125 *Doe v. Leavitt*, 552 F.3d 75 (1st Cir. 2009).

An Arkansas circuit court held on February 27, 2009 that Baptist Health's economic credentialing policy was unenforceable and permanently enjoined its application in a case brought by several cardiologists with ownership interests in competing facilities. n126 At issue was the Economic Conflict-of-Interest Policy (Policy) that Baptist Health's board adopted in 2003 mandating the denial of initial or renewed professional staff appointments or clinical privileges to any practitioner who, directly or indirectly, acquires or holds an ownership or investment interest in a competing hospital.

n126 American Medical Ass'n v. Baptist Health, No. CV 2004-2003 (Ark. Cir. Ct. Feb. 27, 2009), available at www.ama-assn.org/ama1/pub/upload/mm/395/order-for-permanentinjunction.pdf (last visited July 8, 2009).

The court cited several ways the economic credentialing policy at issue violated public policy, including interfering with patient-physician relationships and compromising the continuity of care:

[E]conomic credentialing punishes physician investment in specialty hospitals and punishes physicians for engaging in conduct that is wholly legal, negatively affects patient care, impedes advancements in medical technology and the construction of a modern healthcare infrastructure, and interferes with patient choice and patient-physician relationships. n127

n127 *Id.* at 13.

The court also agreed with plaintiffs that the Policy constituted an unconscionable trade practice that violated the Arkansas Deceptive Trade Practices Act. According to the court, the evidence showed Baptist Health adopted the Policy in connection with its "business, trade, or commerce," caused the plaintiffs actual injury by disrupting their relationships with patients and referral sources, and that the Policy was unconscionable as it violated public policy.

Tax

The ongoing dispute between the Internal Revenue Service (IRS) and medical schools regarding the issue of whether medical residents are subject to Federal Insurance Contributions Act (FICA) taxes continued last year. Although most employees and employers are required to pay taxes on wages to support the Social Security system, Congress historically has excluded students whose work is linked to their studies. Court opinions before 2005 typically sided with medical schools, finding that residents were students and qualified for the exemption. In a 2005 regulation, the IRS attempted to clarify matters, specifying that anyone who works at least forty hours a week is a full-time employee subject to Social Security taxes, even if his or her work has educational or training aspects. n128

n128 The 2005 regulation is available on the IRS website at www.irs.gov/pub/irs-regs/td_9167.pdf, codified at 26 C.F.R. Part 31.

On February 26, 2009, the Sixth Circuit remanded a case involving whether certain medical residents qualified for the student exemption from Social Security taxes under FICA, saying more facts were needed to make the determination. n129 Although the government argued that a resident as a per se matter could never be a student, the appeals court left open the possibility that, depending on the facts and circumstances, a resident could qualify for the exemption. As an initial matter, the Sixth Circuit questioned whether the exclusion of "scholarships" or "fellowships" from gross income under 26 U.S.C. § 117 necessarily meant they also were not subject to FICA taxes. The appeals court said it need not resolve the issue, however, because it agreed with the lower court ruling in this case that the stipends were not scholarships or fellowships under Section 117.

n129 *United States v. Detroit Med. Ctr.*, 557 F.3d 412 (6th Cir. 2009).

Thus, the appeals court remanded to the lower court, requesting a specific set of additional facts about typical residents, including:

- . how many hours per week they spend at the hospital;
- . how many hours per week they spend in the classroom;
- . what other responsibilities they have under the program, and the time spent on average carrying out these responsibilities;
- . how their time at the hospital usually is spent (i.e., patient care, supervising, other activities);
- . the role Wayne State professors play in supervising residents;
- . who employs the residents (Wayne State or Detroit Medical); and
- . whether there are any other state or federal programs under which the residents or their families would be (or would have been) eligible for disability or survivor benefits of the kind provided by the Social Security program.

In March 2009, the Second Circuit found that the student exemption from Social Security taxes under FICA is not per se inapplicable to medical residents. n130 In so doing, the appeals court joined several other circuit courts in rejecting the government's argument that the issue could be decided as a matter of law.

n130 *United States v. Mem'l Sloan-Kettering Cancer Ctr.*, 563 F.3d 19 (2d Cir. 2009).

The "student exception" to FICA payroll taxes excludes from the definition of "employment" any services performed by a student "in the employ of a school, college, or university[,] . . . who is enrolled and regularly attending classes at such school, college, or university." n131 Thus, the provision expressly defines the scope of the student exception: It includes students who are "enrolled and regularly attending classes," the appeals court decided. According to the opinion, the question of whether medical residents are students under FICA is a factual one and cannot be decided as a matter of law.

n131 23 U.S.C. § 3121(b)(10).

Then, however, the Eighth Circuit, which had sided with medical schools and teaching hospitals in cases before 2005, ruled that U.S. tax law "is silent or ambiguous" on whether a medical resident who works full-time at a university hospital is a student or an employee, giving the IRS leeway to adopt reasonable guidelines. n132 Under the 2005 regulation, the panel of three judges observed, "anyone who works at least forty hours a week is a full-time employee subject to Social Security taxes, even if [his or her] work has educational or training aspects." n133 The court panel explained that "the U.S. Treasury Department has latitude to interpret the Internal Revenue Code and made a 'permissible interpretation' that medical residents are full-time employees subject to payroll taxes." n134 As of the writing of this article, no decision has been made on whether to appeal this ruling to the full court.

n132 *Mayo Found. for Med. Educ. & Research v. United States*, Nos. 07-3242, 08-2192 (8th Cir. June 12, 2009).

n133 *Id.*

n134 *Id.*

Conclusion

In the June 11, 2009, issue of *The National Law Journal*, one of the headlines summarized what the increased attention to healthcare reform means to attorneys: "*One Practice Area That Isn't Ailing: Health Care.*"ⁿ¹³⁵ *The National Law Journal* report notes that law firms are strategically adding attorneys with healthcare expertise as clients begin to request assistance in preparing for a healthcare overhaul. "Firms are recruiting corporate, regulatory, and transactional lawyers who have experience working in the healthcare, pharmaceutical, biotechnology, and medical device industries," the article states.ⁿ¹³⁶

ⁿ¹³⁵ Lynne Marek, *One Practice Area That Isn't Ailing: Health Care*, *The National Law Journal* (June 11, 2009), available at www.law.com/jsp/nlj/PubArticleNLJ.jsp?id=1202431375642&slreturn=1 (last visited July 8, 2009).

ⁿ¹³⁶ *Id.*

In an interview with AHLA staff on May 19, 2009, James Stansel (former acting general counsel of the U.S. Department of Health and Human Services and currently Co-Chair of the Life Sciences Practice Group at Sidley Austin LLP) confirmed this trend.ⁿ¹³⁷ When asked to comment on how the downturn in the economy over the past year might impact the practice of health law overall, Mr. Stansel responded:

I do expect growth. I think that healthcare in general is a bright spot in the economy. Everybody needs to go see the doctor or take their medication, things like that. I think that it is a more stable environment than others, but I also think there is a lot of room to grow in the area and, certainly with healthcare reform happening, it may increase significantly. Healthcare is a huge portion of [Gross Domestic Product] already, and estimates are that it will continue to grow no matter what happens. I think that as it grows, and certainly as there is change, there will be more of a need for lawyers who understand what is happening and can advise their clients to best position themselves to be in compliance with the law and to profit from what is happening in the reform debate. I do expect it to grow, probably significantly.ⁿ¹³⁸

ⁿ¹³⁷ Interview with James Stansel, former Acting General Counsel of the U.S. Department of Health and Human Services and current Co-Chair of the Life Sciences Practice Group at Sidley Austin LLP (May 19, 2009).

ⁿ¹³⁸ *Id.*

Clients will need to prepare for the healthcare regulation and enforcement changes promised by the new Administration and will want to shape these changes. Already evolving at a rapid pace, this area of the law is destined for more fast-paced and expansive change.

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LENGTH: 18762 words**TITLE:** "No-Hire" Clauses in Healthcare Sector Contracts: Their Use and Enforceability**AUTHOR:** W. Eugene Basanta *

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TEXT:

ABSTRACT: In today's healthcare industry, many hospitals utilize outside agencies for both business and clinical functions. This Article acknowledges the prevalence of outsourcing contract labor in the healthcare arena and focuses on the restrictive provisions included in these employment contracts, particularly "no-hire" clauses. No-hire clauses are often included in contracts between healthcare providers and professional groups that provide clinical service employees to the provider, such as a medical practice group providing physicians to a hospital or an agency providing nurses to a **nursing home**. These clauses usually provide that the healthcare provider may not directly hire an employee provided by the professional group, nor may it contract with another professional group that later hires the employee. The purpose of a no-hire clause is two-fold: to protect the professional group's investment of time and money for recruiting, training, and establishing the employee's clinical practice, and to give the professional group leverage to retain its employees. While noncompete clauses in employment contracts have traditionally been the subject of litigation, no-hire clauses raise distinct legal issues. Case law provides conflicting views as to the enforceability of these provisions. Some courts find no-hire clauses to be *per se* illegal restrictions on trade, while others will permit them when they are reasonable within a specific context. The author proposes that a multifactor test be applied on a case-by-case basis to determine the reasonableness of the no-hire provision in a given employment contract and suggests drafting improvements to facilitate enforcement.

The delivery of healthcare services today is a complex undertaking, involving multiple business and professional relationships. Beyond traditional relationships, such as those involved in the hospital-medical staff structure, there have evolved within the healthcare sector numerous other contractual arrangements that are critically important to the delivery of healthcare services. Examples include hospital-physician joint ventures, as well as exclusive arrangements with physician and other providers for various hospital clinical services. n1 Hospitals today also make extensive use of outside agencies to help staff particular components of their operations on a temporary basis. n2 Further, like many other businesses, hospitals utilize consulting arrangements regarding a range of business matters, including billing and coding, information technology, and other key functions. Finally, hospitals increasingly "outsource" many business and clinical functions, from pharmacies to patient support services (*e.g.*, food services). n3

n1 See generally Roger D. Strobe, *Hospital-Physician Joint Ventures: Threat--or Opportunity?*, 58 HEALTHCARE FIN. MGMT. 80 (2004) (discussing ancillary services, joint ventures, physician medical director-management relationships, and exclusive specialty services contracts).

n2 PAUL SHOEMAKER & DOUGLAS H. HOWELL, TRENDS IN THE USE OF CONTRACT LABOR AMONG HOSPITALS 1-2 (2005), available at www.ahd.com/LaborStudy040820.pdf (last visited Sept. 23, 2006).

n3 Michael Romano; *Outsourcing Everything: Accelerating Use of Outsourcing Adds to Public Policy Debate While Raising Questions About Hospitals' "Charitable" Status*, 34 MOD. HEALTHCARE 24, 24 (2004).

Such arrangements can enhance both the efficiency and quality of healthcare service delivery. As is true in any complex business setting, these arrangements also often involve significant investment by the parties, as well as the expectation of sustained, mutually beneficial interaction. The emergence and evolution of these arrangements has also predictably brought with it recognition of the need, within the terms of the parties' contract, to account for and protect the value of their investment when and if their ongoing relationship comes to an end. A common, long-established example of this is the "covenant-not-to-compete" found in many physician employment contracts. Such clauses facilitate hiring physicians, in part by **protecting** the hospital's or medical group's investment in recruiting new physicians and establishing them in practice in an area. While their use is well-established, physician noncompetition agreements remain the subject of controversy and litigation. n4

n4 See generally Andrew B. Cripe, *Restrictive Covenants in Physician Contracts: An Emerging Public Policy Battleground*, 20 HEALTH CARE L. 8 (2004). In *Murfreesboro Med. Clinic v. Udom*, 166 S.W.3d 674, 678 (Tenn. 2005), the Supreme Court of Tennessee found such covenants to be against public policy. In contrast, the Supreme Court of New Jersey rejected the argument that physician restrictive covenants are *per se* unenforceable. *Cnty. Hosp. Group, Inc. v. More*, 869 A.2d 884, 887 (N.J. 2005). The Kansas Supreme Court likewise upheld physician covenants in *Idbeis v. Wichita Surgical Specialists*, 112 P.3d 81, 86-7 (Kan. 2005). See also CODE OF MEDICAL ETHICS OF THE AMERICAN MEDICAL ASSOCIATION: CURRENT OPINIONS WITH ANNOTATIONS § 9.02 (Council on Ethical and Judicial Affairs, Am. Med. Ass'n 2006) (discouraging the use of covenants-not-to-compete in physician contracts).

This Article focuses on another type of clause commonly seen in healthcare industry contracts, variously referred to as a "no-hire," "noninterference," or "anti-raiding" clause. As an example, when a hospital contracts with a medical group on an exclusive basis to furnish anesthesia or other clinical services within the hospital, the contract may contain a provision stating that the hospital, for some stated period of time, will neither directly hire any physician employed by the medical group to provide the services at the hospital, nor contract with another service provider that subsequently employs that physician. Such clauses may also be found in contracts with temporary staffing agencies, in consulting contracts, and in other business agreements. n5

n5 Even in the absence of a no-hire clause, an employer may have an action for tortious interference with contractual relations against a customer hiring away its employees. See *Labor Ready, Inc. v. Williams Staffing, LLC*, 149 F. Supp. 2d 398, 410-11 (N.D. Ill. 2001).

In this context, justifications for no-hire clauses include **protecting** the medical group's recruiting, training, and other investments in the individual in question. Further, a no-hire clause may help to increase the likelihood that a firm will retain part of the assets critical to its financial success, its employees. n6 While present in many healthcare contracts, such clauses have not been subject to nearly as much litigation or critical analysis as covenants-not-to-compete. Further, while a no-hire clause bears some similarity to a noncompetition clause, and in fact may be used in tandem with such a clause, it raises its own distinct legal and policy issues.

n6 While obviously no business "owns" its employees' services the way it owns its office equipment, computers, and so on, the fact remains that human capital is a critical part of any business. This is particularly true in professional/service businesses. As one commentator has stated, "people are the only asset a business has which can be neither copied, mass produced or grown in a test tube." Pippa Reffold,

People a Truly Valuable Business Asset, BUSINESS FOCUS, at www.business-focus.co.uk/detail.asp?navid=&tid=53&did=59 (last visited Sept. 23, 2006).

This Article explores the use of no-hire clauses in the healthcare context, examines the issues that they pose, and suggests some factors relevant to their drafting and enforcement. It begins with some detailed examples and discussion of such clauses in various healthcare settings in order to see some of their common features. It then provides in Part II a review of the case law, both in the healthcare context and in some other situations where no-hire clauses have been analyzed by the courts.ⁿ⁷ The courts are in conflict as to whether a no-hire clause is inherently an unenforceable restraint of trade or can be enforced if certain criteria are met. Part III offers an analysis of the factors that may be relevant to assessing the enforcement of a no-hire clause and some insights into the legal and policy factors to consider in negotiating and drafting such provisions. The position taken is that a *per se* rule is inappropriate and that instead, no-hire clauses should be subject to a reasonableness analysis on a case-by-case basis, taking into account a range of criteria.

ⁿ⁷ This Article addresses state trade restraint law in relation to no-hire clauses. It should be kept in mind that a no-hire clause may also raise federal antitrust law issues. See, e.g., 2 RUDOLF CALLMANN, UNFAIR COMPETITION, TRADEMARKS, AND MONOPOLIES § 16:43 (Louis Altman ed., 4th ed. 1981); Brian R. Henry & Joseph M. Miller, "Sorry, We Can't Hire You... We Promised Not To": The Antitrust Implications of Entering into No-Hire Agreements, 11 ANTITRUST 39 (1996). In *Eichorn v. AT&T Corp.*, 248 F.3d 131 (3d Cir. 2001), for example, the court rejected an antitrust challenge by employees to a no-hire clause in connection with the sale of a business. The court applied a "rule of reason" analysis in concluding that the no-hire agreement was an enforceable covenant-not-to-compete.

I. No-Hire Clauses in the Healthcare Sector--Context and Examples

One of the most common situations in which a no-hire clause may be used is when a hospital enters into a contract with a professional group to furnish a particular clinical service within the hospital, such as radiology or anaesthesiology. While common in this context, no-hire clauses are also not unusual in other health-related situations.

This section presents examples of no-hire clauses gathered in discussions with various healthcare organizations.ⁿ⁸ These examples provide a useful backdrop to review case law and policies regarding no-hire clauses. Together with the examples found in the cases discussed in Part II, this should provide a good sense of what no-hire clauses look like and the functions they may serve.

ⁿ⁸ Copies of the contracts containing the examples are on file with the author.

Several of the cases discussed in Part II illustrate no-hire clauses in the clinical service contract context. A good example can be found in *Hospital Consultants, Inc. v. Potyka*, which included a clause prohibiting a hospital from hiring the plaintiff's emergency room physicians and calling for \$ 50,000 as "liquidated damages" for any breach.ⁿ⁹ The following clause, taken from an exclusive agreement between a hospital system and a professional corporation to provide physicians for the hospital system's emergency departments reflects a differently designed clause of this type.

Corporation shall not include any penalty or other provision in its contracts with the Physicians that would preclude Physician from practicing or providing services at [Hospital System] in the event this Agreement expires or is terminated. In recognition that Corporation expends resources and efforts to make qualified Physicians available to serve as Emergency Department Physicians, [Hospital System] agrees that following the date of termination of this agreement without cause, [Hospital System] will compensate Corporation in the amount of no less than twenty-five thousand dollars for each Full-Time Physician:

i. That Corporation has recruited within eighteen (18) months prior to the date of notice of said termination;

ii. Who provided Services under this Agreement;

iii. Who becomes employed, utilized or otherwise engaged, either directly or indirectly, by [Hospital System] at any Practice Site...

n9 *Hosp. Consultants, Inc. v. Potyka*, 531 S.W.2d 657, 659 (Tex. Civ. App. 1975); *see* *Emergency Med. Care, Inc. v. Marion Mem'l Hosp.*, 94 F.3d 1059, 1061 (7th Cir. 1996) (holding that hospital did not violate a contract with medical center when it hired former medical center physicians); *Spectrum Emergency Care, Inc. v. St. Joseph's Hosp. and Health Ctr.*, 479 N.W.2d 848, 852 (N.D. 1992).

Rather than expressly prohibiting the hospital from hiring a physician employed by the emergency service provider and calling for "liquidated damages" to be paid for a breach, this clause allows the hospital system to hire the service provider's physicians. If the enumerated conditions are met, however, hospital system must pay a fee of at least \$ 25,000 for any such hire.

This clause also illustrates some other important facets of a typical no-hire provision in the healthcare context. Often such clauses, like this example, include self-serving but still potentially important language reciting that the service provider has invested significantly in recruiting, training, and placing physicians to furnish clinical services, in order to justify the no-hire clause. Further, the duration of the no-hire period is important, as are any specifications or limitations as to when the clause takes effect (*e.g.*, this clause only applies if termination of the contract is without cause). Also, the scope of a no-hire clause is a key feature. Here, the clause attempts to reach any subsequent relationship between the hospital system and a physician-employee. Finally, this clause is designed to cover only physicians who had worked for the emergency services provider at specific practice sites within the hospital system, as opposed to physicians who may have worked for the service provider at other hospitals or hospital systems under contract with it.

Another situation in which a no-hire clause may be used involves physician peer review services. A hospital may, for various reasons, contract with a firm to provide physicians to review medical records and otherwise assess the appropriateness and quality of care provided in a given case or assist a hospital department in improving the quality of patient care. n10 Given the need for many hospitals to recruit physicians to their staffs, the hospital's administration may later seek to recruit a physician-reviewer with whom a relationship has developed. To preclude this, the peer review service contract may contain a provision such as the following:

[Peer Review Service] has expended considerable time and resources in developing and maintaining its professional quality review program, including establishing a roster of potential physician reviewers, and the loss of such reviewers to [Peer Review Service] program would constitute, therefore, a loss of a valuable asset of the program. Accordingly, the Hospital agrees not to employ or offer employment to [Peer Review Service] personnel or Physician Reviewer during a project or for a period of one year after completion of the project. Because of the difficulty in assessing actual damages, which the parties agree may be considerable, breach of this provision shall entitle [Peer Review Service] to liquidated damages in the amount of \$ 16,000.

n10 National Peer Review Corporation is one firm that provides such services. See www.nationalpeerreview.com (last visited Sept. 24, 2006).

Hospital administrators today are often faced with shortages of professional staff, including nurses, physical therapists, pharmacists, and so on. n11 Hospitals needing to hire, on a temporary basis, competent healthcare personnel to fill positions, may contract with a staffing agency to meet their needs. Given the chronic staffing shortages faced by

hospitals, administrators may then wish to retain, as regular employees, temporary personnel furnished by a staffing agency. Most staffing agencies therefore include no-hire clauses in their contracts with hospitals and other healthcare facilities.

n11 See, e.g. AM. ASS'N OF COLL. OF NURSING, NURSING SHORTAGE FACT SHEET (2006), available at www.aacn.nche.edu/Media/pdf/NursingShortageFactSheet.pdf (last visited Sept. 17, 2006).

Two of the cases discussed in Part II, *Heyde Companies, Inc., v. Dove Healthcare, LLC* n12 and *Therapy Services, Inc. v. Crystal City Nursing Center, Inc.*, n13 involve staffing agency contracts with **nursing homes**. The following is another example of a no-hire clause drawn from a contract between a hospital system and a staffing agency:

If the Client elects to hire (on any basis, including as a full-time, part-time or temporary employee) a health care professional presented by [Staffing Agency] or a health care professional who is working (or has worked within the previous one-year period) in the Client facility as an employee of [Staffing Agency], then Client agrees to immediately pay [Staffing Agency] a recruiting/placement fee equal to 30% of what Client would pay for the health care professional's services if Client were to receive those services for a period of one year. The stated 30% fee will be reduced by one percentage point for each week of 30 hours or more during the preceding year in which the health care professional worked with Client as an employee or contractor/subcontractor of [Staffing Agency] pursuant to this Agreement . . . Client shall not be obligated to pay [Staffing Agency] a recruiting/placement fee . . . if more than one year has passed following either the date the health care professional was presented by [Staffing Agency] to Client or the last day the health care professional worked at Client's facility, whichever is later.

During the one-year period following either the presentation of the health care professional to Client or the completion of the health care professional's assignment at Client's facility, whichever is later, Client agrees not to obtain the health care professional's services through any non-employee direct or indirect contractor or subcontractor relationship, other than through [Staffing Agency].

n12 *Heyde Co. v. Dove Healthcare, LLC*, 654 N.W.2d 830 (Wis. 2002).

n13 *Therapy Serv., Inc. v. Crystal City Nursing Ctr., Inc.*, 389 S.E.2d 710 (Va. 1990).

The following no-hire provision is also drawn from a staffing agency contract.

You may wish to enter into a direct long-or short-term relationship with a [healthcare professional] who has worked with you or has been introduced through [Staffing Agency]. Our business depends on preserving our temporary services network, which we have expended considerable resources to develop. Therefore, as separate consideration for our efforts in locating and referring a [healthcare professional] to you, you agree to pay us a recruitment fee in the amount of 30 percent of the first year's salary ... for any [healthcare professional] introduced to you by [Staffing Agency] ... or who has provided services for you through [Staffing Agency] who:

. accepts a position, during the term of this Agreement or within two years after its termination and whether or not in the area served by your facility or practice where the [healthcare professional] performed, or was introduced to perform temporary services for you, with you or any affiliate..., or

. accepts a position in the area served by your facility or practice in which the [healthcare professional] provided temporary coverage under this agreement, during the term of this Agreement or

within two years after its termination, if you assist in obtaining the position or receive any services or benefits as a result of the [healthcare professional's] placement, or

. engages in temporary coverage, other than through [Staffing Agency], for you or any of your affiliates... whether or not in the area served by your practice or facility where the [healthcare professional] performed temporary services for you, during the term of this Agreement or within two years after its termination.

The restrictions and obligations of this LATER PLACEMENTS section will last during the term of this Agreement or for two years after its termination, at any time or for any reason, and regardless of whether either of us is in breach of any other terms of this Agreement.

The issues raised by no-hire provisions are not limited to healthcare professionals. Hospitals, like many other businesses today, purchase or lease various business services or systems, such as billing and coding, information technology systems, patient support services, and operations management from outside vendors.ⁿ¹⁴ Further, many hospitals regularly engage outside firms to provide consulting and similar services. For example, a hospital may contract with a third party to review and recommend changes in its coding and billing operations. Similarly, a hospital may seek assistance in structuring and procuring its information technology systems.

ⁿ¹⁴ Romano, *supra* note 3, at 24.

In these situations, the hospital may develop a relationship with the vendor's or consulting firm's personnel and seek to hire them directly as its own employees. To deal with this possibility, vendors and consultants may include no-hire provisions in their contracts with hospitals. As an example, in its contract to provide IT consultative services to a hospital, a consulting firm included the following no-hire clause:

For the duration of the Assignment, and for 12 months after its termination or completion, Client will not employ or procure a third party to employ any [Consulting Firm] employee who has taken part in the performance of the Assignment.

Should Client offer employment to such a [Consulting Firm] employee, and [Consulting Firm] gives its consent, and the employee accepts the offer, then Client will pay a recruitment fee to [Consulting Firm]. The recruitment fee will be calculated at 30% of the relevant employee's gross annual compensation with your **company**.

Similarly, when a hospital system purchased a new, fully-integrated IT system, the vendor's contract included a mutual no-hire clause:

During the 24 months after the initial License of the Products, neither Party (or its recruiters acting on the Party's behalf) will directly solicit the employment of any employee of the other Party whose job responsibilities relate to the Products or Support.

The examples provided here certainly are not exhaustive. They do illustrate, however, some of the typical situations in which a no-hire clause may be encountered in the healthcare sector.ⁿ¹⁵ Further, given the specific context, they reflect the common concerns that justify the inclusion of such a clause--concerns about **protecting** the value of and recovering the investment in recruiting, training, and placing employees in a facility to provide clinical care or other business/professional services.

ⁿ¹⁵ This Article considers those situations in which no-hire clauses are typically seen in the healthcare sector. No-hire clauses are used

in many other situations that have not generally been seen in the healthcare context, although they certainly could. For example, a no-hire clause may be used as part of an employment agreement when the employee agrees that if he leaves his current employment, he will not solicit other employees to join his new firm. *See ReadyLink Healthcare v. Cotton*, 24 Cal. Rptr. 3d 720 (App. 2005). In *ReadyLink*, the employment contract between a nurse staffing agency and a nurse recruiter included a clause which, among other things, prohibited him from soliciting the agency's employees for three years after termination of his employment. When the recruiter left and tried to take some of the agency's nurses, the court issued an injunction to prevent this. *See also* *Smith, Barney, Harris Upham & Co., Inc. v. Robinson*, 12 F.3d 515, 517 (5th Cir. 1994); David F. Rolewick, *Can Employers Prevent Former Workers from Hiring Current Employees?*, 94 ILL. B.J. 34, 35-36 (2006). Additionally, a no-hire clause may be used in the context of the sale of a business. For example, the seller of a business may agree not to rehire any employees who went with the buyer at the time of the sale. *See* *Eichorn v. AT & T Corp.*, 248 F.3d 131, 136 (3d Cir. 2001); *see also* *Pactiv Corp. v. Menasha Corp.*, 261 F. Supp. 2d 1009, 1011 (N.D. Ill. 2003) (involving a no-hire clause in connection with negotiations for sale of business). Competing businesses agreeing not to hire each others' employees, however, may run afoul of federal antitrust regulations and state regulations. *See* *Roman v. Cessna Aircraft Co.* 55 F.3d 542, 543 (10th Cir. 1995); *see also* CALLMANN, *supra* note 7, § 16:43.

Despite the apparent practical business justifications for no-hire clauses in these sorts of contracts, the fact is they represent a "restraint of trade." A promise, by one party to a contract, not to hire the other party's employees for some period of time (or to pay some amount for doing so) serves to limit competition and to restrict the activities in the employment marketplace of both the promisor and the employee, though the employee is not a direct party to the no-hire arrangement and may not even be aware of it.

Of course, nearly all contracts relating to business or professional transactions restrain trade in some fashion since they restrict the promisor's freedom of conduct. If a hospital agrees, for example, to contract exclusively with a single professional partnership or corporation to staff and operate the hospital's pathology service (or some other service or department) for a set term, clearly the hospital's freedom of conduct has been limited. Further, other physicians and firms that might wish to provide pathology services to the hospital during the contract period will be precluded from doing so. Yet, such agreements are generally upheld by the courts against various challenges. n16

n16 Bryan A. Liang, *An Overview and Analysis of Challenges to Medical Exclusive Contracts*, 18 J. LEGAL MED. 1, 5 (1997).

The common law, recognizing that all contracts restrain trade in some manner, generally only makes a promise unenforceable as a restraint of trade if the restraint imposed is "unreasonable." Gauging the reasonableness of any restraint may be difficult for a court. The cases discussed in Part II show how different courts have dealt with this question in the context of no-hire clauses.

II. No-Hire Clauses in the Courts

As previously mentioned, the case law surrounding no-hire clauses is relatively scarce. Further, there is a split of authority concerning their enforceability, with a wide variety of judicial opinion on the matter. An apparent reluctance to squarely address the issue has also contributed to the shortage of case law in this area, especially within the healthcare context. n17 The discussion here begins with two cases that are particularly useful in illuminating the various viewpoints with regard to enforceability, in part because of their sharply contrasting positions in factually similar situations. Other decisions are then considered to highlight where various jurisdictions have fallen on the issue, and to point out arguments both in favor of and in opposition to enforceability.

n17 For example, the United States Court of Appeals for the Seventh Circuit avoided the issue of enforceability of a no-hire clause by finding that the plain meaning of the contract language, which barred a hospital from "directly or indirectly" entering into an agreement with physicians formerly associated with a provider service, did not include "utilization" of the same physicians if done by the hospital through a third party. *Emergency Med. Care, Inc. v. Marion Mem'l Hosp.*, 94 F.3d 1059, 1061 (7th Cir. 1996).

Throughout this review of the case law, it may be helpful to bear in mind a few concepts that various courts have identified as factors vital to enforceability. First, some courts have identified employee knowledge of and consent to a no-hire provision as a crucial factor to its enforceability. n18 Other courts, however have squarely rejected the idea that

employee knowledge or consent is relevant to the enforceability of such a clause. n19 Second, several courts have expressed concern about the lack of separate consideration running to the employees covered by a no-hire clause to support the restrictions imposed on them, while others express no such concern. n20 Finally, some courts have identified no-hire provisions as analogous to employee covenants-not-to-compete or restrictive covenants, while others have recognized them as a related, yet different form of contract in restraint of trade. n21

n18 *See, e.g., Heyde Co., v. Dove Healthcare, LLC*, 654 N.W.2d 830, 836 (Wis. 2002).

n19 *See, e.g., Therapy Servs., Inc., v. Crystal City Nursing Ctr., Inc.*, 389 S.E.2d 710, 712 (Va. 1990).

n20 *Compare Webb v. West Side Dist. Hosp.*, 144 Cal.App. 3d 946, 954 (1983) (concerned with lack of consideration given to employee), *overruled on other grounds*, *Moncharsh v. Heily & Blase*, 832 P.2d 899 (Cal. 1992)(en banc), *with Hosp. Consultants, Inc. v. Potkya*, 531 S.W.2d 657, 662-63 (Tex. Civ. App. 1975) (no such concern voiced).

n21 *See, e.g., H & M Commercial Driver Leasing, Inc. v. Fox Valley Containers, Inc.*, 805 N.E.2d 1177, 1183-84 (Ill. 2004) (a no-hire clause is conceptually distinct from a noncompete clause).

A. **Heyde Companies, Inc. v. Dove Healthcare, LLC**

In *Heyde Companies, Inc. v. Dove Healthcare, LLC*, the Supreme Court of Wisconsin held that where an employee has no knowledge of a no-hire provision affecting her contract, her individual freedom to contract cannot be restricted by a contract between two employers. n22 The majority in *Heyde* reasoned that a no-hire provision functions as an unreasonable restraint of trade, violating Wisconsin public policy n23 as expressed by both state common and statutory law, unless the employee has knowledge of and agrees to the provision. n24

n22 *Heyde Co.*, 654 N.W.2d at 836.

n23 *Id.* at 837-38 (citing WIS. STAT. § 103.465 (2000)). Some state courts have applied particular state statutes to invalidate no-hire clauses. For example, the Supreme Court of North Dakota struck down a no-hire clause in a contract between an emergency services provider and a hospital as violative of a state statute that provided, "Every contract by which anyone is restrained from exercising a lawful profession, trade, or business of any kind is to that extent void." *Spectrum Emergency Care, Inc.*, 479 N.W.2d at 851 (emphasis removed) (quoting N.D. CENT. CODE § 9-08-06 (2005)); *see* *Commation Technical Sys., Inc. v. Densmore*, 583 N.W.2d 125, 128 (S.D. 1998) (applying a South Dakota trade restraint statute to a no-hire clause in a computer services contract); *Crown Castle USA, Inc. v. Howell Eng'g & Surveying, Inc.*, 2005 WL 1994256 at *2 (Ala. Civ. App. 2005) (applying a similar Alabama statute). In contrast, other courts have rejected arguments that such statutes invalidate no-hire clauses. *See, e.g., Dickinson County Mem'l Hosp. v. N. Prof'l Emergency Physicians*, 367 N.W.2d 833; 835-36 (Mich. Ct. App. 1984).

n24 *Heyde*, 654 N.W.2d at 831. Judge Thomas, in his specially concurring opinion in *H&M Commercial Driver Leasing, Inc. v. Fox Valley Containers, Inc.*, found the issue of knowledge and consent alone to be determinative, and opined that no-hire provisions agreed to by employers, which restrict employment opportunities of employees without their consent, should be deemed unreasonable restraints upon trade. 805 N.E.2d at 1184-85.

In *Heyde*, Dove Healthcare operated a facility providing **nursing home** services. n25 In order to obtain physical therapists for its **nursing home** residents, Dove contracted with Greenbriar Rehabilitation, a subsidiary of **Heyde Companies, Inc.**, which was in the business of furnishing physical therapists to **nursing homes**. n26 The Dove/Greenbriar contract contained a no-hire clause, which provided that Dove would

not, directly or indirectly, solicit, engage, permit to be engaged or hire any Greenbriar therapists or therapist assistants to provide services for [Dove] independently, as an employee of [Dove] or as an employee of a services provider other than Greenbriar or otherwise during the term of this Agreement . . .

and for a period of one (1) year thereafter. n27

n25 *Heyde Co.*, 654 N.W.2d at 832.

n26 The therapists were hired as at-will employees by Greenbriar. *Id.*

n27 *Id.* (changes in original).

The no-hire clause applied not only to employees who had worked at Dove, but to any employees of Greenbriar who had provided physical therapy services at any **nursing home** under contract with Greenbriar. n28 Finally, the contract also stated that, with the written approval of Greenbriar, Dove could hire a Greenbriar employee, provided that Dove agree to pay Greenbriar a fee of fifty percent of the employee's annual salary with Greenbriar. n29

n28 *Id.*

n29 *Id.*

Following the termination of the Dove/Greenbriar agreement, Dove hired one current and three former Greenbriar employees (one of whom had never worked at Dove) without getting Greenbriar's consent and without paying Greenbriar fifty percent of the employees' salaries. n30 Greenbriar brought suit for breach of contract seeking payment of the fifty percent fee. n31 Dove moved for summary judgment arguing that the no-hire clause was an unreasonable restraint on trade. n32 The trial court denied the motion and on stipulated facts entered judgment for Greenbriar for \$ 62,000 as "liquidated damages." n33 On appeal, the Wisconsin Court of Appeals reversed. n34 Thereafter, a split Wisconsin Supreme Court upheld the court of appeals' decision. n35

n30 *Heyde Co.*, 654 N.W.2d at 832.

n31 *Id.*

n32 *Id.*

n33 *Id.*

n34 *Heyde Co. v. Dove Healthcare, LLC*, 637 N.W.2d 437, 442 (Wis. Ct. App. 2001).

n35 *Heyde Co.*, 654 N.W.2d at 830.

In finding the contract provision unenforceable, the majority in *Heyde*, led by Judge Bablitch, along with Judge Abrahamson in her concurring opinion, found two facts to be significant. First, none of the affected employees had knowledge of the no-hire provision in the Dove/Greenbriar contract. n36 In fact, some of the employees testified that they had actually inquired of Greenbriar whether they would be subject to a noncompete agreement and were told they would not. n37 Second, Greenbriar had contracts with thirty-four other **nursing home** facilities, most of which were located in the same region as Dove Healthcare. n38 As such, the clause prohibited Dove from hiring any therapist employed at any of these sites by Greenbriar.

n36 *Id.* at 832.

n37 *Id.*

n38 *Id.*

The majority began its analysis by noting that the law generally favors freedom of contract, subject to public policy limitations. n39 Such limitations may emerge from statutes, regulations, or common law rules. From this perspective, the majority turned to the following Wisconsin statute n40:

A covenant by an assistant, servant or agent not to compete with his or her employer or principal during the term of the employment or agency, or after the termination of that employment or agency, within a specified territory and during a specified time is lawful and enforceable only if the restrictions imposed are reasonably necessary for the protection of the employer or principal. Any covenant, described in this subsection, imposing an unreasonable restraint is illegal, void and unenforceable even as to any part of the covenant or performance that would be a reasonable restraint. n41

n39 *Id.* at 833.

n40 *Heyde Co.*, 654 N.W.2d at 833.

n41 WIS. STAT. § 103.465 (2000).

Greenbriar argued this statute was inapplicable here, where the contract at issue was between two employers, rather than an employer and an employee. n42 In Judge Bablitch's view, however, the no-hire provision in this case came within the scope of the statute because such a clause is analogous to an employee covenant-not-to-compete. n43 "The effect of the no-hire provision is to restrict the employment of Greenbriar's employees; it is inconsequential whether the restriction is termed a 'no-hire' provision ... or a 'covenant not to compete' ..." n44 He saw the no-hire provision as an attempt by Greenbriar to do indirectly something that the statute was designed to restrict. n45

n42 *Heyde Co.*, 654 N.W.2d at 833.

n43 *Id.* at 834.

n44 *Id.* (emphasis removed).

n45 *Id.*

The court then analyzed the no-hire provision under the statute in the same manner as a covenant-not-to-compete. Initially it rejected Greenbriar's claim that the clause was necessary to protect its interests and that without such a clause, it would become an "involuntary employment recruiting agency." n46 To protect itself, Greenbriar could have negotiated noncompetition agreements with individual employees. n47 Further, given the design of the no-hire clause, encompassing employees who had worked for Greenbriar at any facility, the court found the coverage of the provision

unreasonable. n48 The majority also reasoned that because a valid covenant-not-to-compete requires the employee's knowledge and consent, as well as consideration, the no-hire provision here was "harsh and oppressive to [Greenbriar's] employees and ... contrary to public policy." n49 Upholding the no-hire clause would allow Greenbriar "to circumvent the protections under [the Wisconsin statute] by restricting the employment opportunities of its employees through contracts with other employers without their employees' knowledge and consent." n50

n46 *Id.* at 835.

n47 *Heyde Co.*, 654 N.W.2d at 835.

n48 *Id.*

n49 *Id.* at 836. For an opinion taking a similar view of no-hire provisions, see Judge Rarick's dissent in *H & M Commercial Driver Leasing, Inc. v. Fox Valley Containers, Inc.*, 805 N.E.2d 1177, 1186 (Ill. 2004). Analogizing no-hire provisions to covenants-not-to-compete, Judge Rarick suggested that no-hire provisions should be subjected to the same requirements as to duration and geographic scope and must be reasonably necessary to protect a legitimate business interest such as trade secrets, customer lists, or confidential information. He declined, however, to make the issue of employee knowledge of the no-hire provision dispositive. *Id.* at 1186-90.

n50 *Heyde Co.*, 654 N.W.2d at 836.

Having determined that the no-hire clause violated state statutory law, Judge Bablitch went on to say that the clause was also, under common law rules, an unreasonable restraint on trade for the same reasons identified as violative of the statute. n51 Thus, even in the absence of the statute, the no-hire clause would be unenforceable as a matter of public policy. n52 In her concurring opinion, Judge Abrahamson agreed with the majority's conclusion that the provision was unenforceable as contrary to public policy, but wrote separately to assert that the provision was not governed by the restrictive covenant statute. n53

n51 *Id.* at 837.

n52 *Id.*

n53 *Id.* at 838 (Abrahamson, J., concurring) (citing WIS. STAT. § 103.465 (2000)).

Judge Sykes dissented. n54 In her view, the no-hire provision was not analogous to an employee covenant-not-to-compete because "the no-hire clause did not bind or restrict Greenbriar's employees in any way. It imposed no territorial or other restriction whatsoever on where or with whom they might seek or obtain employment." n55 Thus, Justice Sykes reasoned the Wisconsin restrictive covenant statute was inapplicable. She also argued that since "the statute does not apply, then the expression of public policy contained in it cannot possibly be implicated" by the no-hire clause nor should such a provision be unenforceable because of a "purely theoretical injury to Greenbriar's employees"--the injury being theoretical because the suit did not involve any employees, but only the two employers. n56

n54 *Id.* at 839 (Sykes, J., dissenting).

n55 *Heyde Co.*, 654 N.W.2d at 840. (Sykes, J., dissenting).

n56 *Id.* at 841.

Thus, the majority found that the Wisconsin statute and common law public policy constituted two separate bases for its decision when it stated that "[p]ublic policy may be expressed... by the court's expression of the policy of the common law." n57 Further, in her concurring opinion, Judge Abrahamson argued that the "purely hypothetical injury" to the employees should furnish a sufficient basis to strike down the no-hire clause because "freedom to contract, like other freedoms, has limitations. ... The limitation on the freedom to contract in the present case is the public's interest in not allowing businesses to unduly and unfairly limit the ability of former employees to seek new employment." n58

n57 *Id.* at 833.

n58 *Id.* at 839 (Abrahamson, J., concurring).

B. Therapy Services, Inc. v. Crystal City Nursing Center

In contrast to the *Heyde* case, the Supreme Court of Virginia held in *Therapy Services, Inc. v. Crystal City Nursing Center, Inc.*, that a no-hire clause is not inherently unenforceable, even when the employees have no prior knowledge of it. n59 In *Crystal City*, the court reasoned that the provision was not a covenant-not-to-compete between employer and employee, but was rather a contract in restraint of trade. n60 Thus, the court found that the provision constituted a reasonable restraint if it was "such only as to afford a fair protection to the interests of the party in favor of whom it is given, and not so large as to interfere with the interest of the public." n61

n59 389 S.E.2d 710, 712 (Va. 1990).

n60 *Id.* at 711.

n61 *Id.* There are a number of nonhealthcare cases that uphold no-hire clauses. *See, e.g., Freund v. E.D. & F. Man Int'l, Inc.*, 199 F.3d 382, 385 (7th Cir. 1999) ("[A]n employer who has made a substantial enough investment in the human capital of its employees to enforce a covenant by his employees not to compete with him (for a reasonable time and within a reasonable geographical and product space) can also enforce a promise by another employer not to hire away these employees, provided the contract does not unreasonably restrain competition between the two employers."); *Am. Food Mgmt., Inc. v. Henson*, 434 N.E.2d 59, 64 (Ill. App. Ct. 1982) (enforcing no-hire provision by injunction). *But see Szabo Food Serv., Inc. v. County of Cook*, 513 N.E.2d 875, 877 (Ill. App. Ct. 1987) (holding that such provisions unreasonably restrict the freedom to contract of members of the public who are not parties to the contract).

The facts in *Crystal City* were nearly identical to those of *Dove Healthcare*. Therapy Services was a provider of "skilled rehabilitative services" through employed professionals, n62 and Crystal City Nursing Center was a "skilled nursing facility." n63 Under the terms of their contract, Therapy Services provided certified physical, occupational, and speech therapists to Crystal City. n64 Crystal City agreed not to hire any of the staff provided by Therapy Services for the duration of the contract and for six months following its termination. n65 Crystal City, in accordance with the contract, notified Therapy Services that it was terminating the agreement. n66 Subsequently, Crystal City solicited for hire, both directly and through a physician, several of the Therapy Services personnel who were working at Crystal City. n67 Therapy Services brought suit seeking an injunction enforcing the contract's no-hire provision. n68 The trial court found that because the therapists were unaware of the no-hire clause, it was unenforceable as against public policy. n69

n62 *Crystal City*, 389 S.E.2d at 710.

n63 *Id.* at 711.

n64 *Id.*

n65 *Id.*

n66 *Id.*

n67 *Crystal City*, 389 S.E.2d at 711.

n68 *Id.*

n69 *Id.*

On appeal, the Virginia Supreme Court reasoned that the no-hire clause was reasonable in that Therapy Services had "a legitimate business interest" in **protecting** its professional personnel. n70 The court adopted the argument that without the protection of a no-hire clause, Therapy Services would become an "involuntary and unpaid employment agency" for Crystal City. n71 The court also reasoned that the provision was not so large as to interfere with the public interest. n72 In making this finding, the court found persuasive a number of Therapy Services' arguments. n73

n70 *Id.* at 711-12.

n71 *Id.* at 712.

n72 *Crystal City*, 389 S.E.2d at 712.

n73 *Id.*

First, the restriction on the therapists' employment was limited solely to employment at Crystal City during the six months following termination of the agreement. n74 As such, in the court's view, the restriction was reasonable because it did not inhibit the therapists from seeking employment at other facilities in the Northern Virginia area, where therapists were in low supply and high demand. n75 Second, the court accepted the argument that the therapists' lack of knowledge of the no-hire provision was simply immaterial. n76 Various types of contracts, such as exclusive dealing arrangements, will have an impact upon others who are not parties to such contracts, and yet they are legally enforceable. n77 Finally, the court noted that the clause's restriction had no impact on the availability of therapists in the region, and thus no adverse affect on the public at large. n78

n74 *Id.*

n75 *Id.* Note the contrast to the clause at issue in *Heyde*, which was substantially more restrictive.

n76 *Id.*

n77 *Crystal City*, 389 S.E.2d at 712.

n78 *Id.*

In summary, the courts in *Heyde* and *Crystal City* adopted conflicting positions regarding the enforceability of no-hire clauses. In *Heyde*, the court's majority recognized that the clause was overly broad in its reach and interfered with the employees' potential employment opportunities without their knowledge or consent. In contrast, the court in *Crystal City* viewed the no-hire clause in that case as a reasonable effort to protect legitimate business interests regardless of the employees' knowledge of the clause. The public policy positions of the two courts seem to be fundamentally at odds.

C. Other Cases Involving No-Hire Clauses

Other cases in the healthcare context support the view that no-hire agreements are enforceable if the restraint on trade is a reasonable protection of a legitimate business interest.

In *Webb v. West Side District Hospital*, the court applied a balancing test in assessing a no-hire provision in a contract between the defendant-hospital and Dr. Webb, who had agreed to provide emergency room staff for the hospital. n79 The contract could be terminated by either party with thirty days notice during its first year. n80 Thereafter, the contract had a three-year, automatically renewable term. n81 The contract's no-hire provision specifically acknowledged that Webb would expend funds to "recruit, train, and contract with other physicians" to staff the hospital's emergency department. n82 Based on this, it set a two-year post-termination limitation on the direct or indirect hiring of physicians who had contracted with Webb to furnish emergency room service at the hospital. n83 It also called for the payment of a \$ 30,000 fee per physician if the hospital chose to hire any such physicians. n84

n79 *Webb v. W. Side Dist. Hosp.*, 144 Cal. App.3d 946, 949, 952-53 (1983), *overruled on other grounds*, *Moncharsh v. Heily & Blase*, 832 P. 2d 899 (Cal. 1992) (en banc).

n80 *Id.* at 949.

n81 *Id.*

n82 *Id.*

n83 *Id.*

n84 *Webb*, 144 Cal. App. 3d at 949.

Within the first year, the hospital terminated the contract and engaged a cheaper provider to furnish emergency room staff. n85 There was evidence indicating that a hospital administrator suggested to physicians currently working for Webb that they should contact the new provider prior to termination of Webb's contract in order to secure continued employment. n86 Eventually, four physicians who had worked for Webb were hired by the new provider and continued to staff the hospital's emergency department. n87 Webb then sought \$ 120,000 from the hospital under the contract's fee provision. n88 The hospital refused to pay and the matter was submitted to arbitration. n89

n85 *Id.* at 950.

n86 *Id.*

n87 *Id.*

n88 *Id.*

n89 *Webb*, 144 Cal. App. 3d at 950.

The arbitrator rejected the argument that the no-hire clause was an unenforceable restraint on trade. n90 Further, the arbitrator found that the fee provision functioned as a reasonable attempt to compensate Webb for expenses incurred and not recouped by him due to the early termination of the contract. n91 The arbitrator concluded that the hospital and the new emergency room provider had engaged in conduct specifically designed to take advantage of Webb's efforts to recruit and train emergency physicians. n92 The arbitrator's award of \$ 122,000 was confirmed by the trial court and the hospital appealed. n93

n90 *Id.*

n91 *Id.* at 950-51.

n92 *Id.* at 951.

n93 *Id.*

Citing Webb's economic investment in recruiting, placing, and training physicians to staff the hospital's emergency department, the appeals court used a balancing test to uphold the trial court's enforcement of the no-hire agreement.

The reasonableness of contracts which tend to restrain trade is measured by a number of factors, including the appropriateness of the restraint to advancing the interests to be protected; the availability of less harmful alternatives; the nature of the interest interfered with; the intent of the parties or the tendency of the restraint to create a monopoly; and the social or economic justification for any monopoly, if it does result. n94

n94 *Webb*, 144 Cal. App. 3d at 953. The court also noted that no-hire clauses are common in contracts of this type. *Id.*

The court held that, in this case, the no-hire clause, when coupled with the fee provision, represented a conscious effort by the parties to permit the hospital to employ physicians initially hired by Webb, while assuring that Webb's investment was protected from unfair exploitation. n95 The court also found that the fee imposed on the hospital had not been shown to impose any undue hardship on it. n96 The court squarely rejected the argument that the no-hire provision should be invalid because it restrained the recruited physicians' occupational opportunities. n97 "Most analogous to the restriction at issue here are exclusive dealing contracts between hospitals and groups of physicians, which, if reasonable, have been upheld even if they completely excluded other physicians from the hospitals." n98

n95 *Id.*

n96 *Id.*

n97 *Id.* at 954.

n98 *Webb*, 144 Cal. App. 3d at 954. In contrast, in *Szabo Food Service, Inc. v. County of Cook*, 513 N.E.2d 875, 877 (Ill. App. Ct. 1987), the Illinois court found a no-hire clause unenforceable in the context of a food services provider contract. The service recipient had agreed not only not to hire directly the provider's employees, but also not to allow those employees to work at its facility for another food service provider for six months after termination of the contract. *Id.* at 876. The court found that the clause was an unreasonable restriction on the right of the former employees to work for another food service provider under contract with the facility. *Id.* at 877.

The *Webb* court cited and distinguished the factually similar Texas case, *Hospital Consultants, Inc. v. Potyka*. n99 In *Potyka*, Dr. Bobbitt entered into a three-year contract with Baptist Memorial Hospital System to hire and furnish physicians to staff the emergency rooms at Baptist's various hospitals in return for a monthly fee of \$ 17,500. n100 The contract contained the following no-hire clause:

So long as an Emergency Room Physician is under contract with (Bobbitt) to provide professional services in the emergency room of any hospital, and for a period of three (3) years thereafter, Baptist and/or Hospitals shall not contract with said Emergency Room Physician to otherwise perform professional services in the emergency room of any Hospital, or allow said Emergency Room Physician to provide professional services in the emergency room of any Hospital, except as provided for in his contract with (Bobbitt). It is understood that the foregoing provisions are for the protection of the rights of (Bobbitt) and are not intended to restrict the rights and privileges of a physician to become an active member of the medical staff of any Hospital after ending his contractual relationships with (Bobbitt).
n101

n99 *Webb*, 144 Cal. App. 3d at 954 n.5.

n100 *Hosp. Consultants, Inc., v. Potyka*, 531 S.W.2d 657, 658-59 (Tex. Civ. App. 1975).

n101 *Id.* at 659.

Additionally, the contract contained a \$ 50,000 liquidated damages provision with respect to this no-hire clause. n102 Bobbitt thereafter hired the plaintiff-physicians to staff the Baptist emergency rooms. n103 Some were hired by him directly, while others were hired by Hospital Consultants, Inc., which had been established by Bobbitt. n104 Each of the physician contracts recited that the physician was engaged to enable Bobbitt to fulfill his contract with Baptist, and each contained a three-year post-employment noncompetition agreement covering a fifty mile radius of any Baptist hospital. n105

n102 *Id.*

n103 *Id.* at 659-60.

n104 *Id.* at 660.

n105 *Potyka*, 531 S.W.2d at 659.

A few months before the Bobbitt-Baptist contract was to expire, rumors circulated that it would not be renewed by Baptist. n106 When asked by the plaintiff-physicians about this, Bobbitt assured them the contract would be renewed, but it was not. n107 Instead, Baptist contracted with another firm to staff its emergency rooms. n108 When the

plaintiff-physicians sought to continue to work for this new firm at the Baptist hospitals, Baptist refused to allow them to do so because of the no-hire clause. n109 The plaintiffs sued Baptist, Bobbitt, and Hospital Consultants seeking a declaration that the no-hire provision was unenforceable and enjoining its enforcement. n110 The trial court agreed with the plaintiffs and directed Bobbitt not to seek to enforce it. n111 Bobbitt and Hospital Consultants appealed. n112

n106 *Id.* at 660.

n107 *Id.*

n108 *Id.*

n109 *Id.*

n110 *Potyka*, 531 S.W.2d at 660.

n111 *Id.*

n112 *See id.* at 660.

In its opinion, the appeals court first analyzed the noncompetition provisions in the contracts between plaintiffs and the defendants. n113 The court explained that a noncompetition agreement in an employment contract "is valid if it is reasonable in view of the circumstances of the particular case." n114 To meet this test, the court held that the covenant must impose only those restrictions that are "reasonably necessary to protect the business and good will of the employer." n115 Using these standards, the court found the non compete clauses unenforceable. n116

n113 *Id.*

n114 *Id.* at 661.

n115 *Potyka*, 531 S.W.2d at 661 (quoting *Weatherford Oil Tool Co. v. Campbell*, 340 S.W.2d 950, 551 (Tex. 1960)).

n116 *Id.* at 663.

The court then turned its attention to the no-hire provision in the Bobbitt-Baptist contract. The court began its analysis by observing that:

It is one thing to uphold a restraint as reasonable where it [is] freely entered into by the person whose commercial activities are being restricted ... But where the restriction on B's freedom results, not from B's voluntary agreement with A, but from A's agreement with C, the difference in the situation and in the policy considerations to be balanced is obvious. n117

n117 *Id.* at 664.

Like the Wisconsin court in *Heyde*, the *Potyka* court attached significance to the employees' lack of knowledge and

consent to the no-hire clause. In such a case, the employee "is deprived of his freedom without his acquiescence and with no resulting benefit to him." n118 The court's decision thus suggests that without the employee's knowledge and consent, and without some form of consideration running to the employee, a no-hire clause is unenforceable.

n118 *Id.* at 664.

Bobbitt argued that the no-hire clause was justified to prevent Baptist and the emergency room physicians whom Bobbitt had "brought together" from contracting directly with each other in order to eliminate him. n119 The court found no evidence to suggest that Bobbitt's contract with Baptist had been terminated because of Baptist's desire to contract directly with his physicians. n120 In fact, as the court noted, the emergency room physicians were not seeking to contract with Baptist at all, but rather with the firm that had replaced Bobbitt after his contract with Baptist ended. n121 The only effect of the clause then was to impede the new firm's ability to compete with Bobbitt. n122 The court also found the no-hire clause in this case too broad.

[The restriction] prevents Baptist from entering into a contract, similar to its contract with Bobbitt, with any physician under contract with Bobbitt, even if such physician had not performed services in the Baptist emergency rooms. It requires great imagination to understand how a physician assigned to another hospital and who had had no association whatever with Baptist, would be in a position to take advantage of the fact that he had been assigned to such other hospital in order to induce Baptist to "eliminate" Bobbitt. n123

n119 *Id.* at 664-65.

n120 *Potyka*, 531 S.W.2d at 665.

n121 *Id.*

n122 *Id.*; see *Szabo v. County of Cook*, 513 N.E.2d 875, 878 (Ill. App. Ct. 1987).

n123 *Potyka*, 531 S.W.2d at 665. The *Webb* court distinguished *Potyka* on the basis that the no-hire clause in *Webb* only applied to physicians who had worked at the defendant-hospital. *Webb v. W. Side Dist. Hosp.*, 144 Cal. App. 3d 946, 954 n.5 (1983), *overruled on other grounds*, *Moncharsh v. Heily & Blase*, 832 P. 2d 899 (Cal. 1992)(en banc).

Despite its observations about the reasonableness and scope of the no-hire clause, the court noted in its analysis that, absent knowledge and consent by the affected employee, a no-hire clause is unenforceable. n124

n124 See *Potyka*, 531 S.W.2d at 665.

Although it is not a healthcare case, *H & M Commercial Driver Leasing, Inc. v. Fox Valley Containers, Inc.*, a 2004 decision from the Illinois Supreme Court, merits discussion in part because the court looked to *Heyde* and *Crystal City* for guidance n125 In doing so, the court followed the *Crystal City* opinion and held that a no-hire agreement is enforceable if the restraint of trade resulting from the contract is reasonably necessary to protect a legitimate business interest and is not unduly injurious to the public. n126 The court in *H & M* rejected the idea that a no-hire clause should be viewed as a covenant-not-to-compete, noting that the case did not involve an employee arguing that employment opportunities had been foreclosed. n127 Nonetheless, the court said such a clause is a restraint of trade because it

restricts one employer's ability to hire former employees of another. n128 The court further held that whether a restraint of trade is reasonable depends upon "whether enforcement will be injurious to the public or cause undue hardship to the promisor, and whether the restraint imposed is greater than is necessary to protect the promisee." n129

n125 *H & M Commercial Driver Leasing, Inc. v. Fox Valley Containers, Inc.*, 805 N.E.2d 1177, 1182-83 (Ill. 2004).

n126 *Id.* at 1183-84.

n127 *Id.* at 1183

n128 *Id.*

n129 *Id.* at 1183-84 (citing *Bauer v. Sawyer*, 134 N.E.2d 329, 331 (Ill. 1956)). Note that here the employee is neither the promisor nor the promisee, but is a third party to the contract at issue.

H & M was in the business of providing or "leasing" truck drivers. n130 It agreed to furnish drivers to Fox Valley Containers in return for per-hour payments. n131 In the contract, Fox Valley agreed not to hire any H & M drivers for a period of one year following the termination of the agreement. n132 The agreement also provided for liquidated damages in the amount of \$ 15,000 per H & M driver hired by Fox Valley, plus any costs and expenses, including attorney's fees, that H & M incurred in enforcing the agreement. n133

n130 *H & M*, 805 N.E.2d at 1178.

n131 *Id.*

n132 *Id.*

n133 *Id.*

While the agreement with H & M was still in effect, Fox Valley hired a driver who had been provided to it by H & M under the agreement. n134 The driver, who terminated his employment agreement with H & M of his own accord due to lack of regular work, solicited Fox Valley for employment. n135 Upon learning of the driver's employment by Fox Valley, H & M claimed Fox Valley had breached the contract. n136 Fox Valley contended that the no-hire provision was a restraint on trade in violation of public policy. n137 The trial court granted H & M judgment on the pleadings and the appellate court affirmed. n138

n134 *Id.*

n135 *H & M*, 805 N.E.2d at 1179.

n136 *Id.* at 1178.

n137 *Id.* at 1179.

n138 *Id.*

On appeal, the majority of the Illinois Supreme Court affirmed and held that the no-hire provision was a reasonable restraint on trade because it protected H & M's sole business asset, its drivers, from being hired away by H & M's customers, rendering H & M "an involuntary and unpaid employment agency." n139 The majority also stated that H & M employees were not unreasonably restricted or otherwise hurt by the agreement, maintaining that although the employees could potentially be rendered less desirable to Fox Valley, this potential harm was merely speculative. n140

n139 *Id.* at 1184 (quoting *Therapy Servs., Inc., v. Crystal City Nursing Ctr., Inc.*, 389 S.E.2d 710, 712 (Va. 1990)).

n140 *H & M*, 805 N.E.2d at 1184.

In his concurring opinion in the *H & M* case, Judge Thomas expressed his support for the position, similar to that of the court in *Heyde*, that a no-hire clause is unenforceable as against public policy if not disclosed to the employee. n141 "[E]mployees should be told of such a [no-hire] provision when they begin their employment. Two employers should not be able to contract away an employee's future employment opportunities without the employee's knowledge or consent." n142 He suggested that to protect its business interests, H & M could have included a restrictive clause in its employment contract with the driver. n143 Because nothing in the record indicated that the driver was unaware of the no-hire clause, Judge Thomas concurred with the court's majority. n144

n141 *Id.* at 1185 (Thomas, J., concurring).

n142 *Id.* at 1185.

n143 *Id.* at 1186.

n144 *Id.*

Judge Rarick dissented. In his view, the appropriate analytical approach was to treat a no-hire clause like a noncompetition agreement and measure its validity in terms of its reasonableness in scope, duration, and interests to be protected. n145 With these criteria in mind, Justice Rarick found that a judgment on the pleadings was inappropriate. n146

n145 *H & M*, 805 N.E.2d at 1187 (Rarick, J., dissenting).

n146 *Id.* at 1190.

III. Enforcing No-Hire Clauses--Legal and Policy Considerations

As previously discussed, a no-hire clause is a form of trade restraint and its enforcement raises important public policy issues. Among the issues to consider is whether to allow for the use of such clauses at all, and if so, under what circumstances and with what limitations. Part III explores these issues and offers analysis and insights regarding enforcing no-hire clauses in the healthcare context.

A. Should No-Hire Clauses be Inherently Unenforceable?

An initial question to confront is whether to enforce a no-hire clause at all--or to adopt a position that such a clause

is inherently against public policy. The position of the Supreme Court of Wisconsin in *Heyde Companies, Inc. v. Dove Healthcare, LLC*, seems to support the latter approach, at least where the employee is unaware of the clause, has not consented to it, and has received no separate consideration to support it. n147

n147 *Heyde Co. v. Dove Healthcare*, 654 N.W.2d 830, 838 (Wis. 2002). The court in *Hospital Consultants, Inc. v. Potyka*, 531 S.W.2d 657 (Tex. App. 1975), expressed a similar view, as did Judge Thomas in his concurring opinion in *H & M Commercial Driver Leasing v. Fox Valley Containers*, 805 N.E.2d 1177 (Ill. 2004).

Although the *Heyde* court purported to use a multifactor "reasonableness" test to evaluate the no-hire clause at issue, in its analysis the court took the position that it is against public policy to foreclose an employee's employment opportunities by way of an agreement to which the employee is not a party and to which he or she has not assented. As Judge Abrahamson stated in her concurring opinion:

The limitation on the freedom to contract ... is the public's interest in not allowing businesses to unduly and unfairly limit the ability of former employees to seek new employment. It is an unfair and an undue limitation on an employee's right to seek employment for an employer to contract away an employee's freedom of future employment without that employee's ever knowing about or consenting to the limitation. n148

n148 *Heyde*, 654 N.W.2d at 839 (Abrahamson, J., concurring).

Under this approach, most no-hire clauses will necessarily fail. n149

n149 *See id.* at 842 (Sykes, J., dissenting). This seems to be the view of the dissent in *Heyde* with respect to the impact of the majority's analysis. *Id.* at 842-43. An approach that might address these concerns would be to include in the employee's written contract (if there is one) a clause requiring the employee to acknowledge that the employer may include no-hire provisions in its contracts with customers and that these provisions may have an impact on the employee's employment opportunities with the employer's customers.

While initially there is some appeal to this viewpoint, upon examination it seems mistaken for several reasons. In particular, almost any contract will have an impact on third parties who have not agreed to its terms. An exclusive provider agreement between a hospital and a clinical service provider, by definition, impacts directly the opportunities of other providers who are not parties to the agreement and have not assented to it. Yet, current law does not hold that all such agreements violate public policy. n150

n150 *See, e.g., Mateo-Woodburn v. Fresno Cmty. Hosp.*, 270 Cal. Rptr. 894, 902 (Ct. App. 1990).

Furthermore, when compared to the usual covenant-not-to-compete in an employment contract, a no-hire clause will often be arguably *less* burdensome to the employee. A covenant-not-to-compete will usually bar the former employee from *any* employment or other relationship with *any* competitor of the employer in a defined geographic area for a stated duration. In contrast, a no-hire clause only applies to employment with a specific employer (or group of employers), leaving the employee with a broader range of remaining employment opportunities in the area. n151

n151 *See Heyde*, 654 N.W.2d at 840. (Sykes, J., dissenting).

The position of the *Heyde* court may be supported by the theoretical distinction that the employee has bargained for

and agreed to the noncompetition arrangement, while the no-hire clause is neither known nor agreed to by the employee. In reality, however, a covenant-not-to-compete will often be imposed by the employer with no real opportunity for negotiation by the employee--the restrictive covenant simply is part of the "standard" employment contract and is not the subject of meaningful discussion or bargaining. Recognizing this reality, courts have subjected employee noncompetition clauses to greater scrutiny than covenants in other contexts (*e.g.*, business sale agreements) and have strictly construed such provision against the employer. n152

n152 *See, e.g.*, Valley Med. Specialists v. Farber, 982 P.2d 1277 (Ariz. 1999); Rash v. Toccoa Clinic Med. Assocs., 320 S.E.2d 170, 173 (Ga. 1984) ("[I]t is generally true in the employer/employee relationship that the employee goes into a transaction. . . at a great bargaining disadvantage . . . [Thus,] the courts have traditionally given greater scrutiny to restrictive covenants within employment contracts, as opposed to such covenants contained in business sales agreements.")

Finally, although employees (and the public) certainly have a significant interest in maintaining their ability to earn a living without unreasonable restrictions, employers also have significant, legitimate interests in utilizing the protection of a no-hire clause. Both the investment in recruiting, training, and placing employees in various settings, and the value of these employees as business assets can be significant. The no-hire clause represents one approach to **protecting** this investment as an alternative, or in addition, to a covenant-not-to-compete. The fact that the employer could use a noncompetition covenant alone to try to achieve its goals should not be reason enough to overcome the public policy favoring freedom of contract.

In light of these considerations, it seems appropriate to approach a no-hire clause like other trade restraints and subject it to a "reasonableness" analysis, rather than adopting a *per se* rule invalidating it. n153

n153 Glenn v. Diabetes Treatment Ctrs. of Am., Inc., 116 F.Supp.2d 1098, 1105 (S.D. Iowa 2000); see CALLMANN, *supra* note 7, § 16.43.

B. What Factors are Relevant in Analyzing a No-Hire Clause as a Trade Restraint?

If adoption of a *per se* rule of unenforceability for no-hire clauses is inappropriate, then the task is to isolate and identify relevant factors to consider in deciding whether a clause in a given case is enforceable. Case law offers guidance on this subject.

1. The Need for the Restraint to be "Ancillary"

Initially, courts have taken the position that any attempt to restrict competition must be "ancillary" to an otherwise valid transaction or relationship. n154 So-called "naked" restraint clauses, whose only purpose is to stifle competition, are inherently unreasonable. n155 Therefore, to uphold any competitive restriction, including a no-hire provision, a party must establish some interest at stake that justifies the need for its protection and that counterbalances the restraint imposed by it. n156 The competitive restriction "must... be subsidiary to an otherwise valid transaction or relationship that gives rise to such an interest." n157

n154 *See* RESTATEMENT (SECOND) OF CONTRACTS § 187 (1979). Arguably, the ancillary concept simply is a different way of stating the second element of the analysis set out here, namely that the employer have a legally-protectable interest. While this may be true, most courts still include the ancillary concept as a separate analytical element.

n155 *See* E. ALLEN FARNSWORTH, FARNSWORTH ON CONTRACTS § 5.3 (3d ed. 2004).

n156 *See id.* § 5.3.

n157 RESTATEMENT (SECOND) OF CONTRACTS § 187 cmt. b.

The typical no-hire clause should satisfy the "ancillary" requirement. It will be included as part of a contract for services between the employer-service provider and another party that may develop an interest in hiring away the employees who have provided services to it during the term of the contract. The employer has an interest in preventing its employees from being pirated away and thereby losing its investment in recruiting, training, and placing its employees who are a critical business asset.

Assuming that the no-hire clause meets the ancillary test, the next analytical step is to assess whether the restrictions imposed are reasonable under the circumstances. In examining the typical employee noncompetition covenant, the courts have developed a general analytical approach that looks at whether the restraint is reasonable in light of the covenantee's interests to be protected and at whether the restraint imposes any undue hardship on the covenantor or is unreasonably injurious to some public interest. n158 The courts in this context focus their attention on the scope of the covenant in terms of the activities it restricts, its geographic reach, its duration, the circumstances of the employee's termination, and any relevant public needs. n159 A similar analytical approach can be used to examine a no-hire clause. n160

n158 *See id.* § 188; FARNSWORTH, *supra* note 155, § 5.3.

n159 FARNSWORTH, *supra* note 154, § 5.3.

n160 *See, e.g.,* Pactiv Corp. v. Menasha Corp., 261 F. Supp. 2d 1009 (N.D. Ill. 2003).

2. The Employer's Protectable Interests

In determining the enforceability of a no-hire clause, one must first consider the interests of the employer that are involved. For example, in the context of a contract to staff a hospital department such as anesthesiology, the employer-service provider incurs significant costs in recruiting and contracting with physicians to provide anesthesia services at various hospital sites. Although less likely, the employer in such a case may also have educational and training costs for some of its physician-employees. There are also the costs associated with negotiating the contracts with hospitals to staff their anesthesiology departments, together with the costs of placing the appropriate physicians in these departments and generally managing the services provided. If a hospital can directly hire the physicians placed with it by the employer or arrange for their employment with another anesthesiology provider, the employer may be unfairly deprived of its opportunity to recoup its investment in the physicians, as well as lose a major business asset--its physician-employees. n161 Further, the physician-employee may use his or her position to undermine the relationship between the service provider-employer and the hospital, or vice versa.

n161 *See* Reffold, *supra*, note 6. In the context of a no-hire clause, this analysis supports the view that a business has a legitimate interest to protect with a clause that is otherwise reasonable and consistent with public policy.

Similar interests and concerns are at stake with respect to temporary professional staffing agency contracts--for example contracts to provide registered nurses on a temporary basis for a hospital. The staffing agency will incur significant costs in recruiting nurses and may have expenses in training and educating the nurses. In the context of vendor and consulting contracts (e.g., billing and coding services) the employer will likely have a significant investment in educating and training its employees in the complexities of healthcare billing and coding. As a result, in each of these situations the employer has a protectable interest in its employees that may justify a no-hire clause. n162

n162 *But see* National Employment Service Corp. v. Olsten Staffing Service, Inc., 761 A.2d 401, 405 (N.H. 2000) (employer's costs in "recruiting, interviewing, checking references, qualifying, insuring, and placing" at-will employees was not "a legitimate interest protectable by a restrictive covenant in an employment contract").

3. The Scope of the No-Hire Clause and the Burden on the Employee

Assuming that the employer has a protectable interest, the scope and impact of the restrictions imposed by the no-hire clause must be considered. The basic analytical questions to ask are whether the scope of the no-hire clause is reasonable in light of the interests to be protected and whether the clause imposes an undue hardship on the employee.

One dimension of a no-hire clause's scope that has been the subject of dispute is what customers and employees it encompasses. The coverage of a no-hire clause must be reasonably related to the employer's legitimate interests. In *Hospital Consultants, Inc. v. Potyka*, n163 the no-hire clause was written to prevent the hospital from hiring any physician who had been under contract with the emergency services provider regardless of where the physician had worked. The court found that this made the agreement overly broad. n164 In contrast, in *Webb v. West Side District Hospital*, n165 the court specifically distinguished *Potyka* on the basis that the no-hire clause at issue only applied to physicians who had been placed at the defendant-hospital by the service provider. n166

n163 *Hosp. Consultants, Inc. v. Potyka*, 531 S.W.2d 657 (Tex. Civ. App. 1975).

n164 *Id.* at 665; see *Pactiv*, 261 F. Supp. 2d at 1014.

n165 *Webb v. W. Dist. Hosp.*, 193 Cal. Rptr. 80 (App. Ct. 1983), *overruled on other grounds*, *Moncharsh v. Heily & Blase*, 832 P. 2d 899 (Cal. 1992)(en banc).

n166 *Id.* at 84, n.5.

A court's concerns in this context may be heightened in some circumstances. n167 Assume, for example, that an employer-service provider has secured substantial control over a given service (*e.g.*, temporary nurses) in a geographic area through multiple contracts with all or nearly all of the hospitals in the area. Further, assume that each hospital contract contains a broadly worded no-hire clause that encompasses any employee who has worked for the service provider, whether at that hospital or some other. In such a case, virtually all employment opportunities (at least with hospitals) for a given employee in the area will be precluded. This would certainly burden the employee--although no more so (and perhaps less) than a noncompete clause. n168 For example, the employee could still seek employment at other facilities in the area not under contract with the service provider.

n167 In *Heyde Companies, Inc. v. Dove Healthcare*, 654 N.W.2d 830, 835 (Wis. 2002), the court in finding a no-hire clause in a staffing contract with a **nursing home** unenforceable, noted that the clause applied to employees "who never even worked at the [defendant's] facility." Further, the court observed that the staffing agency had contracts with most of the **nursing homes** in the geographic area. None of these facilities could hire any of the agency's employees, regardless of where they had worked.

n168 In the context of a noncompete clause, the fact that enforcement of the clause may require the employee to relocate within the area or even move from the area to find employment is not, in itself, an undue hardship. It is merely the anticipated consequence of enforcement; that is, it is part of the bargain made between the parties. *See, e.g.*, *Canfield v. Spear*, 254 N.E.2d 433 (Ill. 1969).

In most cases, it is appropriate to follow the position taken in *Potyka* and *Webb* limiting coverage of a no-hire clause to only those employees who performed services for the hospital or other entity now seeking to hire them. The service provider's interest in not being unfairly deprived of the value of its investment and its key business assets supports this limitation. If the provider wants to try to go further it can take other steps, such as including a

noncompetition agreement in its employee contracts.

Applying a no-hire clause to all employees regardless of where they have worked goes too far. There is always a risk to an employer that a valued employee will leave--this is unavoidable. The proper purpose of a no-hire clause is to prevent "pirating" of employees by customers who have developed a relationship with the employee through the customers' contract with the service provider. Further, to the extent an employee owes an employer a duty of good faith not to use the opportunity provided by the employment relationship to undermine the employer's customer relations, this duty seems inapplicable where the employee has had no relationship with the customer. For example, if a hospital which has a contact with a staffing agency to provide temporary nurses (with a no-hire clause) places a newspaper ad seeking to hire full time nurses, and a nurse employed by the staffing agency (who has never worked at the hospital) responds to the ad and is hired, this should not breach the no-hire clause. n169

n169 This is supported by the author's interviews with healthcare administrators, who indicate that, if an employee is hired through the regular general hiring process (as opposed to special recruitment efforts), a no-hire clause may not apply.

Another dimension of a no-hire clause to consider is its possible application to situations beyond those in which the hospital or other entity that has received the employee's services seeks to contract with the employee directly. For example, a third party may hire away a physician-employee to provide the same services to the hospital that the original service provider did. In order to preclude this, as previously noted, many no-hire clauses talk in terms of preventing the "direct or indirect" hiring of an employee to provide the same services. In some cases the courts have enforced such clauses, while in others they have not. n170

n170 See, e.g., *Emergency Med. Care, Inc. v. Marion Mem'l Hosp.*, 94 F.3d 1059 (7th Cir. 1996) (refusing to enforce "direct or indirect" no-hire clause when physicians in question were hired by a third party to continue providing services at hospital).

In this context, there are competing concerns to take into consideration. On the one hand, the employer-service provider wants to protect itself from a situation where, through a collaborative effort with a third party, the hospital or other facility indirectly "steals" its employees. This seems to be a valid concern. Without some sort of limitation like this, the no-hire clause could easily be circumvented and would be of little value. On the other hand, absent evidence of some form of collusion with the third party designed to evade the no-hire clause, the employer-service provider may not have a legally protectable interest at stake. As previously noted, employers always face the risk that a valued employee will be hired away by a competitor. In most cases, neither the employee nor the third party knows of or has consented to the no-hire clause, so binding them to it may go too far. Again, if the employer wants to try to avoid this situation, it can negotiate an employee covenant-not-to-compete.

The best approach to take in terms of this facet of the analysis is to ask if there is evidence that the hospital or other entity and the employee participated in a scheme to avoid the no-hire restriction through a third party. The cases support this approach. In *Webb*, the court noted that there was testimony that the hospital administrator actively sought to bring together the new ER provider and physicians under contract with the previous emergency services provider. n171 In *Potyka*, however, the court found no evidence that the hospital had set out to contract with the emergency physicians placed with it through some sort of plan with a third party. n172

n171 *Webb v. W. Side Dist. Hosp.*, 193 Cal. Rptr. 80, 82 (1983), *overruled on other grounds*, *Moncharsh v. Heily & Blase*, 832 P. 2d 899 (Cal. 1992)(en banc).

n172 *Hosp. Consultants, Inc. v. Potyka*, 531 S.W.2d 659, 661 (Tex. App. 1975). In *Szabo Food Service, Inc. v. County of Cook*, 513 N.E.2d 875, 877 (Ill. App. Ct. 1987), the court refused to enforce a no-hire clause involving food service management employees with respect to a third party who had hired the employees away from the prior food service provider. The court noted, however, that the former

employer had not alleged that the service recipient had used the new provider "as a surrogate to evade the restriction prohibiting [it] from hiring [the] managers." *Id.*; see *Emergency Med. Care, Inc.*, 94 F.3d at 1061.

The relevant scope of a no-hire clause also includes its duration. The typical no-hire clause prohibits hiring away employees during the term of the agreement and for a specified period of time thereafter. n173 Just as in the context of an employee covenant-not-to-compete, courts will consider whether the duration of a no-hire clause is reasonable in light of the interests of the employer to be protected and the burden on the employee.

n173 *Heyde Co. v. Dove Healthcare*, 654 N.W.2d 830, 831 (Wis. 2002). Alternatively, the clause may prohibit the hiring of an employee during the duration of his or her employment and for a set period thereafter. See, e.g., *Potyka*, 531 S.W.2d at 659.

As discussed earlier, one employer interest that is often cited as justifying a no-hire clause is the investment of the employer in recruiting, training, and placing the employee. These costs can be significant and the value to the employer of its investment will be lost if the employee is pirated away before the employer can recoup these costs.

Having said this, the fact remains that in many cases these costs should be recovered by the employer during the performance of the contract as a part of the contract price. If so, there is arguably no basis to restrict hiring the employee after the term of the contract has run. In some instances, however, this may not be the case. Some employees may be hired during the term of the contract and so the associated recruiting and other costs may not yet be recovered by the time the term of the contract expires. Further, in some instances (e.g., a short-term consulting contract) the employer may only recover in the contract price a portion of its investment in the employee. In these situations, a post-termination no-hire clause could be justified. One way to try to take this into account is to draft the no-hire clause to apply only to employees hired within some period of time (e.g., one year) *prior* to the contract's termination. n174 Presumably as to these employees, the employer has not yet had the opportunity to recoup its investment.

n174 For example, one of the clauses quoted in Part I above provides that it applies to employees who were "recruited within eighteen (18) months prior to the date of...termination" of the contract. See *supra* text following note 9.

The foregoing discussion assumes that the term of the contract has come to its agreed end. In addressing the question of a no-hire provision's duration, however, another point to keep in mind is that a contract may end earlier than the agreed term. A breach by one party may result in termination by the other. Additionally, the contract may give one or both of the parties the right to terminate the contract early either for some stated "cause" or "without cause" upon prior notice. In such situations, the employer may argue that a post-termination no-hire clause is appropriate because it has not had the opportunity to recover its investment in its employees.

Reviewing various no-hire clauses suggests that they can differ in how they deal with an early termination. Many appear to apply to any sort of termination. In *Heyde Companies*, for example, the contract barred hiring of employees "during the term of this agreement... and for a period of one (1) year thereafter." n175 In *Webb*, however, while the no-hire clause applied for two years "following the termination of this Agreement," the court construed it as only applying in the context of an early termination. n176 Similarly, one of the sample no-hire clauses quoted in Part I only prohibits hiring of employees when the contract is terminated early without cause. n177 Presumably those clauses that apply only to early terminations do so because in such a case the employer has not had the chance to recover its recruiting and other costs.

n175 *Heyde*, 654 N.W.2d at 832; accord *Glenn v. Diabetes Treatment Ctrs. of Am., Inc.*, 116 F. Supp. 2d 1098, 1100 (S.D. Iowa 2000); *Spectrum Emergency Care, Inc. v. St. Joseph's Hosp. and Health Ctr.*, 479 N.W.2d 848, 850 (N.D. 1992). One no-hire clause cited in Part I specifically states that the hiring prohibition applies "during the term of this Agreement or for two years after its termination, at any time or for any reason, and regardless of whether either of us is in breach of any other terms of this Agreement." See *supra* text preceding note 14.

n176 *Webb*, 193 Cal. Rptr. at 82 n.3.

n177 The quoted clause states that "[Hospital System] agrees that following the date of termination of this agreement without cause, [Hospital System] will compensate Corporation in the amount of no less than twenty-five thousand dollars for each Full-Time Physician." See *supra* text following note 9.

With respect to the durational dimension of any particular no-hire clause, the court must look to the specific facts of the case. Given the facts, the court should try to determine if enforcing the clause will serve to protect the employer from the loss of its investment and from unfair exploitation, or whether it goes beyond this and only operates to limit the employee's opportunities and otherwise impede competition.

4. The Impact of the No-Hire Clause on the Public

As in the context of noncompetition covenants, several courts evaluating no-hire clauses have explicitly considered whether enforcing the clause will have some identifiable adverse impact on the public interest. In *Crystal City*, n178 the Virginia Supreme Court considered a no-hire clause involving physical and speech therapists and concluded that the clause would be invalidated if it were "injurious to the public." n179 In the court's view, however, the clause before it did not fail this test:

[T]here was no adverse impact on the interest of the public at large. The availability of therapists' services was not diminished since the affected therapists were not precluded from working in Northern Virginia or any other area. Under these circumstances we cannot conclude that [the no-hire clause] deprived the affected therapists of the "right to seek a livelihood" or that it interfered "with the interest of the public." n180

n178 *Therapy Serv., Inc. v. Crystal City Nursing Ctr., Inc.*, 389 S.E.2d 710 (Va. 1990).

n179 *Id.* at 711.

n180 *Id.* at 712.

The Illinois court in *H & M Commercial Driver Leasing, Inc. v. Fox Valley Containers, Inc.*, n181 where a **company** provided temporary truck drivers to carriers, likewise considered the question of public injury in terms of a no-hire clause. Citing *Crystal City*, the court found "no adverse impact" on the interests of the public because "nothing in the record suggests that the availability of truck drivers [in the area] was diminished" as a result of the agreement. n182

n181 *H & M Commercial Driver Leasing, Inc. v. Fox Valley Containers, Inc.*, 805 N.E.2d 1177, 1180-81 (Ill. 2004).

n182 *Id.* at 1184.

The reasoning of the courts in these cases will likely apply in most no-hire clause situations. As previously discussed, a no-hire clause typically restricts employment only as to particular customers of the service provider who might be interested in hiring one of the provider's employees. Absent a valid noncompetition agreement, the employee remains free to provide services independently or through other employers in the area.

A situation noted earlier--when an employer-service provider has secured substantial control over a given service in

an area and has, in its contracts with its customers, broadly worded no-hire clauses that encompass any employee who has worked for the service provider, whether for that customer or not--may raise concerns not only as to the burden on the employees of the no-hire clause, but also as to the public's interest in terms of access to services. Unless the services of the employee are somehow unique or highly specialized, however, it seems unlikely there would be any meaningful public injury. Presumably the prospective employer already has (or can obtain) sufficient other employees to meet the community's service needs.

A final point to consider with respect to a no-hire clause's possible injury to the public is any effect on patients. With respect to physician noncompetition agreements, several courts have ruled that they are injurious to the public and therefore invalid because they interfere with the physician-patient relationship. n183 Would a similar argument succeed in the context of a no-hire clause? It seems unlikely.

n183 *See, e.g., Murfreesboro Med. Clinic v. Udom*, 166 S.W.3d 674, 683 (Tenn. 2005) (In striking down physician noncompetition agreements, the court emphasized the importance of patients having the opportunity to freely choose physicians, as well as the importance of preserving established physician-patient relationships.).

Many no-hire clauses in the healthcare sector do not involve physicians at all, but other personnel, such as nurses or pharmacists). Those that do concern physicians typically involve "hospital-based" physicians (*e.g.*, emergency room physicians) who provide services without developing ongoing relationships with patients. Even as to physicians or other health care professionals who might develop a relationship with their patients, a no-hire clause should not interfere with that relationship in the way a noncompetition agreement can. Unlike a noncompete provision, a no-hire clause does not limit the employed professional from practice in an area, but only restricts who that professional can be employed by. To the extent a patient wishes to continue to see a particular professional, in most instances a no-hire clause should provide no impediment.

5. No-Hire Clauses and Liquidated Damages.

Many of the no-hire clauses in the cases reviewed, as well as in the examples provided in Part I, specify that the employee may be hired if the hiring party pays some set amount for doing so. Depending on the wording, this sort of provision may function either as a liquidated damages clause or as a clause allowing for alternative performances.

In several cases involving no-hire provisions, the language of the provision specifically talks in terms of liquidated damages. n184 For example, in *Emergency Medical Care, Inc. v. Marion Memorial Hospital*, n185 the contract called for the payment of \$ 20,000 as "liquidated damages in . . . full, final and complete payment for all damages." n186 Similarly, in *Hospital Consultants, Inc. v. Potyka*, n187 the no-hire clause specified that the hospital must pay \$ 50,000, "as liquidated damages and not . . . a penalty" in the event of a breach. n188

n184 *See, e.g., H & M*, 805 N.E.2d at 1178.

n185 *Emergency Med. Care, Inc. v. Marion Mem'l Hosp.*, 94 F.3d 1059 (7th Cir. 1996).

n186 *Id.* at 1060.

n187 *Hosp. Consultants, Inc. v. Potyka*, 531 S.W.2d 657 (Tex. Civ. App. 1975).

n188 *Id.* at 659.

Other clauses are written simply to provide that if an employee is hired away, the hiring entity will pay an agreed to

"fee" and do not include any direct prohibition on hiring as such. n189 In *Webb v. West Side District Hospital*, n190 the contract, after acknowledging the investment in emergency room physicians undertaken by the service provider, Dr. Webb, called for the hospital to pay Webb \$ 30,000 for each physician directly or indirectly employed by the hospital with the understanding that this fee "accurately reflects the reasonable value of [the provider's] time and costs." n191 In such a situation, the hospital has made alternative promises to either have the service provider furnish its emergency department staff, or to pay a fee to the provider if it (or a third party) hires away its physicians to do so.

n189 *See, e.g., Heyde Co. v. Dove Healthcare*, 654 N.W. 2d 830, 832 (Wis. 2002).

n190 *Webb v. W. Side Dist. Hosp.*, 193 Cal. Rptr. 80 (Ct. App. 1983), *overruled on other grounds*, *Moncharsh v. Heily & Blase*, 832 P. 2d 899 (Cal. 1992)(en banc).

n191 *Id.* at 81.

If the no-hire provision is written as a liquidated damages clause, the court should follow a relatively well-established analytical framework to determine the enforceability of the provision. The Restatement (Second) of Contracts offers the following relevant criteria:

Damages for breach by either party may be liquidated in the agreement but only at an amount that is reasonable in the light of the anticipated or actual loss caused by the breach and the difficulties of proof of loss. A term fixing unreasonably large liquidated damages is unenforceable on grounds of public policy as a penalty. n192

n192 RESTATEMENT (SECOND) OF CONTRACTS § 356 (1981).

The question a court must consider in this context is whether the liquidated damage provision appears to be a reasonable attempt to predict the amount of actual damages that may occur should the no-hire clause be breached, or if it is designed to coerce performance or discourage a breach. Three basic points are considered in the analysis: the purpose of the clause; any difficulty in proving actual damages; and the proportionality of the agreed damage amount to the anticipated or actual damages sustained.

While the use of liquidated damage provisions is common in no-hire clauses, there are few no-hire cases that examine such provisions in detail. In his dissenting opinion in *H & M Commercial Driver Leasing, Inc.*, however, Judge Rarick offered a detailed discussion of a no-hire provision's liquidated damages clause. n193

n193 *H & M Commercial Driving Leasing, Inc. v. Fox Valley Containers, Inc.*, 805 N.E.2d 1177, 1187 (Ill. 2004) (Rarick, J., dissenting).

H & M Commercial Driver Leasing, Inc involved a contract between a carrier and a firm that "leased" truck drivers to the **company**. n194 The contract contained a no-hire clause calling for the payment of \$ 15,000 as liquidated damages in the event the carrier hired one of the drivers. n195 The trial court rejected the carrier's argument that the no-hire clause was "violative of public policy" and granted the leasing **company** judgment on the pleadings. n196 Both the appellate court and the state supreme court affirmed.

n194 *Id.* at 1178.

n195 *Id.*

n196 *Id.* at 1179.

In his dissent, Judge Rarick took the position that the liquidated damages clause was an unenforceable penalty for several reasons. n197 First, looking to the potential damages that the parties might have anticipated at the time of contracting, Judge Rarick found two potential damage categories to consider: lost revenues, and lost driver training and placement costs. n198

n197 *Id.* at 1186.

n198 *H & M*, 805 N.E.2d at 1188.

As to lost revenues, Judge Rarick reasoned that because the driver was an at-will employee, the leasing **company** could not be certain that the driver would work for it for any period of time to generate any sort of revenue. n199 Therefore, in his view, the amount of anticipated revenue was "entirely speculative" n200 and the \$ 15,000 liquidated damages amount could not possibly be a reasonable prediction of anticipated loss due to a breach of the no-hire clause. n201 Indeed, under his analysis, no amount of loss could be reasonably anticipated. n202

n199 *Id.* at 1189.

n200 *Id.*

n201 *Id.* at 1188.

n202 *Id.* at 1189.

It is, however, this very problem that arguably justifies the liquidated damages provision. The leasing **company** certainly anticipates some revenue from its business activities with its customer-carriers. The revenue any given driver may generate is uncertain, in part because he or she may leave the leasing **company** at any time. That is a risk the leasing **company** takes when it uses at-will employees. If, however, one of its customers deprives the leasing **company** of the chance to make any revenue from a driver by using its contract with the leasing **company** to pirate away that driver, the leasing **company** has suffered the loss of the possibility of revenue. This is a different risk, a risk that the **company** can properly seek to avoid through a no-hire clause, and a reasonable liquidated damages figure seems to be an appropriate attempt to do so. n203

n203 In *Blase Industries Corp. v. Anorad Corp.*, 442 F.3d 235, 239-40 (5th Cir. 2006), a case involving a no-hire clause in a computer software consulting agreement, the court found that, in the absence of a valid liquidated damages provision, an employer of an at-will employee could not recover lost profits when the no-hire clause was breached because the amount of loss was too uncertain.

Judge Rarick also looked at another possible damage component for the leasing **company**, namely lost training and placement expenses. n204 In this regard, he speculated that the leasing **company** must have to recover this investment quickly after hiring a driver because it could not count on having the driver work very long for it. n205 With nothing in the record addressing this, Judge Rarick was still willing to conclude that the leasing **company** must have "already recovered all of its expenses attributable to the driver by the time the driver went to work for [the carrier]." n206 Furthermore, he felt that any training or placement expenses incurred by the **company** would not be difficult to prove

and were thus not properly subject to a liquidated damages provision. n207

n204 *H & M*, 805 N.E.2d at 1189.

n205 *Id.*

n206 *Id.*

n207 *Id.*

Of course, Judge Rarick was simply guessing here. The record in the context of a judgment on the pleadings did not answer any of these questions. One could alternatively (and reasonably) speculate that the leasing **company**, mindful of the uncertain duration of its relationship with any particular driver and knowing that it has a significant investment in training and placing its drivers, set the agreed damages amount in a reasonable effort to account for this very uncertainty and assure for itself that it would recover an appropriate, allocable portion of its overall training and placement costs. This seems rational and plausible.

The importance of Judge Rarick's liquidated damages discussion in *H & M Commercial Driver Leasing, Inc.* comes not from his analysis or from how it can be responded to, but rather in how it reflects the sort of conflict that may be encountered when a no-hire provision includes a liquidated damages clause. If challenged, the proponent of such a clause will have to address the critical analytical points involved with such clauses. Doing so can present real problems. As law students over the years have learned in their contracts courses, despite a general policy position favoring freedom of contract and the private settlement of disputes, courts have been hostile to liquidated damages provisions. n208 Judge Rarick's dissent reflects this hostility.

n208 FARNSWORTH, *supra* note 155, § 5.3; CHARLES KNAPP ET AL., PROBLEMS IN CONTRACT LAW: CASES AND MATERIALS 989 (5th ed. 2003).

It may be possible to avoid some of these problems by using an alternative performance approach in the context of a no-hire clause as in the *Webb* case. n209 Under such an approach, a party is given the choice or "option" to perform as agreed or pay a set sum. n210 Using this approach, the contract in *Webb* simply called for the payment of an agreed "fee" representing "the reasonable value" of the employer's time and costs for any physician that the hospital hired away. n211 Thus, the hospital was given a choice under the contract; either it did not hire away Dr. Webb's physicians or, if it chose to do so, it paid a fee. In either case, exercising the option given by the contract was not a breach and thus, the provision was not one for liquidated damages.

n209 *Webb v. W. Side Dist. Hosp.*, 193 Cal. Rptr. 80 (Ct. App. 1983), *overruled on other grounds*, *Moncharsh v. Heily & Blase*, 832 P. 2d 899 (Cal. 1992)(en banc).

n210 FARNSWORTH, *supra* note 155, at § 5.3; *see, e.g.*, *Prenalta Corp. v. Colo. Interstate Gas Co.*, 944 F.2d 677, 689 (10th Cir. 1991) (detailing a "take or pay" clause in natural gas purchase agreement allowing buyer to pay a minimum amount and not take any gas).

n211 *Webb*, 193 Cal. Rptr. at 81.

If understood as an alternative performance provision, it is arguable that the analysis required for a liquidated damages clause will not be called for. Still, the provision might be subject to challenge, on the basis that it is simply a

disguised penalty provision. n212 The *Webb* court also suggests that such a fee provision might function as an illegal trade restraint, although on the record in the case it found it did not. n213

n212 FARNSWORTH, *supra* note 155, § 12. 18.

n213 *Webb*, 193 Cal. Rptr. at 81.

6. No-Hire Clauses and the "Blue Pencil Rule"

A final point to consider in analyzing a no-hire clause is the possible application of the "blue pencil rule" should a court find the clause, as written, unenforceable. n214 This rule is most often applied to covenants-not-to-compete, but it can be and is applied to other sorts of contract terms, including no-hire clauses. n215 Under this rule, if a court finds a no-hire clause too restrictive in terms of its scope or effect, it can modify the provision to make it reasonable and then enforce it as modified.

n214 RESTATEMENT (SECOND) OF CONTRACTS § 184 (1981).

n215 *Pactiv Corp. v. Menasha Corp.*, 261 F. Supp. 2d 1009 (N.D. Ill. 2003); *see* RESTATEMENT (SECOND) OF CONTRACTS § 184, reporter's note (1981).

Not all courts follow this rule. n216 Some courts must either uphold the challenged term as drafted or invalidate it entirely. Further, some courts, while allowing for some contract modification, follow a less flexible approach and will do so only if the portion of the provision that is objectionable can literally be deleted from the contract and the rest of the provision enforced as written. n217

n216 *See Ceramic & Metal Coatings, Inc v. Hizer*, 529 S.E.2d 160 (Ga. Ct. App. 2000); *Moore v. Eggers Consulting Co.*, 562 N.W.2d 534 (Neb. 1997).

n217 *See, e.g., Valley Med. Specialists v. Farber*, 982 P.2d 1277 (Ariz. 1999) (en banc); *see also* FARNSWORTH, *supra* note 155, § 5.8.

Pactiv Corp. v. Menasha Corp. n218 illustrates how a court might analyze a no-hire clause under the "blue pencil rule." *Pactiv* involved a no-hire clause that had been included in a confidentiality agreement between a large multinational corporation and a potential buyer who was considering whether to purchase one of the corporation's subsidiaries. n219 The buyer wanted access to information about the subsidiary in order to make its decision. In the confidentiality agreement, the potential buyer agreed for three years not to solicit or hire any of the corporation's "Restricted Employees" as defined in the agreement to include any management-level employee of the corporation or any of its subsidiaries. n220 Within three years after the buyer determined not to go ahead with the purchase, it hired one of the corporation's managers from another of its subsidiaries. n221 The corporation filed suit to enforce the no-hire clause. The court found that the broadly drafted clause was not enforceable. n222 The corporation then asked the court to modify the clause in order to make it enforceable. The court declined to do so. n223

n218 *Pactiv Corp.*, 261 F. Supp. 2d at 1009.

n219 *Id.* at 1011.

n220 *Id.*

n221 *Id.* at 1012.

n222 *Id.* at 1015.

n223 *Pactiv Corp.*, 261 F. Supp. 2d at 1016.

The district court judge in *Pactiv* observed that in deciding whether to exercise its equitable power to "blue pencil" the no-hire clause, a court has to consider the fairness of the clause as written. n224 If the clause is substantially unfair, requiring drastic modification in order to make it enforceable, the court should refuse to do so. *Pactiv* also reflects the related idea that refusing to modify overbroad agreements may encourage future employers to draft such clauses in a fair and reasonable manner. n225 Many courts take the view that if an employee restraint appears to be the result of intentional efforts at overreaching by the employer, then the court should decline to protect the abusive employer by modifying the agreement. n226

n224 *Id.* at 1015.

n225 *Id.* at 1016.

n226 FARNSWORTH, *supra* note 155, § 5.8.

Although the judge in *Pactiv* found that the plaintiff was not seeking a drastic modification of the no-hire clause, he nonetheless refused to modify it. The parties disputed the nature and interrelationship of the subsidiary businesses involved in the no-hire clause and, as a result, the district judge simply declined to alter the no-hire clause to fit one party's view of the case. n227

n227 *Pactiv Corp.*, 261 F. Supp. 2d at 1016.

One other point considered by the court in applying the "blue pencil rule" in *Pactiv* was the inclusion of a severability clause in the confidentiality agreement. n228 The judge found that, consistent with the contract's severability clause, the no-hire provision could be struck down without invalidating the rest of the agreement or threatening the basic legitimate interest it was designed to protect. n229 Thus, there was no real need for the court to modify the no-hire clause. n230

n228 *Id.*

n229 *Id.*

n230 *Id.*

Pactiv demonstrates the type of questions a court will likely ask in deciding whether to modify an overly broad no-hire clause. The initial question is whether, and in what form, the court recognizes the "blue pencil rule" at all. Assuming it does, then the degree to which the no-hire clause seems to represent a good faith effort on the part of the employer to protect its legitimate interests will likely be a critical factor in the court's decision. If the clause seems to be

designed more to disadvantage the employee than to protect the employer's real interests, equitable modification is less likely. It should be kept in mind that, unlike a covenant-not-to-compete, a no-hire clause typically involves an employee who was neither aware of, nor agreed to the clause in the first instance, so concern about overreaching by the employer may be particularly important to the court.

IV. Conclusion

Members of the healthcare industry will likely continue to use no-hire clauses in their contracts. They can serve an important and legitimate purpose to help protect an employer's investment in its business and its employees. Given this, a no-hire clause should not be viewed by the courts as a *per se* unenforceable restraint on trade. Rather, courts should apply a reasonableness analysis to such clauses, taking into account the employer interests to be protected, the scope of the no-hire provision, its burden on the employee, and its impact on the public.

Care needs to be taken in drafting a no-hire clause to avoid including provisions that may lead to its invalidation in the event of litigation. This includes the need to carefully draft either a "liquidated damages" provision or an alternative fee payment stipulation as a part of the no-hire clause. While some courts may be willing to use the "blue pencil rule" to modify an otherwise unenforceable no-hire clause to make it enforceable, drafters must be aware that not all courts will do so, and that the possibility of judicial correction is no substitute for careful drafting of the no-hire provision in the first instance.

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TITLE: Unions, Nurses, and the Health Care Industry: Recent Administrative and Judicial Developments

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TEXT:

INTRODUCTION

Although revenues in the health care industry have been steadily rising, spiralling costs, increasing competition, and decreasing reimbursement have shrunk profit margins to the point where health care organizations are in a constant state of reorganization through downsizing, mergers, and acquisitions. n1 Nursing professionals are feeling the effects of this upheaval, with the result that many are looking for new positions. n2

n1 See Patricia Brider, *Where Did the Jobs Go?*, AM. J. NURS., Apr. 1993, at 38 (noting the health care industry had \$ 8.2 billion of profits in 1990 and \$ 10 billion in profits in 1991); Rahul Jacob & Shelley Neumeier, *The Winners and Losers*, FORTUNE, Jan. 14, 1991, at 76, 80 (reporting the health care industry has a grim prognosis because expenses continue to outpace inflation); Lawrence Wu, *Hospitals End 1990 with Negative Patient Margin in Aggregate*, HOSPITALS, May 5, 1991, at 34 (health care industry revenues increased by 10.9% in 1990, but expenses increased by 11.1%).

n2 See Brider, *supra* note 1, at 31 (discussing the downsizing of the health care industry which has caused decreasing job openings and lower salary increases for nurses); Carole A. Anderson, *Restructured Organizations: Traversing Hills and Valleys*, 41 NURS. OUTLOOK 198 (1993); Iris C. Frank, *Managers Ask and Answer*, J. EMERG. NURS., April, 1993, at 151.

Health care restructuring obviously affects union-management relations as employers view staff reductions as a ready way to cut costs. n3 Additionally, unions become less able to protect the jobs and wages of their members because traditional economic weapons, such as strikes, do not deter employers now willing to replace workers or to do without them altogether. n4

n3 See Brider, *supra* note 1, at 31, 33-34.

n4 *Id.* at 33-34 (reporting health care employees used strikes 27 times in 1992, whereas the industry average from 1987 to 1990 was 39 strikes a year).

In an industry as labor intensive as health care, n5 the pressures that restructuring exerts on health care employers and employees make National Labor Relations Board (NLRB or Board) and federal court decisions defining workplace rights more critical than ever in deciding the fate of organizations and individual employees. n6 This Article summarizes recent Board and court decisions which may in the future, or may already, significantly affect labor relations within the health care industry. Although these decisions are not limited to the health care industry, they address issues which have repercussions beyond the specific factual settings in which they arose and maybe viewed as applicable to situations facing health care providers.

n5 See Julie Kosterlitz, *The Growth Industry*, 48 NAT'L J. 2917, 2919 (1991) (reporting the health care industry provides 8.3 million jobs, which is approximately 9% of the jobs in the private sector); Royce Diener, *Controlling Hospital Costs: Government Rationing or the Voluntary Effort*, NAT'L J., June 2, 1979, at 929, 933 (stating labor costs amount to 60% of hospital costs).

n6 A review of recent literature in the health care industry reveals the relationship between unions, employees, and employers is a topic of great concern for these groups. See Annamarie Barros, *A Management Primer on Labor Relations*, MED. LAB. OBSERVER, Jan. 1992, at 22; James A. Krasnansky, *Time to Stop the Debate*, REG. NURS., May 1992, at 116; Marquis & Huston, *Motivation to Join or Reject Unions*, J. NURS. ADMIN., Feb. 1994, at 4.

A NURSE'S RIGHT TO PROTECTION UNDER FEDERAL LABOR LAW

The most recent Supreme Court decision affecting employees within the health care industry concerned nurses' right to protection under the National Labor Relations Act (NLRA). n7 In *NLRB v. Health Care & Retirement Corp.*, n8 the Court held that nurses who had no supervisory responsibilities other than directing fellow employees in the performance of patient care duties are not covered by or protected under the NLRA because they are "supervisors."

n7 Under the NLRA, employees have a protected right to engage in the following activities: "[S]elf-organization, to form, join or assist labor organizations, and to engage in other concerted activities for the purpose of collective bargaining or other mutual aid or protection, and shall also have the right to refrain from any or all of such activities. . . ." National Labor Relations Act, 29 U.S.C. § 157 (1935) (1988).

n8 *NLRB v. Health Care & Retirement Corp.*, 114 S.Ct. 1778 (1994).

To prevent a conflict of interest between the employer and its management, "supervisors" are not given statutory protection under the NLRA to engage in organizational activities. n9 Section 2(11) of the NLRA defines a "supervisor" as:

any individual having authority, in the interest of the employer, to hire, transfer, suspend, lay off, recall, promote, discharge, assign, reward, or discipline other employees, or responsibility to direct them or to adjust their grievances, or effectively to recommend such action, if in connection with the foregoing the exercise of such authority is not of a merely routine or clerical nature, but requires the use of independent judgment. n10

n9 Supervisors originally were entitled to NLRA protection. The United States Supreme Court upheld this principle when it affirmed a Board decision that absent an express exclusion, supervisors were to be included within the NLRA's scope. *Packard Motor Co. v. NLRB*, 330 U.S. 485 (1947). Responding to this decision, Congress amended the NLRA in 1947 to specifically exclude supervisors. 29 U.S.C. § 152(3) (1988). See THE DEVELOPING LABOR LAW 1608-15 (Patrick Hardin et al. eds., 3d ed. 1992), for a general discussion of the supervisory exemption.

n10 29 U.S.C. § 152(11) (1988).

Although supervisors are not covered by the Act, Section 2(12) specifically extends the protections of the Act to "professional employees" who, among other things, must engage in the consistent use of independent judgment when

performing their duties to qualify as professional employees. n11

n11 29 U.S.C. § 152(12) (1988) provides in relevant part:

The term 'professional employee' means-

(a) any employee engaged in work (i) predominantly intellectual and varied in character as opposed to routine mental, manual, mechanical, or physical work; (ii) involving the consistent exercise of discretion and judgment in its performance; (iii) of such a character that the output produced or the result accomplished cannot be standardized in relation to a given period of time; (iv) requiring knowledge of an advanced type in a field of science or learning customarily acquired by a prolonged course of specialized intellectual instruction and study in an institution of higher learning or a hospital, as distinguished from a general academic education or from an apprenticeship or from training in the performance of routine mental, manual, or physical processes.

For health care employees a fine line often exists between a professional employee who is using independent judgment in performing her job and a supervisory employee who is using independent judgment to engage in any of the eleven supervisory tasks listed in Section 2(11). n12 For example, non-management nurses often exercise independent judgment when caring for patients and use that judgment when instructing lesser skilled employees in performing patient care services. n13 At the same time, however, directing other employees is one indicia of supervisory status. n14 Since 1967 when the NLRB first asserted jurisdiction over proprietary hospitals, the Board has had the difficult task of deciding when a nurse is a statutorily protected professional employee and when she is a statutorily unprotected supervisory employee. n15

n12 *Health Care & Retirement Corp.*, 114 S.Ct. at 1784.

n13 *See, e.g., Doctor's Hospital*, 175 N.L.R.B. 354 (1969) (holding nurses are not supervisors although they inform lesser skilled employees of the work to be done for patients).

n14 *Health Care & Retirement Corp.*, 114 S.Ct. at 1784.

n15 *See Medical Ctr. Hosp.*, 168 N.L.R.B. 266 (1967); *Univ. Nursing Home*, 168 N.L.R.B. 263 (1967) (first case deciding whether a nurse was a supervisor).

To make this determination the NLRB created its "patient care" analysis, which consists of three elements. n16 The Board first determined whether a given health care professional performs any of the eleven supervisory acts in Section 2(11); second, whether the exercise of those tasks required the use of independent judgment; and third, whether the task was being performed in the employer's interest. n17

n16 The Board coined the term "patient care" analysis. *Beverly Enter.*, 313 N.L.R.B. 491 n.12 (1993).

n17 *Newton-Wellesley Hosp.*, 219 N.L.R.B. 699, 699-700 (1975).

When analyzing the third element, the Board drew a distinction between tasks performed "in the interest of the employer" and those performed "in the interest of the patient." n18 According to the Board, nurses who assigned or directed other employees how to attend to a patient were acting solely in the interest of the patient and were not supervisors unless they performed some other supervisory task such as hiring, disciplining or terminating. n19 But if the nurse also imposed discipline or grants promotions, then she was found to act in the interest of the employer and is a statutory "supervisor." n20 The Board's rationale for differentiating between conduct "in the interest of the employer" and "in the interest of the patient" is that this distinction allowed it to discern the supervisory status of professionals "who assign and direct other employees incidental to their treatment of patients." n21 In recognizing this distinction, the Board believed it was accommodating both the NLRA's coverage of professionals and its exclusion of supervisors.

n18 NLRB v. Res. Care, 705 F.2d 1461, 1466 (7th Cir., 1983).

n19 Under this third element, the Board's specific inquiry is "whether that individual [health care professional], who may give direction to other employees in the exercise of professional judgment which is incidental to the professional's treatment of patients, also exercises supervisory authority in the interest of the employer." *Newton-Wellesley Hosp.*, 219 N.L.R.B. 699, 699-700 (1975).

n20 *Res. Care*, 705 F.2d at 1465-1466.

n21 *In Beverly Enter.*, 313 N.L.R.B. 491 (1993), the Board recognized employers have an interest in providing patient care since this is their business and, therefore, it can be argued the nurse is necessarily acting in the employer's interest when she directs patient care services. However, the Board rejected this argument as simplistic, for the actions of a nurse are those of a trained professional acting primarily in the patient's interest. Therefore, "the fact that they usually are consistent with the entrepreneurial goals of the employer does not detract from the professional or technical nature of the actions." If the nurse, however, can recommend the discharge of another employee, that action is essentially one of a supervisor acting in the employer's interest.

Despite the Board's use of the "patient care" analysis, the definition of a "supervisor" in Section 2(11) became a source of concern in 1974 when Congress extended NLRA coverage to professional health care employees working in non-profit hospitals. n22 Some legislators believed the Board might classify many health care professionals who direct other employees when exercising their professional judgment as supervisors under Section 2(11) and, thereby, exclude them from the statutory coverage. n23

n22 National Labor Relations Amendments of 1974, Pub. L. No. 93-360, 88 Stat. 395 (1974) (codified as amended at 29 U.S.C. §§ 151-187).

n23 *Beverly Enter.*, 313 N.L.R.B. 491 (1993).

Various groups urged Congress to amend Section 2(11) to explicitly exclude health care employees from the supervisor definition. n24 The Congressional Committee overseeing the health care amendments declined to amend Section 2(11), but stated:

The Committee has studied this [supervisor] definition with particular reference to health care professionals . . . and concludes that the proposed amendment is unnecessary because of existing Board decisions. The Committee notes that the Board has carefully avoided applying the definition of "supervisor" to a health care professional who gives direction to other employees in the exercise of professional judgment, which direction is incidental [to] the professional's treatment of patients, and thus is not the exercise of supervisory authority in the interest of the employer. n25

n24 S. REP. NO. 766, 93d Cong., 2d Sess. 6 (1974), reprinted in 1974 U.S.C.C.A.N. 3946, 3951.

n25 *Id.*

For its part, the Board continued to use its "patient care" analysis to determine the supervisory status of health care professionals. n26

n26 *See, e.g., Newton-Wellesley Hosp.*, 219 N.L.R.B. 699, 699-700 (1975); *Barnett Memorial Hosp. Ctr.*, 217 N.L.R.B. 775 (1975); *Centralia Convalescent Ctr.*, 295 N.L.R.B. 42, 42-43 (1989).

The federal appellate courts differed on the propriety of the Board's analysis. n27 Those disagreeing with the Board found no legitimate distinction between work performed "in the interest of the employer" and "in the interest of the patient." For instance, the Sixth Circuit Court of Appeals observed: "The notion that direction given to subordinate personnel to ensure that the employer's **nursing home** customers receive 'quality care' somehow fails to qualify as direction given 'in the interest of the employer' makes very little sense to us." n28

n27 For decisions agreeing with the Board, *see*: *Misericordia Hosp. Medical Ctr. v. NLRB*, 623 F.2d 808 (2d Cir. 1980); *NLRB v. Res-Care*, 705 F.2d 1461 (7th Cir. 1983); *NLRB v. River Hills Nursing Home West*, 705 F.2d 1472 (7th Cir. 1983); *Waverly-Cedar Falls Health Care Ctr. v. NLRB*, 933 F.2d 626 (8th Cir. 1991); *NLRB v. Doctors' Hosp.*, 489 F.2d 772 (9th Cir. 1973); *NLRB v. Walker County Medical Ctr.*, 722 F.2d 1535 (11th Cir. 1984).

For decisions disagreeing with the Boards' "patient care" analysis, *see*: *NLRB v. Beacon Light Christian Nursing Home*, 825 F.2d 1076 (6th Cir. 1987); *Beverly California Corp. v. NLRB*, 970 F.2d 1548 (6th Cir. 1992); *Health Care & Retirement Corp. v. NLRB*, 987 F.2d 1256 (6th Cir. 1993), *aff'd*, 114 S.Ct. 1778 (1994).

n28 *Beverly California Corp.*, 970 F.2d at 1552.

Ultimately, the United States Supreme Court agreed to review the issue. With the dissent of four justices, the court decided against the Board. In *NLRB v. Health Care & Retirement Corp.*, n29 the majority decided the "patient care analysis" used to determine supervisory status in the health care industry was inconsistent with the statutory language of the NLRA.

n29 *Health Care & Retirement Corp.*, 114 S.Ct. 1778 (1994).

The *Health Care & Retirement Corp.* case involved a **nursing home** which employed nine to eleven registered and licensed practical nurses (LPNs) whose duties included ensuring adequate staffing, making daily work assignments, and monitoring the work of 50-55 lesser skilled employee aides. n30 Four LPNs working at the **nursing home** were disciplined and subsequently filed unfair labor charges against their employer. In its defense the employer argued the LPNs were supervisors and, therefore, not entitled to protection under the Act. Applying the "patient care" analysis, the Board held that since the LPNs' duties were performed for the well-being of the **nursing home** residents, the LPNs were not supervisors because they were not acting in the employer's interest. n31 After the Sixth Circuit Court of Appeals rejected the Board's "patient care" test, the Supreme Court accepted the case for review. n32

n30 *Id.* at 1780.

n31 *Id.*

n32 *NLRB v. Health Care & Retirement Corp.*, 987 F.2d 1256 (6th Cir. 1993), *cert. granted*, 114 S.Ct. 56 (1993).

The Supreme Court set forth several reasons for affirming the court of appeals' decision. n33 First, relying on its prior decisions n34 and the ordinary meaning of the statutory phrase "in the interest of the employer," the Court faulted the distinction between:

acts taken in connection with patient care and acts taken in the interest of the employer. That dichotomy makes no sense. Patient care is the business of a **nursing home**, and it follows that attending to the needs of the **nursing home** patients, who are the employer's customers, is in the interest of the employer. n35

n33 *Health Care & Retirement Corp.*, 114 S.Ct. at 1782.

n34 The Court cited *NLRB v. Yeshiva Univ.*, 444 U.S. 672 (1980) and *Packard Motor Car Co. v. NLRB*, 330 U.S. 485 (1947).

n35 *Health Care & Retirement Corp.*, 114 S.Ct. at 1782.

Next, the Court stated the Board's analysis makes portions of Section 2(11) meaningless. Under Section 2(11), one indicium of supervisory status is the responsible direction of other employees. However, the Court found the Board did not properly consider that factor since the nurse's independent judgment in responsibly directing other employees was being exercised solely for patient care purposes.

Furthermore, although some indicia of supervisory status are ambiguous, and the Board is entitled to discretion in applying them to different employee categories, the Court reasoned this does not give the Board license to distort the "in the interest of the employer" language, which the Court found to be unambiguous.

The Board attempted to defend its approach with the claim that granting "organizational rights to nurses whose supervisory authority concerns patient care does not threaten the conflicting loyalties that the supervisor exception was designed to avoid." n36 However, the Court concluded the NLRA must be enforced according to its terms and the Board lacks authority to create legal categories inconsistent with the Act's meaning. n37

n36 *Id.* at 1783-84. See also, *NLRB v. Res-Care*, 705 F.2d 1461 (7th Cir. 1983) (discussing the conflicting loyalties the supervisor exception was designed to avoid).

n37 *Health Care & Retirement Corp.*, 114 S.Ct. at 1784.

The Board also argued Section 2(11) should not be read to override Congressional intent to extend the NLRA's protection to professional employees. In conjunction with this argument the Board relied on the 1974 Congressional Committee report that condoned the Board's "patient care" analysis. n38 In response, the Court noted Section 2(11) does not exclude professionals from its definition. The Court reasoned the existence of tension between the NLRA's exclusion of supervisors and inclusion of professionals does not justify misreading Section 2(11). Furthermore, the Court was not swayed by the reference to the report, stating the Committee report was not an authoritative interpretation of the statutory language. n39

n38 S.Rep. No. 93-766, 93d Cong., 2d Sess. 5 (1974).

n39 *Health Care & Retirement Corp.*, at 1783.

Labor and nursing organizations have expressed dismay over the Supreme Court's decision. Unions, believing that health care employers will object to units comprised of nurses during initial organizational campaigns and will seek to exclude nurses from existing units, are concerned the decision will make it more difficult to organize and represent nurses. They cite one Montana hospital that announced it will no longer consider its nurses eligible for union membership once its current union contract expires. n40

n40 *Full Impact of High Court Ruling on Status of Nurses Still Unclear*, U.S.L.W.D, Aug. 29, 1994, at d3.

However, little evidence exists that unions have been dealt a serious blow. n41 One reason is that health care employers are more focused on the ongoing global restructuring within the health care industry than on this narrow issue. Additionally, most health care employers are interested in fostering a cooperative relationship with their nursing staffs and avoid measures to antagonize that relationship.

n41 *Id.* Mary Kay Henry, the Health Care Division Director of the Service Employees International Union, stated the Court's decision has not created the "'tidal wave' of employer challenges that [the union] expected."

However, the Court's decision will have some immediate observable effects. A non-union health care employer may, and probably would, use the Court's decision to challenge the bargaining unit status of nursing personnel during a union organizing effort. At the very least, such challenges will result in further litigation and delay as each fact-specific case winds its way through the administrative and then judicial process. Coincidentally, as the health care industry continues to restructure, more nurses may assume greater responsibility and decision-making authority. As employers

try to find ways to do more with fewer staff members, more nurses will fall within the NLRA's supervisory exclusion.
n42

n42 See Brider, *supra* note 1, at 38 (noting many hospitals are downsizing by eliminating positions and reassigning extra duties to the remaining staff).

Not surprisingly, therefore, a combined group of labor organizations has drafted language amending Section 2(11) and are seeking a congressional sponsor. n43 Meanwhile, the NLRB has concluded oral argument in the first cases before it since the Supreme Court decision which raised the supervisory status of nurses. Presumably these cases will provide guidance on how the Board now intends to evaluate the supervisory status of nurses. n44

n43 See *supra* note 41.

n44 NLRB *Review of Supervisory Status May Extend Beyond Health Care*, DAILY LAB. REP., Oct. 31, 1994, at AA-1, No. 208. On October 28, 1994, the Board heard oral argument in two cases: one involves charge nurses at an Alaska hospital and the other involves LPNs at a New York **nursing home**. Providence Hospital, NLRB, No. 19-RC-12866; Ten Broeck Commons **Nursing Home**, NLRB, No. 3-RC-10166.

THE HEALTH CARE BARGAINING UNIT RULES

One of the most frequently litigated issues during a union organizing campaign is the scope of the unit the union seeks to represent. n45 Depending on the union sympathies of particular employees and job classifications, both employer and union often attempt to gerrymander unit size and scope to create the most favorable voting conditions.

n45 John P. Simmons, *Rulemaking: The National Labor Relations Board's Prescription for the Recurring Pains of the Health Care Industry*, 9 J. CONTEMP. HEALTH L. & POL'Y 377 (1993).

To avoid the inevitable litigation regarding unit scope in the health care industry, the Board exercised its substantive rule making powers and issued a Health Care Bargaining Unit Rule in 1989. n46 This Rule provides the Board presumptively will recognize eight bargaining units in acute care hospitals comprised of: all registered nurses; all physicians; all other professionals; all technical employees; all skilled maintenance employees; all business office clerical employees; all guards; and, all nonprofessional employees except for those specifically listed as appropriate above. n47

n46 29 C.F.R. § 103.30 (1992). For a complete discussion of this topic, see Simmons, *supra* note 45.

n47 29 C.F.R. § 103.30(a) (1992).

Despite industry opposition to the Rule n48 because of fear it would result in significantly more union organizing, n49 the Rule has not had the dire consequences the industry expected. n50 For instance, litigation interpreting the new regulations has been sparse. n51 More notably, although there has been some increase in union organizing since the Rule was implemented, organizational activity has not reached the high levels that both labor and the health care industry anticipated. n52

n48 The American Hospital Association challenged the Rule but eventually lost in the Supreme Court. *American Hosp. Ass'n v. NLRB*, 499 U.S. 606 (1991).

n49 The American Hospital Association believed the Rule's immediate effect would be to increase union organizing "by splintering

employee groups within hospitals into unrealistically delineated bargaining units." Rhonda Rhodes, *NLRB Issues Second Notice of Bargaining Unit Proposed Rulemaking: Comments Due Oct. 17*, HEALTH L. VIGIL., Oct. 7, 1988, at 1, 2.

n50 *NLRB's Rule On Bargaining Units in Health Care Industry Appears to be Having Little Effect on Union Organizing*, 143 Lab. Rel. Rep. 193, 201-207 (BNA 1993).

n51 *See, e.g.*, Kaiser Found. Hosp., 312 N.L.R.B. 933 (1993) (skilled maintenance unit cannot be severed from a non-professional employee unit despite 29 U.S.C. § 103.30(c) because that Section applies to petitions to represent a new unit of unrepresented employees, not an established employee unit); Child's Hosp., 307 N.L.R.B. 90 (1992) (health care rule inapplicable to employer consisting of acute-care hospital, **nursing home**, and corporation providing them services); Duke Univ., 306 N.L.R.B. 555 (1992) (when a university institution contains health care facilities and non-health care academic facilities, the NLRB will determine who is a health care employee through reasoned analysis, not on the basis of numerical figures); Park Manor Care Ctr., 305 N.L.R.B. 872 (1991) (non-acute-care bargaining units determined by adjudication not rulemaking).

n52 *See supra* note 50, at 201.

The reasons employers attribute to the slow growth in union organizing activity notwithstanding the Rule include: the low energy level unions have shown in undertaking health care organizing activity; the limited financial and other resources to support such activity; a belief that the issues important to employees are beyond a union's capacity to attain; and increased employer ability to address employee concerns. n53 Unions, on the other hand, blame their modest organizational efforts on an unlevel playing field which they say favors employers, coupled with more aggressive (and often unlawful) anti-union tactics. n54 Regardless of the reasons, one union official predicts union organizing probably will not improve unless the current administration develops "meaningful labor law reform." n55

n53 *Id.* at 205.

n54 *Id.*

n55 *Id.* at 207 (quoting Vicki Saporta, Director of Organization for the Teamsters Union).

THE LEGALITY OF EMPLOYEE PARTICIPATION GROUPS

In response to increasing financial concerns, employee discontent, and the corporate trend favoring a decentralized team approach toward business operations, many organizations, including hospitals, have developed and/or sponsor employee participation programs. n56 These programs "empower" employees by providing a vehicle through which they can participate in the design of workplace policies and procedures. n57 In return, **companies** hope to improve efficiency, enhance employee morale, and decrease the risk of unionization. n58 These programs began catching on in the 1980s, and approximately 30,000 employee participation programs are currently in place. n59

n56 *See* Arnold E. Perl, *Employee Involvement Groups: The Outcry over the NLRB's Electromation Decision*, 44 LAB. L.J. 195, 197 (1993).

n57 *Electromation v. NLRB*, 35 F.3d 1148, 1157 (7th Cir. 1994).

n58 *Id.*; Perl, *supra* note 56, at 197.

n59 Perl, *supra* note 56, at 197.

The continued utility of these programs, however, has been thrown into question by the Board's decision in *Electromation, Inc.* n60 and the Seventh Circuit's appellate decision affirming the Board decision. n61 In *Electromation*, the Board held an employee action committee was an unlawful employer-dominated labor organization in violation of Sections 8(a)(1) and (2) of the NLRA.

n60 *Electromotion, Inc.* 309 N.L.R.B. 990 (1992).

n61 *Electromotion*, 35 F.3d 1148 (7th Cir. 1994).

In *Electromotion* the employer decided to revise its attendance policy and compensation system to minimize financial losses. Responding to employee disgruntlement over these revisions, the employer formed five action committees consisting of management and non-management employees to create solutions the employer would implement if consistent with its budgetary considerations.

The Board held the committees were "labor organizations" which Section 2(5) of the Act defines as any organization in which employees participate for the purpose of dealing with employers concerning wages, hours of work, and other workplace conditions. n62 The Board found the committees were "labor organizations," because they dealt with conditions of employment through a bilateral process involving both employees and management.

n62 The NLRA defines a "labor organization" as follows: "[A]ny organization of any kind, or any agency or employer representation committee or plan, in which employees participated and which exists for the purpose, in whole or in part, of dealing with employers concerning grievances, labor disputes, wages, rates of pay, hours of employment, or conditions of work." 29 U.S.C. § 152(5) (1988).

After it determined the committees were labor organizations, the Board found the employer violated Sections 8(a)(1) and (2) of the NLRA which make it an unfair labor practice for an employer to dominate or interfere with the formation or administration of a labor organization. n63 The Board found unlawful employer domination existed because the employer initiated the committees, unilaterally drafted the committees' purposes and goals, unilaterally determined the number of employees on each committee, appointed management employees to the committees to promote discussion, and permitted employees to conduct committee activities on paid time within a structure the employer completely designed. n64 As a remedy, the Board ordered the employer to disband the committees. n65

n63 29 U.S.C. § 158(2) (1988). This section provides it is an unfair labor practice "to dominate or interfere with the formation or administration of any labor organization or contribute financial or other support to it. . . ."

n64 *Electromotion*, 309 N.L.R.B. at 998.

n65 *Id.* Specifically, the Board ordered the employer to: "(1) cease and desist from dominating, assisting, or otherwise supporting the action committees and in any like manner interfering with, restraining, or coercing employees in the exercise of their Section 7 rights; (2) disestablish the action committees; and (3) post an appropriate notice."

The Seventh Circuit Court of Appeals enforced the Board's order. n66 First, using a broad definition of labor organization, the court determined the employee committees fell within Section 2(5), because the employees participated in the committees; the committees dealt with the employer concerning conditions of employment; and the committees' purpose was not limited to improving **company** efficiency or product quality, but included functioning in a representative capacity. Further, the court found employer domination existed because the committees' continued existence depended on the employer, the employer determined its functions, and the committees lacked independence of action and free choice as guaranteed by Section 7 of the NLRA.

n66 *Electromotion*, 35 F.3d 1148 (7th Cir. 1994).

The court stressed its decision was "narrow" and limited to the specific facts. n67 However, judging by the number of articles written in response to the *Electromotion* decision, n68 employers and commentators are widely concerned about the impact the decision may have on the thousands of other employee participation programs currently in place, many believing these committees are presumptively unlawful. n69 Further, legislation has been introduced to amend the NLRA to make it clear that employee participation programs are lawful as long as both management and

non-management agree to them. n70

n67 *Id.* at 1157. See also, *NLRB Chairman Discusses Electromotion Implications*, 142 Lab. Rel. Rep. 321, 339 (BNA 1993) (stating the decision was "'written in a narrow way' because the case involved a 'fairly garden-variety violation' . . .").

n68 See, e.g., Mark Barenberg, *Democracy and Domination in the Law of Workplace Cooperation: From Bureaucratic to Flexible Production*, 94 COLUM. L. REV. 753 (1994); Robert B. Moberly, *The Worker Participation Conundrum: Does Prohibiting Employer-Assisted Labor Organizations Prevent Labor-Management Cooperation?*, 69 WASH. & LEE L. REV. 331 (1994); Adrienne E. Eaton, *The Survival of Employee Participation Programs in Unionized Settings*, 47 INDUS. & LAB. REL. REV. 371 (1994); Note, *Labor-Management Cooperation After Electromotion: Implications for Workplace Diversity*, 107 HARV. L. REV. 678 (1994); Martin T. Moe, Note, *Participatory Workplace Decisionmaking and the NLRA: Section 8(a)(2), Electromotion, and the Specter of the **Company** Union*, 68 N.Y.U. L. REV. 1127 (1993).

n69 Perl, *supra* note 56, at 196-98.

n70 *Workplace Committee Legislation Introduced*, 147 Lab. Rel. Rep. 193, 217-18 (BNA 1994). The relevant portions of the amendment provide:

[I]t shall not constitute or be evidence of an unfair labor practice under this paragraph for an employer and the employees of such employer, to jointly establish a committee, in which such employer and such employees participate to discuss matters of interest and concern (including but not limited to issues of quality, productivity, improved labor-management relations, job security, organization efficiency and enhanced economic development)

Id. at 218.

Following *Electromotion*, Board Member Devaney warned: "If you want to push the envelope, you better get your lawyers and talk ahead of time." n71 Nevertheless, the anxiety *Electromotion* has caused may decrease somewhat in light of the subsequent Fourth Circuit Court of Appeals decision in *NLRB v. Peninsula Gen. Hosp.*, n72 where the court upheld an employee participation committee comprised of nurses.

n71 Barbara Noble, *Teamwork Concept Faces Challenge*, N.Y. TIMES, Jan. 2, 1993, at L38.

n72 *NLRB v. Peninsula Gen. Hosp.*, 36 F.3d 1262 (4th Cir. 1994).

In *Peninsula Gen. Hosp.*, the committee originally was established to provide a forum for nurses to discuss practice issues, for continuing nurse education, and, according to subsequent by-laws, to "act as a liaison between nurses, all departments, nursing management, and administration." n73 It was a voluntary organization open to all hospital nurses and financially subsidized by the hospital. Although personnel issues were discussed at committee meetings and management employees gave presentations to the committee, the committee never acted on behalf of the hospital's nurses to negotiate terms of employment or discussed general employment concerns with hospital management in a participatory process.

n73 *Id.* at 1265.

The Board found the committee was an employer-dominated labor organization. n74 The Board held that although the committee was originally a social organization, it later satisfied the statutory definition of a "labor organization" when it began "dealing with" the employer concerning conditions of employment. The Board's holding relied largely on one incident in which certain concerns of the hospital's nurses were presented to a nurse manager who was a committee member and who subsequently reported back to the committee that the hospital had taken steps to address some of the concerns.

n74 312 N.L.R.B. No. 97 (1993).

The Fourth Circuit disagreed with the Board n75 and framed the issue in terms of whether the committee's purpose and function was "to deal" with the employer over matters affecting employment. Citing *Electromation*, the court stated "dealing with" means a "bilateral mechanism involving proposals from the employee committee concerning the subjects listed in § 2(5), coupled with real or apparent consideration of those proposals by management." n76 The court summarized the general principles it believed were relevant, stating:

In summary, these principles are: 1) while the term "dealing with" connotes activity which is broader than collective bargaining, an employer does not necessarily "deal with" its employees merely by communicating with them, even if the matters addressed concern working conditions; (2) "dealing" occurs only if there is a "pattern or practice" over time of employee proposals concerning working conditions, coupled with management consideration thereof; (3) isolated instances of the conduct described in number two do not constitute "dealing;" and (4) management may, in certain circumstances, gather information from employees about working conditions and may even act on that information without necessarily "dealing with" them. n77

n75 *Peninsula Gen. Hosp.*, 36 F.3d 1262.

n76 *Id.* at 1271.

n77 *Id.* at 1271-72.

Applying these principles to the facts, the court could not find substantial evidence to support the Board's conclusion that the committee was a labor organization. The court took a common sense view of the facts, stating communication between employee groups and employers differs from "dealing with" each other and finding most of the facts the Board relied upon reflected informal, coincidental communications with the committee rather than an ongoing pattern and purpose of committee involvement and interplay with management in decisions affecting employees. On these facts, the court held the committee is not "dealing with" the employer in the manner contemplated by Section 2(5) of the Act.

UNION ACCESS TO EMPLOYER PROPERTY FOR ORGANIZATIONAL PURPOSES

A recurring litigation issue has been the right of union organizers to gain access to employer property to engage in organizational activities. In *Lechmere v. NLRB*, n78 the United States Supreme Court reconciled the "fundamental statutory right to organize into unions with the competing societal value that private property is sacrosanct." n79

n78 *Lechmere v. NLRB*, 112 S.Ct. 841 (1992).

n79 *Lechmere to Make Organizing More Difficult*, 140 Lab. Rel. Rep. 193, 218 (BNA 1992).

In 1956, the Supreme Court in *NLRB v. Babcock & Wilcox* n80 first discussed the balance between the private property rights of an employer and the organizational rights of a union. The Court held an employer is not required to permit non-employee union organizers to distribute union literature to employees on the employer's private property, unless "the location of a plant and the living quarters of the employees place the employees beyond the reach of reasonable union efforts to communicate with them." n81

n80 *NLRB v. Babcock & Wilcox*, 351 U.S. 105 (1956).

n81 *Id.* at 113.

Subsequent court and Board decisions purported to apply, but often deviated from, this test. n82 The latest Board incarnation of the test was expressed in *Jean Country*, n83 where the Board held the importance of the Section 7 right asserted by the union should be directly weighed against the strength of the property interest involved, with the availability of alternative means of communication factored into the balance. In *Lechmere v. NLRB*, the Supreme Court rejected *Jean Country* and reiterated the one step test it articulated in *NLRB v. Babcock & Wilcox*.

n82 See, e.g., *Hudgens v. NLRB*, 424 U.S. 507 (weighing the particular property right against the Section 7 right); *Montgomery Ward & Co. v. NLRB*, 692 F.2d 1115 (7th Cir. 1982), cert. denied, 461 U.S. 914 (allowing union solicitation in restaurant when incidental to normal use of facility); *Montgomery Ward & Co. v. NLRB*, 728 F.2d 389 (6th Cir. 1984); *Jean Country*, 291 N.L.R.B. 11 (1988). But see *Baptist Medical System v. NLRB*, 876 F.2d 661, 664 (8th Cir. 1989) (allowing public access to area does not mean the employer surrenders right to "control the uses to which that area is put."); *NLRB v. Southern Maryland Hosp. Ctr.*, 916 F.2d 932 (4th Cir. 1990) (similar holding).

n83 291 N.L.R.B. 11 (1988).

In *Lechmere*, union organizers were soliciting employees in a retail store's parking lot. When the employer barred the organizers from the parking lot, the union filed unfair labor charges. Relying on its *Jean Country* analysis, the Board held the employer could not deny the union organizers access to its property.

Denying enforcement of the Board's order, the Supreme Court stated its analysis in access cases has been consistent since *Babcock & Wilcox* and found the Board's *Jean Country* analysis inconsistent with that approach and therefore erroneous. n84 As in *Babcock & Wilcox*, the Court stated the NLRA does not protect non-employee trespasses. However, non-employee union organizers may gain access to private property "in the rare case where 'the inaccessibility of employees makes ineffective the reasonable attempts by non-employees to communicate with them through the usual channels.'" n85 This exception only applies when the employer's facility and the employees' living quarters places the employees beyond the reasonable access of the union.

n84 *Lechmere*, 112 S.Ct. 841 (1992).

n85 *Id.* at 847-48 (quoting *Babcock & Wilcox*, 351 U.S. at 112).

The Court's reiteration of its one-factor test will make it more difficult for unions to organize on private property and, consequently, is of strategic value to employers who may continue to restrict access to non-employee union organizers on their premises. n86

n86 *Lechmere to Make Organizing More Difficult*, 140 Lab. Rel. Rep. 193, 218-19 (BNA 1992). NLRB Chairman Gould stated: "Lechmere is an erroneous interpretation of our statute but it is the law and any policy designed to provide employees with maximum amount of communication and information provided by both unions and employers must come from Congress and not the Board." *Testimony of NLRB Chairman Gould and General Counsel Feinstein*, DAILY LAB. REP., Sep. 30, 1994, at d35, No. 188.

Lechmere already has been applied in a hospital setting. In *Oakwood Hosp. v. NLRB*, n87 the Sixth Circuit Court of Appeals held a hospital could prohibit non-employee union organizers from soliciting hospital workers in its cafeteria, when the union was able to communicate its message to employees through mass mailings and outside meetings. The court stated "(i)f the owner of an outdoor parking lot can bar non-employee union organizers, it follows *a fortiori* that the owner of an indoor cafeteria can do so." n88 The result in *Oakwood* is not surprising since both the Board and the courts have traditionally given special consideration to health care institutions and allowed them to take steps to minimize disruption of their patient care operations. n89

n87 *Oakwood Hosp. v. NLRB*, 983 F.2d 698 (6th Cir. 1993).

n88 *Id.* at 703.

n89 See *Beth Israel Hosp. v. NLRB*, 437 U.S. 483 (1978); *Baptist Hosp.*, 442 U.S. 773 (1979); *Manchester Health Ctr. v. NLRB*, 861 F.2d 50 (2d Cir. 1988).

THE JOINT EMPLOYER DOCTRINE

As pressure mounts to cut expenses, health care employers often attempt to cut labor costs by obtaining nurses through referral agencies on a per-diem basis, rather than hiring their own employees at a higher salary and benefit cost. n90 However, even in these circumstances, it is possible for both the referral agency and its client employer to assume federal labor law obligations for the referral agency's employees under the "joint employer" doctrine.

n90 *Brookdale Hosp. Medical Ctr.*, 313 N.L.R.B. No. 74 n.4 (Nov. 26, 1993). See *Bridger, supra* note 1, at 31 (discussing health care restructuring).

For example, in *Holyoke Visiting Nurses Ass'n v. NLRB*, n91 the First Circuit Court of Appeals held a homecare provider and a nurse referral service were joint employers and both employers were found in violation of the NLRA. Holyoke provided home-based nursing and hospice care through its unionized nurse workforce. At the time of the proceedings, the Holyoke nurses were attempting to renegotiate their labor contract to include a provision dealing with safety given the violent neighborhood in which Holyoke was located. To support their contract demand, the nurses simultaneously arrived at work, entered the building as a group, and exited simultaneously as a group each day.

n91 *Holyoke Visiting Nurses Ass'n v. NLRB*, 11 F.3d 302 (1st Cir. 1993).

O'Connell was a referral agency which provided RNs and LPNs to institutions such as Holyoke on a per diem or hourly rate basis. It referred a nurse to Holyoke who, because of the dangerous neighborhood, made it her practice to arrive at Holyoke at the same time as the Holyoke employees so she could enter the building with them. Believing that she was supporting the union employees' demands, Holyoke asked O'Connell not to assign this nurse to its facility.

The O'Connell nurse filed an unfair labor practice charge with the NLRB, asserting she was denied employment with Holyoke because of her perceived support for the Holyoke employees. Although she did not belong to any union and was employed by O'Connell, the Board held Holyoke could be jointly responsible with O'Connell as a "joint employer" and both had violated Sections 8(a)(1) and (3) of the Act by threatening and denying employment to the referral nurse. n92

n92 310 N.L.R.B. 684 (1993).

Reviewing the case, the court of appeals stated joint employer status requires a factual determination taking into account a number of considerations, such as which employer has the power to hire and fire, discipline, assign work, and participate in collective bargaining. n93 Because Holyoke had the power to reject any nurse referred to it and also exercised control over the daily activities of the referral nurses, the court determined that it and O'Connell were joint employers. Because each **company** had threatened to deny assignments to the referral nurse based on her sympathy with the Holyoke bargaining unit employees, the court upheld the Board's conclusion that both employers had violated the NLRA and were jointly liable to remedy the violation.

n93 *Holyoke*, 11 F.3d at 306.

Conversely, in *Richmond Convalescent Hosp.*, n94 the Board did not find joint employer status between a **nursing home's** employees and the management **company** it retained to run its daily operations. In support of its holding, the Board pointed to the facts that the **nursing home** actually employed the employees while the management **company** was only an agent retained to implement management and personnel policies the home had established.

n94 313 N.L.R.B. 1247 (1994).

HOSPITAL MERGERS AND THE ACCRETION DOCTRINE

In this period of constant affiliations and mergers among health care institutions, employers should be aware of the "accretion doctrine."

Generally, the NLRA requires a union to be "designated or selected for the purposes of collective bargaining by the majority of the employees in a unit appropriate for such purposes." n95 When it recognizes a union without majority support, n96 an employer violates the NLRA because employees have the right to determine whether they want union representation, and if so, which labor organization they want representing them. n97

n95 29 U.S.C. § 159(a) (1988).

n96 29 U.S.C. § 158(a)(2) (1988). *See also*, *ILGWU, AFL-CIO v. NLRB*, 366 U.S. 731 (1961).

n97 *SEIU Local 144 v. NLRB*, 9 F.3d 218, 223 (2d Cir. 1993).

However, under the accretion doctrine, an employer can incorporate a small, similarly-situated employee group into an existing bargaining unit without employee consent if the accredited employees: "(1) do not constitute a separate bargaining unit and (2) do not outnumber the employees who belong to the existing bargaining unit." n98 But because accretion deprives employees of a choice in deciding whether they want union representation, it is applied with caution. n99

n98 *Id.* at 223.

n99 *NLRB v. Stevens Ford*, 773 F.2d 468, 473 (2d Cir. 1985).

In *SEIU Local 144 v. NLRB*, n100 two independent and geographically separate hospitals merged operationally and financially. Employees at only one of the hospitals were unionized. After the merger, the non-unionized employees filed unfair labor charges against the hospital because it decided to accrete them into the existing bargaining unit. The Board ruled the accretion was unlawful, and the court of appeals affirmed. n101

n100 *SEIU*, 9 F.3d 218.

n101 *The Brooklyn Hosp. Ctr.*, 309 N.L.R.B. 1163 (1992).

The Second Circuit Court of Appeals held the Board had balanced the factors for and against accretion properly and had correctly concluded the latter prevailed. n102 Among the facts the Board and court cited were the hospital's own historic actions disfavoring accretion and the federal labor policy against forcing employees to accept a collective bargaining representative not of their choosing.

n102 *SEIU*, 9 F.3d at 224.

CONCLUSION

In a period when the health care industry is undergoing major and ongoing organizational changes, the application of federal labor laws now more than fifty years old still has critical repercussions for how the newly organized industry will operate. Although the influence of labor unions has been diminishing steadily, management and employees alike continue to monitor closely their presence and strength in the labor intensive health care industry. The labor unions' strength is largely a function of how the NLRB and courts interpret the half century old labor laws. And while generalizations are difficult, there is no doubt the Supreme Court has taken a conservative turn and is likely to more narrowly and literally construe federal labor statutes that organized labor increasingly decry as outmoded and ineffectual in **protecting** employee organizational rights.

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LENGTH: 9733 words**TITLE: UNCHARTED WATERS: MANAGED CARE AND LONG TERM CARE PROVIDER CONTRACTS****AUTHOR:** *Malcolm J. Harkins III*, Partner, Proskauer Rose LLP, Washington, DC; A.B., 1973, St. Joseph's College; J.D., *cum laude*, 1976, Saint Louis University School of Law.*Julia McMillen*, B.A., 1991, Michigan State University; M.A., *with honors*, 1992, Western Michigan University; J.D. candidate, anticipated 1998, Saint Louis University School of Law.**TEXT:****INTRODUCTION**

Long term care providers are poised at the intersection of two swelling tsunamis: the greying of the baby boomers and the continued growth of managed care. n1 In the absence of adequate planning, the two waves could swamp the industry. This article, however, charts a course for long term care providers who wish to successfully navigate these waters.

Because the current healthcare environment demands cost effective services for a growing aging population, the time is ripe for managed long term care. n2 To date, however, managed care penetration of the long term care market is spotty. As a result, the long term care industry, as a whole, has little experience delivering care in an environment in which critical aspects of the relationship, such as the terms of payment, are negotiated rather than dictated by government agencies. n3

The primary long term care payors--Medicare and Medicaid--have traditionally reimbursed based on the per diem costs incurred to provide medically reasonable and necessary care. n4 In addition, government reimbursement programs traditionally have paid for different portions of long term care (e.g., institutional services including room and board versus pharmaceuticals, supplies and equipment) through different programs (e.g., Medicare Part A versus Medicare Part B) using different formulae (e.g., cost versus charges) to calculate the payment due for the goods or services. Consequently, long term care providers are not accustomed to aggregating or to allocating costs on a per case or per patient basis. Today, however, federal and state governments are attempting to contain Medicare and Medicaid expenditures by encouraging the development of risk-based managed care programs for their beneficiaries. n5 Moreover, while private insurance currently has a relatively small involvement in the long term care market, that situation is changing. The increasing penetration of the long term care market will likely hasten the trend toward managed long term care. n6 This is the case because the underwriters of private insurance view managed care products as effective vehicles to reduce costs by securing treatment at the lowest possible level of care. n7

Some long term care providers may resist managed care, while others may quickly contract with organizations without truly understanding the risks and opportunities presented. Long term care providers will need to be educated about managed care and managed care plans will need to be educated about the abilities of long term care providers if long term care and managed care are to be successfully married. Among the issues that must be resolved are: 1)

managed care organizations must be assured that long term care providers will be able to furnish needed services and to produce good outcomes; 2) long term care providers need to be assured that they will be able to manage their case mix, to provide the necessary services for the agreed upon price, and to remain financially viable; and 3) both parties will need to be able to assure a high quality of services to their mutual customers, the patients.

This Article presents an overview of the contracting issues critical to long term care providers and managed care organizations. Part II describes the special characteristics of managed care that affect long term care. Part III addresses the major areas of potential concern to long term care providers--including risk, covered services, relationship of the parties, utilization review, and fraud and abuse. Finally, Part IV concludes that despite inevitable growing pains, long term care and managed care will necessarily become partners in this era of cost consciousness.

DEVELOPING THE RELATIONSHIP

The Managed Care Approach v. Traditional Long Term Care

Managed Care

Managed care in the United States dates back sixty years to Henry Kaiser's creation of the prepaid health clinic for workers. n8 As we know it today, managed care is a method of allocating healthcare resources joined to a system of financing of healthcare costs. n9 Managed care seeks to predict actuarially, and to reduce through aggressive oversight, the level and type of healthcare utilization and the associated costs. The managed care organization seeks to (a) provide care using less sophisticated and intense resources than predicted in establishing the premium costs, and (b) transfer, wherever possible, some or all of the risks associated with exceeding the predicted costs to the various parties in the healthcare delivery system. n10 One major factor limiting the growth of managed care in the long term care area is the lack of historic and actuarial data.

Long Term Care Reimbursement and Regulation

Institutional long term care services principally are provided in free standing nursing facilities. n11 Such long term care facilities must be licensed by the state in which they operate. Further, a nursing facility that wishes to participate in the Medicare and Medicaid programs must enter a provider agreement with the federal Health Care Financing Administration ("HCFA") and with the state Medicaid agency. n12 Generally speaking, state survey agencies inspect nursing facilities and certify that the facilities are in compliance with the federal Medicare and Medicaid certification requirements and, therefore, eligible to enter a provider agreement. n13 For purposes of this Article, patients in long term care facilities may be characterized as falling into one of two categories: those admitted for intensive rehabilitation after acute hospitalization and those suffering from chronic, and in many instances, terminal conditions. n14

The primary payors for long term care services are the federal and state governments, through the Medicare and Medicaid programs. n15 Although they use far different formulae, those programs reimburse long term care providers based upon the reasonable costs incurred to provide medically necessary services. n16 Traditionally, Medicare paid long term care facilities for actual costs, subject to routine cost limits. n17 Until October 1, 1997, the "Boren Amendment" required Medicaid to reimburse at rates which, in the case of nursing facilities, take into account the costs (including the costs of services required to attain or maintain the highest practicable physical, mental, and psychosocial well being of each resident) and which are "reasonable and adequate to meet the costs which must be incurred by efficiently and economically operated facilities" in order to provide care and services in conformity with applicable state and federal laws, regulations, and quality and safety standards. n18 As the volume of litigation over Medicaid payment rates--especially the number of cases successfully brought by providers--suggests, state Medicaid programs typically paid providers inadequate or marginally adequate reimbursement rates. n19 Thus, state Medicaid programs, the most significant payor for nursing facilities, created powerful incentives for providers, and especially long term care providers, to deliver services in the most cost effective and economic fashion.

Long term care providers' demonstrated ability to deliver cost effective care makes nursing facilities attractive to

managed care plans. On the other hand, neither the reimbursement rates paid by government programs nor the terms and conditions of treatment of Medicare and Medicaid beneficiaries can be negotiated. Thus, after years of entering provider agreements on terms dictated by statute and regulation, most nursing facilities were caught both unaware of and wholly unprepared for the necessity of negotiating every aspect of their relationship with a managed care plan.

Practical Impact

Perhaps one of the better illustrations of the role that managed long term care can play in the healthcare delivery system is evident from the Medicare program's shift from retrospective cost reimbursement to the prospective payment system for hospitals in the early 1980's.ⁿ²⁰ In an effort to capture some of the savings from improved medical technology, and to reduce utilization of acute hospitals, the Medicare program instituted a prospective payment (or "DRG") system. The DRG system, which implemented limited managed care concepts, provides a fixed payment for each admission based on the patient's diagnosis, effectively transferring the risk of overutilization to the hospitals. Unsurprisingly, implementation of the DRG system resulted in a dramatic drop in the average length of a hospital stay.

Inherent in the risk sharing and cost saving goals of the DRG system, however, were the incentives for hospitals to minimize the length of stay by transferring sicker, riskier, and less stable patients to facilities that were not subject to the prospective payment system.ⁿ²¹ The resultant impact on the long term care industry is referred to as "acuity creep." This is because the DRG system caused **nursing homes** to provide increasingly more complex, technically sophisticated and intense care, blurring the lines between long term care facilities and hospitals.

From the viewpoint of managed care, long term care facilities are especially attractive as alternative, i.e., less costly, providers of some of the types of care that traditionally were provided by acute care hospitals.ⁿ²² Use of long term care facilities to provide subacute care services permits the managed care organization to transfer patients from more expensive acute care to the less expensive subacute facility, and in some instances, allows patients to avoid an acute care hospital stay altogether. In other cases, care can be provided at the least intensive level until it is no longer effective. Patients can then be transferred up the continuum for more intensive services, at higher acuity levels. For example, patients will remain in home care for longer periods before they are transferred to a long term care facility. Long term care facilities may benefit from this trend, but they also must be aware of the demands of treating higher levels of acuity, especially the financial resources and the skilled personnel required to deliver that level of care. This mixed bag of benefits and liabilities represents a key characteristic of managed care.

The Need for Managed Long Term Care

Long term care will be the segment of the healthcare industry experiencing the greatest increase in demand over the next twenty years. Increased demand for long term care services will result, in part, from the growth of the elderly population, especially from the aging of the baby boomers.ⁿ²³ Demand also will be stimulated by the continued pressure created by government payment programs and by managed care plans to shift care to the lowest cost modality.

Total healthcare costs are already at staggering levels. For example, healthcare costs constitute thirteen percent of the GDP,ⁿ²⁴ the highest proportion of any developed nation. Moreover, healthcare costs have increased rapidly in relation to other economic indicators. Such costs now account for twice the proportion of the GDP that they represented in 1960.

Although long term care currently accounts for only about ten percent of total healthcare expenditures,ⁿ²⁵ it is heavily dependent upon government spending. Of total dollars spent on long term care, two-thirds are federal and state government expenditures, primarily through the Medicaid program.ⁿ²⁶ The decreasing funding available to government payors will increase pressures on the long term care industry to find alternative sources of revenue.

Managed care also is perceived by many as a means of slowing the increase in the cost of long term care. Medicaid's long term care spending grew at an average annual rate of 13.2% between 1989 and 1993, and it is often the single largest line item in a state's budget.ⁿ²⁷ During the same period, Medicare long term care spending grew at

33.8%. n28 The average cost for long term care services has reached a record high. n29 The estimate of expenditures based on 1995 data projects a \$ 127 average charge per day for care in a freestanding long term care facility. n30

Because of on-going decreases in federal and state funding for long term care, long term care providers would be wise to expand their markets to serve private insurance while diversifying their range of services into related fields to capitalize on the growing demand for new and innovative long term care services. n31 Managed care presents an opportunity for diversification into both new markets and new services.

NEGOTIATING THE PARTNERSHIP BETWEEN MANAGED CARE AND LONG TERM CARE

Long term care facilities that wish to participate in managed care must be prepared to negotiate relationships with different payors using a variety of payment mechanisms. Such relationships can take several different forms. For example, a long term care facility might: contract with an HMO, an insurance **company**, a Blue Cross/Blue Shield plan, and a provider sponsored organization ("PSO") that in turn contracts with employers, Medicare or Medicaid; n32 participate in an integrated delivery system; n33 or join in a network sponsored by other long term care providers. n34

Today, long term care providers participate in several kinds of managed care arrangements, including: bed reservation agreements, subacute medical and rehabilitation services, and more broad based government managed care programs. n35 Depending on the specific managed care arrangement, the payment mechanisms for these arrangements may include discounted fees, capitation, or a variety of other formulations. n36 However, all managed care payment mechanisms are predicted on some risk sharing basis.

Bed reservation agreements often are little more than fee-for-service referral agreements wherein the HMO or other insurance **company** will negotiate a per diem or discounted rate with long term care providers who agree to make a certain number of beds available for the **company's** patients. n37 In the past, it was common for such agreements to require the long term care provider to provide care to any patient referred by the **company** at any given time. Bed reservation agreements are becoming less common. n38 Such agreements are most prevalent where managed care penetration is low, and when the managed care organization is familiar with long term care utilization patterns. n39

Subacute and rehabilitation services entail a comprehensive inpatient program for individuals who have experienced an acute event, have a determined course of treatment, and do not require hospital-level care. n40 Generally speaking, subacute patients fall into two broad categories--those who have experienced an acute event who are not completely stable and require recuperation; and those patients who, following an acute event, are stable and require intense rehabilitative services. Subacute care is important for managed care both because of the economic factors discussed previously, and because, in many instances, subacute patients can be treated effectively and efficiently in long term care facilities. n41 Indeed, **nursing homes**--which by law must assist patients to achieve and maintain their highest practicable physical, mental and psychosocial functioning level--are better equipped to meet the rehabilitation and recuperative needs of patients than acute care hospitals. n42 This provides a golden opportunity for long term care facilities to expand simultaneously into a new service market and a new payor market. n43

Government managed care programs are a recent development and will continue to evolve. Some Medicare and Medicaid managed care programs, however, have incorporated long term care into their programs. n44 This has introduced a variety of novel and complex factors into the managed care environment, stemming from the elaborate state and federal regulation of long term care facilities, the more general regulation of Medicare and Medicaid providers, and the status of these programs as the dominant payor for long term care.

Thus, depending upon the managed care contract, a variety of different and heretofore unanticipated issues could arise. Managed care is poised to move into a new market; however, the long term care issues are still evolving. The law in this area is very much in flux. It may be helpful, therefore, to review several potentially problematic areas of long term care and managed care arrangements.

Avoiding Risk

Risk is the uncertainty in an undertaking: the possibility that actual experience will differ from predictions. n45 Generally, there are three types of risk with which managed care plans and long term care providers must be concerned: traditional insurance risk, managed care risk, and general business risk. The belief that risk can be understood, predicted, and avoided through management is the cornerstone of managed care. Because the risks inherent in managed long term care have yet to be adequately identified and analyzed, managed care **companies** and long term care providers face difficult business issues. n46

One reason risk is unquantified in the long term care context is the lack of sufficient history to reasonably predict long term care insurance risk. This is the risk that the individuals covered will be sicker and will require more services than predicted. Calculating insurance risk requires actuarial predictions of utilization rates for a given number of people. Such calculations have not been necessary in the past, because the payment mechanisms did not require it. Moreover, given the variations in long term care, such as alternatives to care and external influences, actuarial predictions for long term care traditionally have been considerably more difficult than those for other types of care. n47 An inaccurate assessment of insurance risk could well have a detrimental impact on both the managed care plan and the individual long term care provider.

Long term care providers are also inexperienced with managed care risk. Managed care risk assessment requires data on cost management sufficient to negotiate adequate rates or reimbursement terms. One of the most serious hurdles that long term care providers must overcome is that such providers historically have not negotiated per diem rates. Thus long term care providers have little experience determining unit cost or otherwise establishing a baseline for price negotiations with managed care entities. Moreover, long term care providers historically provided a bundle of services that was dictated by state and federal law. Items and services not included in the bundle frequently would be paid separately from the per diem rate paid for institutional care--often on the basis of the provider's charges rather than its costs--by other branches of government programs. Consequently, long term care providers' difficulty establishing a realistic unit cost or cost per case is further exacerbated, putting such providers at an even greater disadvantage when negotiating with a managed care plan.

The consequences of failure to negotiate a realistic price should cause both long term care providers and managed care **companies** to proceed cautiously. Most **nursing homes** are required by law to provide a high level of care--the care that each resident, including managed care patients--require to reach their highest practicable functioning level. Moreover, **nursing homes** are held to a "zero tolerance" standard of compliance. Inadequate payment for managed care patients could prevent **nursing homes** from complying with licensure and certification requirements. n48 Noncompliance exposes **nursing homes** to a variety of regulatory sanctions that could further impair or even preclude access to services for the managed care organization's subscribers.

Business risk may be the most manageable of the three types of risk. This risk represents the business and administrative costs of entering into an unfamiliar line of business. Such costs are necessary, because the business and administrative functions that comprise these costs make the other risks acceptable. n49 The foray into managed care will have administrative implications, such as the need for additional staff, provider education, new medical technology, utilization management, and management information systems, which long term care providers must accommodate in order to avoid the potential negative consequences of insurance and managed care risk. The key is that the long term care provider must anticipate the type and magnitude of changes that will be required and must retain the ability to determine the extent to which its operations must be modified in response to managed care's demands.

While some aspects of risk are largely within the control of the long term care provider, other risks might not shift from the plan to the provider unless there is express contractual language creating such a shift. For example, an HMO undertakes to deliver a certain level of services in exchange for a premium payment. The HMO's obligation is not diminished by poor actuarial projections. If utilization exceeds projections, the HMO must still provide the services. Therefore, to encourage cost effective utilization management, the plan will seek to shift some of this risk to the providers. For this reason, it is very important that the duties and rights of all parties--plan, beneficiary, and long term care provider--are addressed and clearly identified in the managed care contract before any attempts at risk analysis are

made. n50

Covered Services

Many form contracts use general terms such as "covered services," "physician services," "nursing services," "skilled nursing services," "rehabilitation services," "routine" or "medically necessary" to describe the services covered under the contract. n51 If it accepts such a contract, the long term care provider runs the risk of assuming duties it is financially incapable of performing. n52 Thus, when negotiating an "all inclusive" rate with the managed care organization, it is imperative that the provider obtain a clear and specific definition of the covered services that must be provided at the negotiated rate.

When negotiating, it is important to recognize that disputes concerning the scope of covered services may arise in many contexts. Will the long term care provider be responsible under the contract for supplies or medications? May the long term care provider subcontract with its preferred suppliers and ancillary service providers, or is it required to use those with which the managed care organization has negotiated contracts? For example, long term care providers often have contracts with third parties to supply therapy services or pharmaceuticals to long term care facility residents. Managed care organizations often negotiate exclusive arrangements with such suppliers and the managed care organization may not have contracted with the same entity utilized by the nursing facility. These types of issues must be addressed during negotiations to avoid unnecessary disputes and possible financial hardship.

Early and explicit determination of covered services serves a second function. It can preempt potential disputes among the managed care organization, provider, and beneficiary as to the scope of covered services. This can be of particular concern in the long term care context. The long term care provider typically is very familiar with the services covered by fee-for-service Medicare and Medicaid. n53 However, as an incentive to attract enrollees, a seller of a Medicare or Medicaid managed care product may offer benefits beyond those required of fee-for-service providers. n54 The long term care provider must ensure that all items and services it is expected to provide beneficiaries are stated in the agreement and that it is adequately compensated for the entire package of services that must be provided.

Further, the long term care provider is the point of service and will likely be required to deliver to a patient the perhaps surprisingly bad news that an item or service is not covered. Consequently, unless the agreement is clear, the provider may find itself in an uncomfortable no-win dispute between a patient and the managed care organization. As discussed below, in such a case the provider may find it necessary to provide care and services without compensation.

Thus, the scope of covered services should be determined before pricing determinations are made, and should be defined with specificity in the contract so as to avoid potential disputes between the parties. At a minimum, the long term managed care contract should address nursing, physical, speech and occupational therapy, rehabilitation therapy, ancillary services, pharmacy, and supplies and equipment. n55 Equally important, the contract should specifically address any coverage exclusions. The long term care provider may wish to seek an automatic adjustment in the exclusion language to protect against overlooked exclusions. n56

Independent Obligations to Beneficiaries

Unfortunately, even the most detailed definition of scope of services will not guarantee that the long term care provider will not face coverage surprises. Even if the relationship with the managed care organization is the result of an arms-length, negotiated, independent contractor agreement, the long term care provider may have independent obligations to the patient other than those specifically addressed in the contract. In addition to state common laws, licensing laws and regulations, long term care facilities certified as Medicare and Medicaid providers are subject to a plethora of state and federal regulations as a condition to receiving payment from the programs. In some instances, unless the contract provides some fall back position, these laws and regulations may require a provider to continue to provide care even when a managed care **company** disputes its obligation to pay for such care.

When Medicare and Medicaid become an "indirect" payor by contracting with a managed care organization to

provide the covered services, the clarity of the relationship between Medicare or Medicaid and the long term care provider is muddled. Issues which may arise are whether the long term care contractors are independently bound by the managed care organization's contract with HCFA and whether the provider is subject to the same requirements that are applicable when it enters a provider contract directly with HCFA. This issue is a substantial one. For example, the long term care facility's rights and duties with respect to care and treatment of the managed care patient are defined by the provider's contract with the managed care **company**. The contract may impose conditions on care delivery that are different from, or coextensive with, those imposed by Medicare regulations. Alternatively, the contract may not cover a particular item at all. For example, Medicare certified managed care **companies** are obligated to provide subscribers with at least the same one hundred day nursing facility benefit available to program beneficiaries who are not enrolled in a managed care plan. This requirement creates incentives for Medicare managed care plans to seek to characterize all **nursing home** care as equivalent to the traditional Medicare benefit even if the contract does not mandate care and treatment on the same terms and conditions (e.g., does not require that all covered care be delivered in a Medicare certified bed). Complying with the demands of the managed care plan could cause the long term care facility to incur a higher cost structure than it anticipated when negotiating its managed care contract.

The underlying issue--whether long term care contractors are bound by the HMO's contract with HCFA--has serious consequences. For example, a long term care facility paid pursuant to a traditional provider agreement is subject to penalties for failing to meet certification criteria, including restrictions on a facility's ability to accept new Medicare admissions. n57 Should this restriction apply to new admissions of Medicare HMO enrollees, or just to new Medicare admissions when Medicare is the direct fee-for-service payor? Similarly, Medicare and Medicaid regulations require a thirty-day notification of discharge. n58 Should this notification requirement apply to the long term care facility's Medicare HMO patients, and what if the agreement provides conflicting discharge criteria? To a large extent, the answer depends upon the unresolved question of whether the relationship between the managed care organization and the long term care provider is governed by HCFA's contract with the HMO, or by the contract between the HMO and the long term care provider.

While there is much disagreement concerning a long term care facility's obligations when treating Medicare HMO patients, the managed care organization is in an excellent position to preempt the debate. In the agreement, the managed care organization can merely require the long term care facility to adhere to the conditions of Medicare/Medicaid certification, and thereby sidestep the entire debate. n59 Yet, the managed care organization ought not take such a step reflexively. Eliminating the long term care provider's flexibility to treat patients at the level and intensity of care it believes is required is likely to increase the cost of care for both the nursing facility and for the managed care organization. It bears emphasizing that these issues should be decided before price is negotiated. Failure to anticipate heightened requirements imposed by licensing and certification could result in gross miscalculations of cost--a situation that all involved would profit from avoiding.

Utilization, Control and Review

A key element in the operation of any managed care plan is the control of beneficiary utilization of covered services. The premium payments of any plan are derived from a complex matrix of actuarial considerations that rely heavily on three elements: projections of usage by covered beneficiaries, the mix of cases, and the effectiveness of steering beneficiaries to the appropriate providers. The managed care organization is motivated to manage the care delivery system to meet or fall short of the actuarial expectations by evaluating medical necessity and appropriateness of services in light of accepted practices. n60

Case mix is not a component that is subject to the control of the managed care organization, particularly once the beneficiaries are enrolled. In many instances, even enrollment is subject to limited control. For example, managed care organizations may have discretion in terms of marketing their products. n61 However, Medicare and Medicaid certified organizations are required to market to the entire universe of potential enrollees, including long term care residents, and cannot adopt risk-selective enrollment practices by marketing solely to "mall walkers," health club frequenters, or otherwise particularly healthy individuals. n62

Similarly, steering beneficiaries to the appropriate providers is only moderately subject to managed care organization control. The most important factor for channeling beneficiaries is the use of co-payment penalties for care delivered outside the system. This penalty, however, is fixed at the outset, cannot be altered during the coverage period, and must be "reasonable" or the managed care organization risks pricing itself too high for the market.

As case mix and steering do not provide effective solutions to meeting utilization goals, influencing or controlling the level, length, and intensity of covered services is the principal variable by which a managed care plan can affect its costs once the coverage period commences. n63 This is also the variable that most affects the profitability and risk of a contracting provider and raises the greatest concerns for beneficiaries. Such concerns arise because a fundamental operating precept for managed care organizations is that the greatest amount of care and services must be obtained at the lowest level of the delivery system able to deliver the care.

Faced with cost-containment strategies that may work to limit demand to the detriment of the beneficiary, utilization review is subject to scrutiny by federal and state regulatory agencies and private accreditation organizations. n64 Tension exists between the parties to the managed care contract regarding the role that each is to play in the process of utilization review. The tension has been spotlighted lately as elected officials grapple with adequately **protecting** the interests of the consumer, the providers, and the managed care organization, while ensuring quality of care. n65 Consumers feel threatened by the role that managed care plays in making treatment decisions. Providers, especially those who are at risk financially and under regulatory constraints, will want to maintain some control of utilization review to minimize their risk in the event the managed care organization manages utilization inadequately or inappropriately, and to ensure that beneficiaries have access to necessary and appropriate care and services. Managed care organizations, on the other hand, want to maintain control over utilization review to control their risk of loss. n66

Because utilization review both increases potential liability due to its impact on patient care n67 and is critical to the success of managed care, its format must be clearly defined in the agreement. For example, utilization review can be prospective, concurrent, or retrospective in nature, and takes a variety of forms, including mandatory admission requirements, pre-admission approval, parallel utilization review, treatment and discharge planning, case management or gate-keeping, clinical practice guidelines, and provider profiling. n68 All managed care organizations employ one or more of those devices to retain the maximum degree of control over the utilization of services by covered beneficiaries.

Irrespective of the control device(s) employed, the standards should be carefully addressed at the contract negotiation stage and by specific reference in the agreement. The agreement should clarify the authority and obligation of the managed care organization to establish, implement, and administer the utilization management program, and should hold it to the standards of that program. The agreement also should obligate the long term care facility to participate in the utilization management program, and provide a mechanism for dispute resolution regarding utilization management decisions. The agreement should set standards, at least equal to the industry minimum, against which the program should be measured and held accountable. n69

The long term care facility will want the managed care organization to indemnify and hold it harmless for any acts or omissions of the managed care organization under the utilization management program. While the managed care organization may wish to exclude from the agreement specific utilization review procedures so that it is not required to obtain provider approval for every amendment to the utilization review program, control procedures should not be subject to unilateral amendment by the managed care organization without prior notification and approval of the provider. n70

The following sections focus on several utilization control devices that have unique implications for the long term care provider:

Pre-Admission Approval

Long term care facilities typically operate at an occupancy rate near ninety percent. n71 As a result, pre-admission

approval requirements should be explicit so that the facility can accurately gauge anticipated volume and care level of admissions. Further, the long term care provider must know precisely what must be done to assure that coverage--and payment--will be available. The pre-admission approval process can involve something as simple as a confirmation of coverage and eligibility or as complex as a second opinion and record review.

Since pre-admission approval usually is a pre-condition to coverage, the precise terms should be set forth in the agreement, including: any provisions for emergency transfers and whether those transfers are exempt from pre-admission review; indemnification and "hold harmless" provisions for approvals that are subsequently withdrawn or reversed; and procedures for approvals that do not correspond to the long term care facility's professional judgment as to the level of care required. The latter could resolve situations in which, for example, the managed care organization pre-approves a lower level of care than the facility believes is appropriate, or vice versa. In each of these situations, the provider agreement should address who is financially at risk for the care provided, whether or not it has been pre-approved.

Pre-admission approval is particularly important because federal and state regulations allow long term care facility residents to be discharged only when certain conditions are met. Medicare and Medicaid certification provisions for discharge or transfer of patient are limited to: the resident's welfare; when services no longer are needed; for the safety of other residents; for the health of other residents; when the resident has failed to pay after reasonable notice; or when the facility ceases to operate. n72 Similar or more restrictive provisions may be found in many state licensing regulations. n73 Consequently, such limitations may also apply to any licensed facility, irrespective of Medicare or Medicaid certification.

The long term care facility should ensure that the managed care organization has a system whereby the facility without great difficulty can verify: eligibility; the extent and type of coverage (including limitations); schedules of benefits; covered services requiring pre-authorization; determinations of medical necessity; coinsurance, copayment, and deductible information; coordination of benefits information; prompt notice of pre-approval; and information on the utilization management program. n74 Because of the difficulties associated with discharging patients, the long term care facility should negotiate for immediate decisions on these issues, hold-harmless clauses that will protect the facility against the risk of erroneous admissions, and provisions for payment for services provided those patients.

Long term care facilities face pre-admission requirements even in fee-for-service arrangements. Both Medicare and Medicaid are authorized to use medical necessity or utilization control measures to control costs. n75 Some states are now turning to pre-approval procedures for their Medicaid nursing care benefit. n76 Such pre-screening measures attempt to control increases in Medicaid spending by informing consumers of alternatives to resident nursing care--such as home health and community based care. While Medicare's fee-for-service skilled nursing benefit does not have an official pre-approval process, certain criteria--such as medical necessity and prior three day hospitalization--must be met prior to coverage. n77 Enhanced coordination of providers along the continuum of care raises potential Medicare reimbursement concerns. Discharging a patient from acute care, or in the alternative, avoiding acute care altogether, may be the optimal solution. However, how will that decision affect the long term care facility's reimbursement if the prior three-day hospitalization requirement is not met?

The converse of pre-admission approval arises when enrollees are disenrolled from the managed care organization but continue to receive care from the provider. The issue of who remains responsible for coverage of these enrollees is one over which managed care organizations and providers often disagree. In order to avoid potential disputes and to ensure a proper measure for ascertaining an amount payable in the event of such a dispute, the long term care facility should negotiate protective provisions in the agreement.

An aspect of this issue was recently addressed in a state appellate court decision, *Sanus/New York Life Health Plan Inc. v. Dube-Seybold-Sutherland Management, Inc.* n78 In *Sanus/New York Life*, the managed care organization experienced time lags of one to six months in both adding and deleting covered members to the eligibility list upon which contracting providers' capitation was calculated. n79 A dental services provider incurred actual losses of over \$

200,000 due to the inaccurate eligibility lists and brought suit claiming the managed care organization breached its contract. n80 The lower court held that because capitation was to be based on eligibility lists and plaintiff had no independent means of verifying eligibility, the managed care organization breached the contract by failing to maintain current eligibility records. n81 In assessing damages, however, the lower court determined that the provider contract "did not provide a measure by which a sum payable could be ascertained with reasonable certainty," and the provider was not awarded the entire amount of damages requested. n82 The appellate court affirmed the lower court's holding regarding the breach of contract, but found the lower court erred in its assessment of damages. n83 The appellate court found reasonable certainty in the contractual language to assess the damages. n84 The importance to long term care providers is that, in addition to provisions addressing eligibility determination, providers should ensure that the contract "fixes a measure by which the sum payable [can] be ascertained with reasonable certainty," in the event eligibility issues are disputed. n85

The membership of a managed care plan generally will be in flux and the coverage status of members is always changing. Providers are becoming more aware of this dynamic and are seeking contract provisions that clearly set forth the risks they are willing and unwilling to assume. Long term care providers will want to ensure that payment will not be denied for services to beneficiaries: authorized by MCO pursuant to pre-authorization procedures; determined to be medically necessary at the time they were rendered; or deemed by the facility to be emergency services. Such decisions should not be subject to retrospective review by the managed care organization. The contract should specify the methodology and basis for payment and how any payment disputes are to be resolved. In the absence of authorization, any service provided by the long term care facility will likely not be reimbursed by the managed care organization, but the facility should retain the right to seek payment for non-covered or unauthorized services directly from the beneficiary. n86

It is important for provider contracts to lay out the terms on which pre-approval will be conducted, the facility's responsibility for incorrect coverage determinations, and how a beneficiary is treated if coverage terminates while a resident is in continuing need of care. For example, if a covered family member is a resident and the insured is terminated from the managed care organization, does coverage immediately cease? Who should pay the costs of discharge planning? Can the facility have a back-up guarantor? n87 If a covered family member is also covered by Medicare and a Medigap policy and the managed care organization occupies third position, what happens if the Medicare benefit is exhausted and the Medigap policy declines to pay full rates? Is the managed care organization responsible for coverage? Is it liable to the provider for any shortfall in coverage?

Parallel Utilization Review

Parallel utilization review means that a managed care organization will endeavor to control costs by conducting utilization review of covered residents while a provider conducts its own utilization review. Because the provider and the managed care organization are subject to different, and often contradictory pressures, such review can result in the managed care organization arriving at conclusions about a long term care resident's level of care requirements that are different from the provider's assessment of the resident's needs. Therefore, clear understanding is required as to the precise role that the managed care organization's utilization review process will play.

The provider agreement should indicate the weight attached to the utilization review process for decisions concerning coverage of benefits and the manner in which disagreements shall be resolved. Since "source of payment" is not legitimate grounds for the involuntary discharge of a resident, long term care providers may be reluctant to accept managed care enrollees as residents for fear that they will be at risk of coverage denials that may be significantly influenced by economic as well as care-level considerations. n88

The potential for disagreement on utilization review issues in the managed long term care setting can have significant legal implications. Long term care providers develop and follow treatment or care plans for their patients n89 and typically cannot abdicate that responsibility to a managed care organization's utilization review process. Providers fear that such delegation to the managed care organization could result in either the denial of necessary care to the

enrollee, a violation of Medicare/Medicaid certification or state licensing requirements, or a financial disaster for the long term care facility.

It is particularly important that the facility not place itself in the position of having the utilization review process dictate care that is at variance with its own care plans for the residents. For example, a facility may acquiesce in a plan's utilization review determination that a lower care level is appropriate, such as when the plan's utilization review recommends elimination of specialized equipment that is called for in the facility's care plan. If the resident suffers adverse consequences, the facility may be held liable for failure to follow proper nursing practice. The managed care organization cannot waive a member's rights in such a situation, and even if the plan is employer-sponsored, ERISA does not preempt malpractice claims by injured plan members.ⁿ⁹⁰ Thus, any arrangement with a managed care plan must clearly delineate the provider's ultimate authority with respect to the appropriate care to be rendered to a resident.

To the extent that a managed care organization insists on some degree of control in utilization review, the provider will want to negotiate indemnifications against any resulting liability. The provider will be particularly reluctant to abdicate its responsibilities when it is Medicare or Medicaid certified. Under Medicare and Medicaid survey protocols, the provider is held to the level of care dictated by professionally accepted standards and by its care plan for the resident, regardless of other considerations.ⁿ⁹¹

Post-Discharge Review

Post-discharge review is a process by which the managed care organization makes a retrospective examination of the residents' care and determines whether it was necessary and appropriate. Such review is most familiar in hospital cases in which the admission diagnosis may vary from the discharge diagnosis. Long term care providers are extremely suspicious of this type of review because it may result in reimbursement being denied for care that was already given. The facility should request that any review either precede or be contemporaneous with the delivery of care.ⁿ⁹²

Mandatory Admissions Requirements

Mandatory admission requirements are useful tools to ensure availability of resources. This guarantee can take the form of anything from a "bed hold" agreement on a fixed number of beds to a general agreement that the facility will accept any beneficiary whose coverage is approved. Provisions of this type can involve substantial risk for a long term care facility.

The entire utilization review process of a managed care plan is designed to assure that the plan is getting maximum use of each contracting provider. This means that the plan will attempt to use as much of each provider's capabilities as possible, while pressing to move patients to lower cost providers. In the hospital setting, this means exerting pressure for the earliest possible discharge to the next lower level of care. The same is true of each subsequent care level, including long term care facilities. The effect of this process is to produce early discharges from hospital to **nursing home** for patients who will be among the sickest **nursing home** residents, while accelerating the transfer of patients requiring less intensive care to other less costly settings.

Again, there is a tension between the managed care organization and the long term care provider. The managed care organization or referring provider is concerned with (a) its ability to place its hospital discharge or other patients in need of long term care services into the facility and (b) the long term care provider's willingness to accept those patients. On the other hand, the long term care provider is concerned with (a) its ability to provide the appropriate level of care; (b) the managed care organization's dumping of high acuity patients that it may not be adequately equipped to serve; and (c) losing control over the ability to appropriately match its case mix to available financial and care delivery resources.

A recent federal district court case highlights this tension and the potential for problems arising from mandatory admission policies. In *Juliano v. Health Maintenance Organization*, plaintiffs brought an action against a federally qualified HMO for denial of ERISA benefits.ⁿ⁹³ The beneficiary's contract provided for medically necessary, skilled nursing facilities benefits as defined by Medicare law. The skilled nursing facility initially selected by the family denied

admission, citing the severity of the patient's condition and the level of care required. n94 Subsequent to that denial, a break-down occurred in the HMO's procedures regarding access to skilled nursing benefits, resulting in a denial of benefits to the beneficiary. n95 Although the liability of the skilled nursing facility was not at issue in the case, in calculating the damages for denial of benefit, the court heard testimony from the facility's administrator as to whether the facility would have accepted the beneficiary as a patient at the HMO's reimbursement rates, and would have provided her with the level of care she needed. n96 When the administrator responded in the negative, the court noted that the facility "was bound to admit [the HMO's] members 'immediately upon the availability of a bed,' and could not 'refuse admission on the basis of Member's financial resources nor on the basis of anticipated cost of care of the Member.'" n97 The facility's stated rationale for denying admission demonstrates the difficulty of distinguishing quality of care decisions from financial or economic decisions. Long term care facilities, therefore, must be watchful of any contractual provisions requiring them to admit on the basis of bed availability.

Because long term care providers are unfamiliar with managed care, they are often not fully acquainted with the demands--financial and otherwise--associated with the different levels of care that they provide. But it is essential for all involved that long term care providers not be compelled to treat patients whose care requirements exceed the facility's capabilities. Otherwise, the long term care provider is at serious financial risk and, more importantly, the patient may not receive adequate care. Thus, the long term care facility should attempt to avoid any contract calling for it to do anything other than to provide the services explicitly set forth in the agreement, to beneficiaries who meet the long term care facility's admission criteria, and who are otherwise authorized to receive such services. The long term care facility should retain the right to refuse to admit if these criteria are not met.

Fraud and Abuse

The long term care industry is increasingly under HHS' anti-fraud and abuse spotlight. n98 This focus results from a variety of factors, including: the amount of state and federal dollars allocated to long term care through the Medicare and Medicaid programs; the multiplicity and complexity of coverage issues; the belief that long term care patients are a vulnerable population; and the presumed prevalence of fraud and abuse in this area. n99 Similarly, there has been significant recent attention devoted to fraud and abuse in managed care. n100 While fee-for-service healthcare fraud and abuse enforcement focuses on unnecessary and overutilized services, managed care presents incentives for failing to deliver necessary services. Managed care organizations have been charged with marketing fraud, i.e., attempting to attract enrollees with no realistic ability or intention to provide future care, and other income maximizing and risk minimizing activities, sometimes in concert with providers. n101 Many of the issues covered within the scope of the federal anti-kickback n102 and self-referral n103 laws, such as those relating to physician incentive plans, n104 raise concerns that may apply to entities in the managed care environment. While it is yet unknown how the advent of managed care will influence fraud and abuse enforcement in long term care, the following highlights one emerging concern.

The federal Medicare-Medicaid Antifraud and Abuse Amendments prohibit any remuneration for referring, furnishing or arranging a good or service for which payment could be made under a federal healthcare program. n105 In addition to the federal anti-fraud provisions, many states are enacting their own Medicaid managed care anti-fraud provisions. n106

A potentially thorny issue may arise under anti-kickback statutes when the long term care provider negotiates price reductions, or discounts, with a managed care organization. The long term care provider offers a discount to the managed care plan in return for the managed care plan's agreement to steer or channel managed care plan enrollees, some of whom may be or may become Medicare or Medicaid beneficiaries, to the long term care provider. While offering discounts in the normal course of business transactions is not deemed unlawful, such agreements between providers and managed care organizations may, at some point, begin to resemble payments for referrals. n107 For example, some may contend the long term care provider pays "remuneration" in the form of the discount given to a managed care entity in return for the referral of plan enrollees whose care may be covered in part by Medicare or Medicaid.

The "safe harbor" regulations do provide exceptions for discounts given to Medicare-certified "risk sharing" HMOs organizations. n108 It is not clear, however, that all forms of discounts will fit within the statute's safe harbor. For example, "a reduction in price offered to a beneficiary" and "a reduction in price applicable to one payor but not to Medicare or a State healthcare program" are not included within the scope of the safe harbor. n109 Care must be taken to structure discount arrangements with non-risk sharing HMOs in a manner that avoids any suggestion of improper referral inducing remuneration. Discounts should be applied in a uniform manner, determined in advance, unrelated to the volume of business and disclosed, as appropriate, in any Medicare or Medicaid filings.

In 1996, special provisions addressing discounts offered to HMOs, CMPs, and PPOs by contract healthcare providers were adopted. n110 The new provisions created a safe harbor for price reductions of usual charges offered by providers to health plans so long as certain conditions are met. n111 For the most part, the conditions preclude the plan and the provider from shifting the cost of the discount to Medicare or Medicaid; require the discount to be in writing, for a minimum of one year, determined in advance, and reported on appropriate Medicare and Medicaid cost reports; and require that the discount be disclosed to Medicare and Medicaid. n112

Some argue that fraud and abuse provisions, in general, place "fewer restraints on managed care arrangements" than on fee-for-service arrangements and therefore may "have little relevance for managed care." n113 However, several commentators criticize these new managed care safe harbor provisions as too narrow and failing to cover a number of arrangements presently used in the managed care marketplace. n114 Because of the overlay of federal and state certification and licensing requirements for long term care facilities, there may be other, equally appropriate means of addressing the more troublesome managed care fraud and abuse concerns (denial of care, barriers to access). However, given the state of the long term care market and the economic incentives driving the primary payors, it is likely that long term care will remain the focus of attention. Consequently, providers should give careful attention to the structure of any managed care arrangements--with suppliers of items or services, beneficiaries, and managed care plans--to assure that the safe harbor requirements are satisfied.

CONCLUSION

This brief summary of legal issues involving provider contracts and managed care is intended to be neither exhaustive nor negative. The area holds great promise for both managed care organizations and long term care providers, but contains many uncharted areas. Providers are becoming more aware of the significance of the managed care agreement and are proceeding cautiously. The ability of managed care organizations to penetrate the long term care market will depend upon the flexibility of the managed care industry. The inherent attractiveness of long term care facilities, however, eventually will result in a loyal and fruitful partnership between long term care and managed care.

REFERENCE: n1. See Margaret G. Farrell, *ERISA and Managed Care: The Law Abhors a Vacuum*, 29 J. HEALTH & HOSP. L. 268, n. 2 (1996) (estimating managed care enrollment at over 50 million); Lauren A. McCormack et al., *Consumer Information Development and Use*, 18 HEALTH CARE FIN. REV., Sept. 1, 1996 at 15 (estimating managed care enrollment for employed americans at 67%).

n2. The number of Medicare and Medicaid beneficiaries enrolled in managed care is growing, and will continue to grow in light of the new Balanced Budget Act of 1997 Medicare provisions. See Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251 (1997) [hereinafter Balanced Budget Act]. Medicare managed care enrollees appear generally satisfied with managed care; therefore, even if they were "cherry picked" by the managed care organization, those enrollees likely will remain enrolled as they age, and become more sick and frail. Eighty percent of Medicare beneficiaries enrolled in HMOs recently surveyed said they would re-enroll. Towers Perrin Press Release, July 16, 1997, cited in Medicare & Medicaid Guide (CCH) No. 966 at 6 (July 24, 1997).

n3. AMERICAN HEALTH CARE ASS'N, A GUIDE TO MEDICARE MANAGED CARE FOR LONG TERM CARE PROVIDERS (1995) [hereinafter AHCA].

n4. 42 U.S.C. § 1395y(a)(1)(A)-(D)(1997); *State ex rel. Bodnar v. Department of Health and Human Servs.*, 903 F.2d 122 (2d Cir. 1990).

n5. *See, e.g.*, 42 C.F.R. § 417.472 (1997). Several provisions in the Balanced Budget Act specifically relate to developing Medicare and Medicaid managed care. *See* Balanced Budget Act, *supra* note 2, §§ 4001-4006 (Medicare+Choice), 4014 (Social HMOs), 4701 (Medicaid Managed Care), 4801-04 (Medicare and Medicaid PACE Program). For a discussion of Medicare managed care, see generally U.S. GENERAL ACCOUNTING OFFICE, MEDICARE HMOs: RAPID ENROLLMENT, GAO/HEHS-96-63 (1996); Jonathan B. Oberlander, *Managed Care and Medicare Reform*, 22 J. HEALTH POL. POL'Y L. 595 (1997). For a discussion of Medicaid managed care, see U.S. GENERAL ACCOUNTING OFFICE, REPORT ON MEDICAID MANAGED CARE PROGRAMS, GAO/HRD-93-46 (1993); U.S. GENERAL ACCOUNTING OFFICE, MEDICAID MANAGED CARE: CHALLENGE OF HOLDING PLANS ACCOUNTABLE REQUIRES GREATER STATE EFFORT, GAO/HEHS-97-86 (1997).

Some states are enrolling Medicaid recipients into long term managed care. According to the National Academy for State Health Policy, in 1996, nine states enrolled elderly residents of long term care facilities in risk-based managed care. Trish Riley, Latest Developments in Managed Long Term Care, Address at Transitioning Long-Term Care into Managed Care (May 19-20, 1997) (Global Business Research, Ltd.). Those states are: Arizona, Florida, Wisconsin, Minnesota, Colorado, Texas, Maryland, Massachusetts and Maine. *Id.* Sixteen states enroll Medicare/Medicaid dual eligibles in their Medicaid managed care programs, either on a mandatory or voluntary basis. *Id.* The Robert Wood Johnson Foundation and the University of Maryland Center of Aging fund an \$ 8 million grant project to encourage states to integrate Medicaid long term care with Medicare acute care using managed care models. *Robert Wood Johnson Foundation and the University of Maryland, MANAGED MEDICARE & MEDICAID*, Dec. 16, 1996. Michigan recently issued a "Call for Ideas" on a Michigan managed care long term care initiative. The summary of responses is available at <<http://www.mdmh.state.mi.us/msa/longterm>>. Despite recent innovations in this area, Medicaid long term care managed care implementation may be much slower than that for AFDC populations due to the substantial interest group politics of groups representing the elderly and long term care providers. Karl Kronenbusch, *Medicaid and the Politics of Groups: Recipients, Providers, and Policy Making*, 22 J. HEALTH POL. POL'Y & L. 839, 872-73 (1997).

n6. Private long term care insurance represented only \$ 200 million of \$ 107.8 billion spent on long term care in 1993. U.S. GENERAL ACCOUNTING OFFICE, LONG TERM CARE: CURRENT ISSUES AND FUTURE DIRECTIONS, GAO/HEHS-95-109 (1995) [hereinafter GAO LONG TERM CARE ISSUES]. However, since 1987, long term care insurance sales have grown at an average of 23% per year. *LTC Insurance Sales Reach All-Time High*, HFMA EXPRESS NEWS (Healthcare Fin. Mgmt. Ass'n) June 6, 1997 (quoting Health Insurance Association of America survey findings released May 17, 1997).

n7. Furthermore, although subject to public debate, long term care facilities argue they can provide certain levels of care more effectively than hospitals. *See* Daniel M. Gitner, *Nursing the Problem: Responding to Patient Abuse in New York State*, 28 COLUM. J. L. & SOC. PROBS. 559, 607 n.2 (1995) (high cost acute care forces transfer of elderly into less expensive long term care facilities); James C. Robinson, *Administered Pricing and Vertical Integration in the Hospital Industry*, 39 J. L. & ECON. 357, 360 (1996) (long term care facilities are a more cost-effective locale than hospitals for treating non-acute care). *But see* Alison Barnes, *The Policy and Politics of Community-Based Long Term Care*, 19 NOVA L. REV. 487, 492 (1995) (highest inflation rate in service cost shifted from acute care to long term care); Richard L. Peck, *It's Time for SNFs to Wake Up to Some New Realities*, **NURSING HOMES**, Apr. 1, 1997 available in Westlaw 1997 WL 9913494 (fallacy that **nursing homes** can provide subacute care at half the cost of hospitals; "pricing," not "cost," is the difference).

n8. Historians have actually documented managed care as early as the fourteenth century, when physicians, for a fixed annual sum, agreed to treat "every illness that requires the art of medicine." MICHAEL R. MCVAUGH, *MEDICINE BEFORE THE PLAGUE* (Cambridge University Press 1994). For a history of managed care, see 1996 *Managed Care Explained* (CCH) PP 600-640 [hereinafter CCH *Managed Care Explained*].

n9. See generally Jonathan P. Weiner & Gregory de Lissovoy, *Razing a Tower of Babel: A Taxonomy for Managed Care and Health Insurance Plans*, 18 J. HEALTH POL. POL'Y & L. 75 (1993); CCH Managed Care Explained, *supra* note 8, P 505.

n10. See AHCA, *supra* note 3, at 2, 13-14. For an application of financial risk theory to capitation to demonstrate the effects of the various components of risk, see Andrew Ruskin, *Capitation: The Legal Implications of Using Capitation to Affect Physician Decision-Making Processes*, 13 J. CONTEMP. HEALTH L. & POL'Y 391, 393-400 (1997).

n11. Long term care includes health, social, housing, transportation, and other supportive services for people with physical, mental, or cognitive conditions that constrain their ability to function independently. GAO LONG TERM CARE ISSUES, *supra* note 6; CYNTHIA POLICH ET AL., MANAGING HEALTH CARE FOR THE ELDERLY § 2.2(b), at 19, 22 (1993); JOAN M. KRAUSKOPF ET AL., ELDERLAW: ADVOCACY FOR THE AGING § 12.1, at 429 (2d ed. 1993).

n12. Federal Medicare and Medicaid certification requirements are found at 42 U.S.C. §§ 1395i-3 (Medicare), 1396r (Medicaid) (1997); 42 C.F.R. pts. 483, 488 (1997). See generally, KRAUSKOPF, *supra* note 11, §§ 12.3-12.4, at 432-33; BARRY FURROW ET AL., HEALTH LAW §§ 1-6 to 1-7, 1-14 (2d ed. 1995).

n13. 42 U.S.C. § 1395aa (1997); 42 C.F.R. § 488.11. See generally 42 C.F.R. pt. 488 (state survey and certification requirements; long term care survey forms). Traditionally, there were two distinct levels of **nursing home** licensure and certification: skilled nursing and intermediate care. Regulations have eliminated most of the distinctions between the two, and because of "acuity creep" (discussed further herein), any practical distinction has also been eliminated. See *Newman v. Kelly*, 848 F. Supp. 228 (D.D.C. 1994).

n14. KRAUSKOPF, *supra* note 11, § 12.2, at 430.

n15. See GAO LONG TERM CARE ISSUES, *supra* note 6. The Medicare benefit for long term care services is part of extended care services furnished in a skilled nursing facility after a period of hospitalization. See 42 U.S.C. § 1396r; 42 C.F.R. §§ 409.20-409.36. The Medicaid benefit for long term care services is usually part of a nursing facility service benefit. See 42 U.S.C. §§ 1396a(a), 1396d(a); 42 C.F.R. §§ 440.140, 441.100-106 (1997).

n16. Medicare reimburses for "reasonable costs" subject to "routine cost" limitations. See Social Security Act § 1861 (v)(1)(A), 42 U.S.C. § 1395x(v)(1)(A) (reasonable cost reimbursement); 42 C.F.R. § 413.30 (1997) (routine cost limits).

n17. *Id.* See generally FURROW ET AL., *supra* note 12, § 13-17. Providers can seek exceptions or exemptions from routine cost limits. 42 C.F.R. § 413.30.

n18. 42 U.S.C. 1396a(a)(13). The Boren Amendment was repealed, effective October 1, 1997. Balanced Budget Act, *supra* note 2, § 4701.

n19. According to one source, Boren Amendment suits are documented in 36 states. John M. Burman, *Judicial Review of Medicaid Hospital and **Nursing Home** Reimbursement Methodologies Under the Boren Amendment*, 3 ANNALS HEALTH L. 55, 63 n. 56 (1994). For a collection of Boren Amendment cases with respect to **nursing home** reimbursement, see Gerard F. Anderson & Mark A. Hall, *The Adequacy of Hospital Reimbursement Under Medicaid's Boren Amendment*, 13 J. LEGAL MED. 205, 207 n.17 (1992).

n20. For inpatient hospital services, Medicare pays providers a predetermined amount based upon the patient's diagnosis. See 42 C.F.R. pt. 412 (1997). See also David M. Frankford, *The Medicare DRGs: Efficiency and Organizational Rationality*, 10 YALE J. ON REG. 273 (1993); Judith R. Lave, *The Impact of the Medicare Prospective Payment System and Recommendations for Change*, 7 YALE J. ON REG. 499 (1990); Bruce C. Vladek, *Medicare's*

Prospective Payment System at Age Eight: Mature Success or Midlife Crisis?, 14 U. PUGET SOUND L. REV. 453 (1991).

n21. Frankford, *supra* note 20, at 310-13 (survey of studies on site of care after PPS). *See generally* Jacqueline Kosecoff et al., *Prospective Payment System and Impairment at Discharge: The "Quicker-and-Sicker" Story Revisited*, 264 JAMA 1980 (1990) (finding a 43% relative change in the number of patients "discharged unstable" after PPS was implemented).

n22. Because the hospital prospective payment system encouraged "quicker, sicker" discharges, many long term care facilities are able to provide high intensity services (with the exception of intensive and surgical care). Thus, there has been somewhat of an overlap in the market definition of "hospital" and "long term care" services. This overlap will likely continue with the advent of managed care. *See* Robinson, *supra* note 7, at 376.

n23. Persons 65 years of age and over numbered 34.2 million in 1995 and are expected to number 60.8 million by 2025 and 89.9 million in 2100. HFCA Statistics: Populations, Table 8 Aged Population/Projected, (Sept. 25, 1997) <<http://www.hcfa.gov/stats/hstats96/blustats.htm#Table8>>. *See generally* U.S. GENERAL ACCOUNTING OFFICE, LONG-TERM CARE: DIVERSE, GROWING POPULATION INCLUDES MILLIONS OF AMERICANS OF ALL AGES, GAO/HEHS-95-26 (1995); GAO LONG TERM CARE ISSUES, *supra* note 6; Katharine R. Levit et al., *Data View: National Health Expenditures, 1995*, 18 HEALTH CARE FIN. REV., Sept. 1, 1996 at 175, 188.

n24. In 1995, national health expenditures reached \$ 988.5 billion, between 13.5 and 13.6% of GDP. *See* Levit et al., *supra* note 23, at 175. *See generally* GAO LONG TERM CARE ISSUES, *supra* note 6.

n25. *See* GAO LONG TERM CARE ISSUES, *supra* note 6 (estimated \$ 107.8 billion spent on long term care in 1993).

n26. *Id.*

n27. *See* GAO LONG TERM CARE ISSUES, *supra* note 6. New York, an extreme example, pays 74% of all **nursing home** costs. *A Long Term Care Financing Task Force*, MANAGED MEDICARE & MEDICAID, July 12, 1996, available in Westlaw, 1996 WL 15557967.

n28. *See* GAO LONG TERM CARE ISSUES, *supra* note 6; *see also* Levit et al., *supra* note 23.

n29. *Senior Care Industry Breaks Price Records*, HFMA EXPRESS NEWS (Healthcare Fin. Mgmt. Ass'n) Apr. 25, 1997 (citing a report by Irving Levin Associates, Inc.).

n30. Levit et al., *supra* note 23, at 189

n31. *See* GAO LONG TERM CARE ISSUES, *supra* note 6 (private long term care insurance represented only \$ 200 million of \$ 107.8 billion spent on long term care in 1993). However, since 1987, long term care insurance sales have grown at an average of 23% per year. *LTC Insurance Sales Reach All-Time High*, *supra* note 6. However, despite increases in private health insurance coverage, its share of total long term care expenses has not changed in recent years. Levit et al., *supra* note 23, at 189.

n32. Although they may provide opportunities for long term care providers to participate in managed care, future regulations will address whether federally qualified PSOs that contract directly with HCFA to enroll Medicare beneficiaries will be required to provide long term care services.

n33. Long term care members of vertically integrated delivery systems are somewhat rare and present their own special issues, which are beyond the scope of this Article. For example, a long term care component of an integrated delivery system ("IDS") is dependent, as are other components, upon the premium income that the IDS receives to

provide the full range of services. The premiums are set based on actuarial projections. If actual utilization exceeds projected utilization, the IDS must still provide the services it contracted for, and the IDS must cut costs or it will incur operating losses because it can not raise premiums during the plan year. The long term care component of the IDS may find itself with less revenue than expected as a result of this need to avoid overall operating losses.

The Employee Retirement Income Security Act of 1974 presents another example. Employer sponsored managed care arrangements are subject to ERISA. ERISA plans have a fiduciary relationship with the covered beneficiaries and the plan. If an employer contracted with an IDS to provide the full range of healthcare services for its employees, the relationship might result in the IDS and its members being held to a higher duty than an ordinary provider would. *See* PATRICIA A. YOUNGER ET AL., *MANAGED CARE LAW MAN.* (Supp. 4 1996); *see generally* Farrell, *supra* note 1 (for a discussion of ERISA and managed care).

The number of integrated delivery systems comprising long term care members may be growing, according to some experts in the hospital industry. *See* Peck, *supra* note 7. Others claim that unified ownership of hospitals and long term care facilities is encouraged by Medicare's reimbursement policies. *See generally* Robinson, *supra* note 7.

n34. Subject to antitrust laws, long term care providers may join forces and form horizontal networks to lower costs and leverage favorable contracts, but payors are able to avoid such attempts as long term care is not currently an integral part of managed care products.

n35. AHCA, *supra* note 3, at 2-3.

n36. *See generally* Ila S. Rothschild et al., *Recent Developments in Managed Care*, 32 *TORT & INS. L. J.* 463, 465-67 (1997) (payors' mechanisms to manage costs generally take the form of discounts, capitation, or global risk sharing). Discounts are negotiated on a fee-for-service basis and may be associated with a bonus payment for keeping utilization rates below a targeted rate. *Id.* at 465-66. Capitation pays the provider an actuarially determined fee on a per-member basis, regardless of services provided. *Id.* at 466. Global risk sharing is often associated with carve-out services, such as subacute care, where a particular specialty or particular procedures can be isolated and for which the provider will be paid according to an established fee schedule. *Id.* at 467.

n37. AHCA, *supra* note 3, at 2.

n38. *Id.* at 10.

n39. *Id.*

n40. AMERICAN HEALTH CARE ASSOCIATION, *SUBACUTE CARE: MEDICAL AND REHABILITATION DEFINITION AND GUIDE TO BUSINESS DEVELOPMENT 2* (1994).

n41. *Id.* at 1. *See supra*, citations collected in note 7; *see also* Levit et al., *supra* note 23, 189-90.

n42. 42 U.S.C. §§ 1395i-3(b)(2), (b)(4) (Medicare requirements for SNFs), 1396r(b)(2), (b)(4) (Medicaid requirements for nursing facilities).

n43. For an example of a long term care group's transition from nursing to subacute care, see Jonathan S. Sherwin, *Subacute Diversification: The Road Ahead*, **NURSING HOMES**, Feb. 1, 1997, available in Westlaw 1997 WL 9913475. *See also* Richard L. Peck, *A Subacute Network for Nursing Homes*, **NURSING HOMES**, Mar. 1, 1997, available in Westlaw, 1997 WL 9913488.

n44. *See generally* 1996 *MANAGED CARE RESOURCE INFORMATION DIRECTORY*, HEALTH CARE FINANCING ADMINISTRATION; *Hearings on Fraud and Abuse in Nursing Homes Before the Subcomm. on Human Resources of the House Comm. on Government Reform and Oversight*, 105th Cong. (July 10, 1997) (testimony of

Kathleen A. Buto, HCFA). HCFA's Social Health Maintenance Organization (SHMO) demonstration project integrates medical, social, and long term care. The demonstration projects are financed through capitation payments from both Medicare and Medicaid, and from member premiums and co-payments. In 1996, there were six demonstration projects. Similarly, HCFA's demonstration Program for All-inclusive Care for the Elderly (PACE) coordinates Medicaid, Medicare, and community long term care services. In 1997, there were 11 PACE programs. Both the SHMO and PACE demonstration programs were set to expire December 31, 1997. However, the programs were continued and expanded by the Balanced Budget Act. *See* Balanced Budget Act, *supra* note 2, §§ 4001-4006 (Medicare+Choice), 4014 (Social HMOs), 4701 (Medicaid Managed Care), 4801-04 (Medicare and Medicaid PACE Program).

n45. Black's Law Dictionary (West 6th ed. 1990). For a general discussion of the types of risk involved with risk-based contracting, see David C. Hillman, *A Primer on PHO Capitation Contracts*, 29 J. OF HEALTH & HOSP. L. 288 (1996). For a survey of state risk regulation, see Katherin E. Kudner, *Risk Regulation: A 50-State Survey*, HEALTH LAW DIGEST-DIGEST ANALYSIS (Nat'l Health Lawyers Ass'n, Jan. 25, 1997).

n46. AHCA, *supra* note 3, at 39.

n47. *Id.* at 41.

n48. *See* 42 U.S.C. §§ 1395i-3(b)(2), (b)(4) (Medicare requirements for SNFs), 1396r(b)(2), (b)(4) (Medicaid requirements for nursing facilities); 42 C.F.R. pt. 483.

n49. Hillman, *supra* note 45, at 290.

n50. For an application of financial risk analysis to provider capitation, see Ruskin, *supra* note 10.

n51. *See* David C. Hillman, *Drafting Risk Based Managed Care Contracts: Key Contractual Issues and Terms to Negotiate*, Address at 30th Ann. Meeting (June 22-25, 1997) (Am. Acad. Healthcare Att'ys).

n52. *See, e.g.,* AHCA, *supra* note 3, at 35, 53-60; Lance Malkind, *Determining Whether Medicaid Risk is Right for Your HMO: A Primer in Assessing Whether State's Rates are Satisfactory*, MANAGED MEDICARE & MEDICAID, July 7, 1997, available in Westlaw 1997 WL 941136.

n53. *See* 42 C.F.R. §§ 409.31-409.35 (requirements for Medicare covered services).

n54. *See* 42 C.F.R. §§ 417.440(b)(2),(3), 434.20(d), 440.250(g) (1997); HCFA HMO/CMP MAN. § 2109, reprinted in *Medicare & Medicaid Guide* (CCH) P 13,960.05.

n55. *See* 42 C.F.R. §§ 483.30-483.60 (requirements for long term care facilities), 409.20-409.36 (skilled nursing care). *See also* AHCA, *supra* note 3, at 53-60; Hillman, *supra* note 51.

n56. Hillman, *supra* note 51.

n57. 42 C.F.R. § 488.417.

n58. 42 U.S.C. §§ 1395i-3(c)(2)(B)(I)(I), 1395i-3(c)(2)(B)(ii), 1395r(c)(2)(B)(I)(I), 1395r(c)(2)(B)(ii) (1997); 42 C.F.R. § 483.12. *Podolsky v. First Health Care Corp.*, 50 Cal. App. 4th 632 (1996) (discharge requirements apply equally to Medicare/Medicaid and private pay patients).

n59. The real effect of such an approach may be to interfere with the cost savings that the government anticipates achieving through making use of managed care for the Medicare and Medicaid programs.

n60. *See generally* FURROW ET AL., *supra* note 12, § 8-7; YOUNGER ET AL., *supra* note 33, at Utilization Management.

n61. All Medicare beneficiaries, for example, are considered enrolled under Medicare managed care plans as individuals. 42 U.S.C. § 1395mm (1997); HCFA OFFICE OF MANAGED CARE, OPERATIONAL POL'Y LTR. NO. 48 (Jan. 13, 1997), *reprinted in* Medicare & Medicaid Guide (CCH) P 45,589.

n62. *See* 42 U.S.C. § 1395mm(c)(3)(C). *See also* HCFA HMO/CMP MAN. §§ 2200-2202, *reprinted in* Medicare & Medicaid Guide (CCH) P 13,963.05 (general marketing criteria); HCFA HMO/CMP MAN. §§ 2211, *reprinted in* Medicare & Medicaid Guide (CCH) P 13,963.65 (prohibited marketing activities).

n63. *See generally* U.S. GENERAL ACCOUNTING OFFICE, UTILIZATION REVIEW: INFORMATION ON EXTERNAL REVIEW ORGANIZATIONS, GAO/HRD093-22FS (1992); John D. Blum, *An analysis of Legal Liability in Health Care Utilization Review and Case Management*, 26 HOUSTON L. REV. 191, 192-93 (1989) (utilization review is external evaluation based on clinical criteria to evaluate the appropriateness of medical care).

n64. For example, the California Department of Corporations, the state regulatory agency with jurisdiction over health maintenance organizations, recently levied a \$ 500,000 fine against an HMO for failure to provide adequate medical care when the HMO refused to reimburse for a member's out-of-network specialized cancer surgery that the HMO was unable to adequately provide through use of in-plan physicians. *See* Rothschild et al., *supra* note 65; Julie Johnson, *Health Maintenance Organization Coverage Battle Rages On*, AM. MED. NEWS, Feb. 26, 1996, at 3; *The Health Care Revolution*, L.A. TIMES, Aug. 28, 1995, at 8-9.

The National Committee for Quality Assurance has extensive utilization review standards. NCQA STANDARDS FOR THE ACCREDITATION OF MANAGED CARE ORGANIZATIONS, UTILIZATION MANAGEMENT 1.2 (1995).

n65. *See, e.g.*, CAL. HEALTH & SAFETY CODE, §§ 1370.2, 1363.5.

n66. For an overview of legal implications of utilization review, see Ruskin, *supra* note 10; Rothschild et al., *supra* note 36; Vernelia R. Randall, *Managed Care, Utilization Review, and Financial Risk Shifting: Compensating Patients for Health Care Cost Containment Injuries*, 17 U. PUGET SOUND L. REV. 1 (1993); Linda V. Tiano, *The Legal Implications of HMO Cost Containment Measures*, 14 SETON HALL LEGIS. J. 79 (1990).

n67. *See, e.g.*, Hughes v. Blue Cross, 215 Cal. App. 3d 832 (1989) (denial of psychiatric hospitalization benefits constituted bad faith breach of contract); Wickline v. State, 192 Cal. App. 3d 1630 (1986) (third party payors may be liable for patient injuries suffered as a result of denial of medical care).

n68. Retrospective review is of limited value as a cost-containment strategy; the costs have already been incurred and retrospective denial often leads to costly disputes between payors, providers and consumers. *See* Sarchett v. Blue Shield, 729 P.2d 267 (Cal. 1987) (en banc).

n69. Hillman, *supra* note 51, at 394.

n70. AHCA, *supra* note 3, at 66.

n71. *See* GENEVIEVE W. STRAHAN, NAT'L CTR. FOR HEALTH STAT., CTRS. FOR DISEASE CONTROL & PREVENT., HHS, AN OVERVIEW OF **NURSING HOMES** AND THEIR CURRENT RESIDENTS: DATA FROM THE 1995 NATIONAL **NURSING HOME** SURVEY 4-5 (Jan. 23, 1997) (occupancy rates range from 83.2% for facilities in western states to 91.5% for homes in northeastern states).

n72. 42 U.S.C. §§ 1395i-3(c)(2)(A)(i-vi) (Medicare), 1396r(c)(2)(A)(i-vi) (Medicaid); 42 C.F.R. § 483.12(a).

n73. *See, e.g.*, 13 MO. ADMIN. CODE § 15-9.010(17)(A). For an overview of transfers and discharges of long term care facility patients, see Kathleen Knepper, *Involuntary Transfers and Discharges of Nursing Home Residents*

Under Federal and State Law, 17 J. LEGAL MED. 215 (1996).

n74. Hillman, *supra* note 51, at 397.

n75. 42 C.F.R. § 440.230(d). *See also* Cowan v. Myers, 187 Cal. App. 3d 968 (1986).

n76. Several states are considering or have implemented pre-screening measures for **nursing home** care. *See, e.g., Illinois Takes Managed Care Cue: Nursing Care Scrutinized*, MANAGED MEDICARE & MEDICAID, June 21, 1996, available in Westlaw 1996 WL 15557940. Illinois expects to save \$ 39 million annually upon full implementation of the pre-screening program, simply by providing access to information on alternatives to care. *Id.*

n77. 42 U.S.C. § 1395d(a); 42 C.F.R. § 409.30(a)(1). The skilled nursing benefit is available if the patient requires skilled nursing care that could only have been provided under the supervision of a professional in a skilled nursing facility on an inpatient basis. *See* 42 C.F.R. §§ 409.30 - 409.36.

n78. 837 S.W.2d 191 (Tex. Ct. App. 1992).

n79. *Id.* at 194.

n80. *Id.* at 198.

n81. *Id.* at 198-99.

n82. *Id.* at 200-02.

n83. *Id.*

n84. *Id.* The measure was capitation based on the eligibility and capitation reports that the court found were inaccurate because although they identified those seeking treatment from provider, they failed to identify those enrolled who had yet to seek treatment. *Id.* at 198. If the reports had been timely and accurate, the proper amount of damages *could have been* ascertained under the contract. *Id.* at 201.

n85. *Id.* at 201.

n86. *See, e.g.,* HCFA HMO/CMP MAN. § 2170, *reprinted in* Medicare & Medicaid Guide (CCH) P 13,965.20 (HCFA guidelines allowing plans to recover for non-covered services).

n87. Applicable statutes make it unlawful to require third-party guarantors as a condition of admission, but do not otherwise prohibit such guarantees. 42 U.S.C. §§ 1395i-3(c)(5)(A)(ii), 1396r(c)(5)(A)(ii). *See also* Podolsky v. First Healthcare Corp., 58 Cal. App. 4th 632, 645-46 (1996).

n88. For Medicare and Medicaid provisions for discharge and transfer, see 42 U.S.C. §§ 1395i-3(c)(2)(A)(i)-(iv) (Medicare), 1396r(c)(2)(A)(i)-(iv) (Medicaid); 42 C.F.R. § 483.12(a).

n89. 42 U.S.C. §§ 1396r(b)(2)-(3), 1395i-3(b)(2)-(3); 42 C.F.R. § 483.20(d).

n90. *See, e.g.,* Elsesser v. Hospital of the Philadelphia College of Osteo. Med., 795 F. Supp. 142 (E.D. Pa. 1992); DeGenova v. Ansel, 555 A.2d 147 (Pa. Super. Ct. 1988); Independence HMO, Inc. v. Smith, 733 F. Supp. 983 (E.D. Pa. 1990).

n91. *See* 42 C.F.R. pt. 483 (requirements for long term care facilities).

n92. *See* HCFA HMO/CMP MAN. § 2112, *reprinted in* Medicare & Medicaid Guide (CCH) P 13,960.75. HCFA guidelines for HMOs and CMPs regarding skilled nursing facility and home healthcare state that HMOs and CMPs

should not retroactively review a level of care determination already made by the physician. *Id.* § 2112.1.

n93. *Juliano v. Health Maintenance Org.*, No. 93 CIV. 8960, 1997 WL 83405 (S.D.N.Y.).

n94. *Id.* at *3. The skilled nursing facility indicated it would be "unethical" for it to accept a patient for whom it could not adequately care. *Id.* at *5.

n95. *Id.* at *8-10. The beneficiary died before the case was decided.

n96. *Id.* at *12.

n97. *Id.*

n98. For example, Operation Restore Trust, a federal demonstration project, is a collaborative effort of federal and state agencies (including OIG, HCFA, Department of Justice, offices on aging, state survey and certification agencies, and state Medicaid agencies) to combat fraud and abuse in Medicare and Medicaid, focusing on **nursing homes**, among others. Operation Restore Trust, HHS/OIG Fact Sheet, May 20, 1997, *reprinted in* Medicare & Medicaid Guide (CCH) P 13,913.06. *See also* *Hearings on Fraud and Abuse in Nursing Homes*, *supra* note 44 (testimony of Kathleen A. Buto, HCFA).

n99. *See, e.g.,* *Hearings on Fraud and Abuse in Nursing Homes*, *supra* note 44. One example that HCFA testified to at this hearing described long term care providers' ability to "game the system" by playing Medicare and Medicaid off one another and billing both programs for the same item or service. *See id.* (testimony of Kathleen A. Buto, HCFA). *See also* Edward S. Kornreich & Susan F. Scharf, *Inspector General's Pronouncements Offer Home Health Agencies, Medical Suppliers, Nursing Facilities and Hospices Little Guidance in Subtleties of Anti-Kickback Law*, 8 HEALTH LAW. 18 (Winter 1996), available in Westlaw, 8-WIN HEALTHLAW 18; *Fraud and Abuse: IG Launches Multi-Prong Attack on Fraud in Nursing Homes, Home Health Agencies*, Health Care Daily (BNA) at 4 (May 5, 1995).

n100. *See generally* Sharon L. Davies & Timothy Stoltzfus Jost, *Managed Care: Placebo or Wonder Drug for Health Care Fraud & Abuse?* 31 GA. L. REV. 373 (1997); Beth Schermer & Lawrence Foust, *Assumption of Risk: Federal Regulation of Physician Incentive Plans*, 30 J. HEALTH & HOSP. L. 1 (1997) (regulation of fraud and abuse in the managed care context); YOUNGER, *supra* note 33, at "Fraud and Abuse Issues Affecting Managed Care Entities."

n101. *See generally* Davies & Jost, *supra* note 100; Schermer & Foust, *supra* note 100.

n102. 42 U.S.C. § 1320a-7b (1997).

n103. *Id.* § 1395nn.

n104. *Id.* §§ 1395nn(e), 1395mm(i)(8)(A)(I).

n105. *Id.* § 1320a-7b. Anti-kickback safe harbors are found in 56 Fed. Reg. 35,952 (1991), 57 Fed. Reg. 52,729 (1992) and 61 Fed. Reg. 2122 (1996) and are codified at 42 C.F.R. §§ 1001.951-1001.953.

n106. *See, e.g.,* New Mexico S.B. No. 267, 43d Leg. 1st Sess. (enacted 4/8/97); Maryland H.B. No. 1059 (approved 5/22/97).

n107. *See* S. REP. NO. 95-143, 95th Cong. 12 (1977), *in* Medicare & Medicaid Guide (CCH) P 13,931.25 (discounts not illegal, and in fact are encouraged).

n108. 42 C.F.R. § 1001.952(h)(1)(ii), (2)(I).

n109. *See id.* § 1001.952(h)(3)(iii)-(iv).

n110. *See* 61 Fed. Reg. 2122 (1996) (codified at 42 C.F.R. § 1001.952(l)-(m)). Other provisions adopted in 1996 create a statutory exception for qualifying Medicare risk-sharing arrangements that place the provider at "substantial financial risk." 42 U.S.C. § 1320a-7b(b)(3)(F). An HHS advisory committee is developing an interim final rule on the scope of the shared risk exception, but committee members remain at odds as to whether a "bright line" standard or a more flexible approach to defining "substantial financial risk" should be adopted. *See* 62 Fed. Reg. 28410 (1997); Executive Briefing, Health Care Daily (BNA) (Oct. 14, 1997).

n111. 42 C.F.R. § 1001.952(m).

n112. *Id.* § 1001.952(m)(1)(I)-(iv).

n113. Davies & Jost, *supra* note 100, at 409.

n114. *See* 61 Fed. Reg. 2122 (1996) (comments on proposed regulations).

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LENGTH: 7592 words**TITLE:** Health Care Rate Regulations: The Need For a Reinvigorated "Takings" Analysis**AUTHOR:** Frederic C. Dreyer, Jr., President of Charlton Memorial Hospital, Fall River, Massachusetts. B.S., 1963; M.B.A. Health Care Administration, 1965, George Washington University.**TEXT:**

INTRODUCTION

Hospitals in Massachusetts, as in many states, are confronted with a myriad of regulations. For example, state regulatory agencies control everything from capital improvements [n1] to the maximum rates hospitals may charge for services provided. [n2] Moreover, through Medicaid, [n3] the state itself is the second largest purchaser of health care services. Thus, the state has the ability to set its own purchase price. Not surprisingly, Massachusetts has set the rates at which it reimburses hospitals for Medicaid-covered services at an amount below their fair market value. [n4] With the extraordinary power to set its own purchase price, the state is able to pocket the difference between the fair market value for the services it purchases and the rate it sets.

In the early part of this century, the United States Supreme Court would have carefully scrutinized, and most likely invalidated, this type of rate regulation either because it exceeded the police power of the state, or because such confiscatory regulation amounted to a violation of due process, or was a taking of private property. [n5] Since the late 1930s, however, the Supreme Court has refused to read the Constitution as proscribing rate regulation statutes. [n6] On the contrary, the Court has allowed state governments nearly total discretion to regulate under their police power. [n7] At the same time, the Supreme Court has minimized the significance of the explicit economic rights provisions of the Constitution, including its proscriptions on governmental takings of private property without just compensation and on laws which impair private contracts. [n8] Moreover, while the Fourteenth Amendment's due process and equal protection clauses have been vigorously applied to invalidate laws infringing upon individual liberty, the Supreme Court has refused to enforce these provisions to vindicate economic rights. As a result, the ability of states to regulate economic and social affairs with impunity under the police power has gone unfettered.

Current constitutional law doctrine limits state rate regulation only when such regulation is deemed to be confiscatory and denies the regulated entity a reasonable rate of return on its investment. [n9] Specifically, rate regulation is valid if it yields a "just and reasonable" rate. [n10] The procedure for setting rates may also be challenged if it is totally arbitrary or irrational and not related to any legitimate governmental purpose. [n11] The Supreme Court in modern times, however, has upheld as just and reasonable state regulation which effectively denies the regulated entity the fair market value of its goods and services. [n12]

This Article is divided into two central parts -- the first descriptive, the second normative. The Article discusses the foundation and extent of state police power to regulate rates. It also examines the permissible scope of rate regulation of private entities (including health care providers) by the state in the face of potential constitutional barriers. The

Article then takes a critical look at the present status of constitutional law doctrine in the areas of those economic rights described. Specifically, the Article focuses on state regulation of rates of health care providers or other private entities for goods and services below fair market value.

This Article concludes that the present judicial deference to rate regulation is constitutionally unwarranted and unnecessary. The Supreme Court has read the permissible scope of state police power far too broadly, while it has read the explicit constitutional prohibition against taking private property by the state much too narrowly. A reinvigorated application of the Constitution's explicit prohibition against state takings of private property without just compensation [n13] is necessary to prevent the state from setting rates below the fair market value of services provided. As applied to health care providers and Medicaid, the state should be prohibited from setting prices at which it purchases medical services below the fair market value of those services. Permitting states to do so legitimizes an unconstitutional taking of private property -- measured by the difference between the Medicaid reimbursement rate and the fair market value of the service -- without just compensation.

While the prospects for altering current judicial takings doctrine are slim, there is some hope the present Supreme Court may be more amenable to expanding the cramped constitutional protection now afforded to regulatory takings of private property.

RECOGNIZED STATE POWER TO REGULATE RATES AND RESTRICTIONS ON THAT POWER

States currently have the power to regulate rates. An examination of recent jurisprudence concerning the ability of states to regulate rates requires a review of two concepts: the constitutional basis and scope of state power [n14] and the restrictions the Constitution places on a state's exercise of this power. [n15] Courts today have held that the scope of state power to regulate is virtually unlimited. [n16] Constitutional restrictions on a state's power to regulate include due process, [n17] the prohibition on the impairment of contracts, [n18] and the prohibition on state taking of private property without just compensation. [n19]

The Police Power

Courts have consistently held that both the United States and Massachusetts Constitutions [n20] contain exceedingly broad grants of authority to regulate all aspects affecting the health, safety, morals and general welfare of the people. This includes the power to regulate rates charged by private entities such as health care providers. Prior to the New Deal, courts held limits existed on the subjects upon which states could regulate. [n21] Since that time, however, no challenge to a state's exercise of its police power has been successful.

The United States Constitution Grants Broad Authority to the States to Govern. The federal government is one of specifically enumerated powers; [n22] it can act only to effectuate the powers granted to it by the United States Constitution. In contrast, the federal Constitution does not specifically enumerate the powers granted to states. States have a general "police power," which is an inherent power to act to protect the general welfare. [n23] The ability of a state to act for the general welfare is a founding principle of the American governmental system; in the 1780s, James Madison wrote:

The powers delegated by the proposed Constitution to the federal government are few and defined. Those which are to remain in the state governments are numerous and indefinite. The former will be exercised principally on external objects, as war, peace, negotiation, and foreign commerce. . . . The powers reserved to the several States will extend to all the objects which, in the ordinary course of affairs, concern the lives, liberties, and properties of the people, and the internal order, improvement, and prosperity of the State. [n24]

The retention by the states of regulatory authority is derived from the Tenth Amendment of the United States Constitution, which provides, "[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." [n25]

State Constitution's Grant of Police Power Encompasses the Power to Regulate Rates. While all states possess the inherent authority under the United States Constitution known as the police power, [n26] many states include provisions to that effect in their own constitutions. [n27] The people have the power to define and/or limit in their state constitutions the scope of the police power inherently granted by the federal Constitution. In Massachusetts, the police power is generally attributed to Article 4 of the state constitution. [n28] This provision states:

And further, full power and authority are hereby given and granted to the said General Court, from time to time, to make, ordain, and establish, all manner of wholesome and reasonable Orders, laws, statutes, and ordinances, directions and instructions, either with penalties or without; so as the same be not repugnant or contrary to this Constitution, as they shall judge to be for the good and welfare of this Commonwealth, and for the government and ordering thereof, and of the subjects of the same. [n29]

Traditionally, courts have interpreted this provision as providing the authority for the state to prescribe regulations that promote the public health, safety, morals and general welfare. [n30] The validity of state exercise of the police power for these purposes has been universally accepted since the founding of the republic. [n31]

While the power of the Massachusetts legislature to act in the interest of public health is unquestioned, it does not necessarily follow that the regulation of hospital rates is an appropriate use of the police power. [n32] In determining whether state regulation is constitutionally valid, however, courts have applied an exceedingly deferential test. To constitute a valid exercise of the police power, regulation need only be rationally related to the promotion or preservation of public health, safety, morals or general welfare. [n33] Moreover, in determining whether the contested regulation rationally relates to a valid police power function, courts will consider every conceivable rationale for the regulation -- regardless of whether the rationale was actually considered by the legislature. [n34] In practice, application of this standard [n35] means that courts in Massachusetts rarely invalidate regulations on the ground that they exceed the state's police power. [n36]

Under the present standard, state regulation of hospitals would no doubt constitute valid exercises of the state's police power to regulate public health. The impetus for much of the existing regulation of the health care industry in Massachusetts was the need to reduce health care costs and improve efficiency. [n37] This is obviously the state's justification for paying lower than market rates for health care services. The state's desire to control rising health care costs would be a legitimate end, and the regulation of hospital finance in an attempt to control such costs -- whether or not this attempt is ultimately misguided -- is not irrational and therefore would be within the permissible bounds of state legislative authority.

Courts Have Accepted the Regulation of Hospital Costs as a Valid Exercise of a State's Police Power. Modern courts have accepted that the police power gives states the power to regulate the health care industry. In fact, the First Circuit examined aspects of the Massachusetts health care reimbursement structure and upheld it. [n38] In *Massachusetts Medical Soc'y v. Dukakis*, the practice of "balance billing" was at issue before the First Circuit. [n39] Massachusetts passed a law forbidding physicians from charging a Medicare beneficiary any amount in excess of the "reasonable charge." [n40] The court concluded that medical fee regulation was traditionally an area of state concern, and that the Massachusetts statute was not preempted by the federal Medicare Act. [n41]

Moreover, in *Massachusetts Nurses Ass'n v. Dukakis*, [n42] the plaintiffs challenged the Massachusetts Hospital Payment Law [n43] establishing a prospective reimbursement system for hospital costs. Plaintiffs alleged the hospital payment law interfered with the Labor Management Relations Act [n44] by giving state hospitals a negotiating advantage in collective bargaining. The district court described the Massachusetts Hospital Payment Law [n45] as "the result of an effort by the Massachusetts legislature to contain health care costs and to eliminate the perceived unfairness in the allocation of hospital costs among Medicaid and Medicare patients, Massachusetts Blue Cross, commercial insurers, and self-paying patients." [n46] The plaintiffs attacked the statute on several grounds, arguing that the level of rates set by the statute [n47] is largely dependent on the provisions of HA-29, an agreement negotiated between the Massachusetts Hospital Association and Blue Cross. [n48] The district court upheld the statute, reasoning:

. . . it is clear that the Massachusetts legislature has sought to regulate the amount of revenue that can be generated annually by the hospitals of the state. State regulation of hospital costs and other health care costs has become widespread and several states have regulatory schemes similar to the Massachusetts approach. The statute was clearly designed to put pressure on hospitals to cut costs and increase efficiency by decreasing the rate at which hospitals can increase their revenues. [n49]

The district court observed that the state legislature's right to regulate the health care industry was not directly challenged in the case. [n50] The court noted, however, that the plaintiffs were clearly trying to challenge the state's authority to regulate hospital health care rates in an indirect manner. In response, the court reasoned that Congress encouraged such state regulation, and that a valid state interest existed in regulating hospital rates. [n51]

Although *Massachusetts Nurses Ass'n* dealt with a challenge based on labor relations grounds, the district court opinion does a great deal to validate the Massachusetts system of regulating hospital finance. In affirming the district court's opinion, the First Circuit specifically recognized that the subject of hospital cost containment lay within the traditional police powers of the state. [n52] Subsequent decisions have cited *Massachusetts Nurses Ass'n* as authority for this principle. [n53]

After reviewing these recent federal cases, it is hard to imagine any law which a court would strike down on the ground that it went beyond the scope of a state's police power. Unfortunately, courts have all but abandoned constitutional review in this area.

DUE PROCESS

The Fourteenth Amendment to the United States Constitution, which was ratified in 1868, provides that no state shall "deprive any person of life, liberty, or property, without due process of law. . . ." [n54] Between 1897 and 1937 the Supreme Court, on many occasions, carefully scrutinized economic regulation adopted by federal and state governments. [n55] In applying due process, the Court evaluated the legitimacy of the legislation's objective and the means used to accomplish the objective. [n56] If the Court determined that the regulation would not serve its intended purpose or that a less restrictive means could achieve the same purpose, the law would not withstand constitutional scrutiny. [n57]

The end of serious scrutiny of economic regulation began with *Nebbia v. New York*, [n58] and economic due process terminated with the Court's decision in *West Coast Hotel v. Parrish*. [n59] *Nebbia*, which was a 5-4 decision, involved state setting of milk prices. [n60] In an attempt to protect milk producers, New York passed a law giving a milk control board vast powers to regulate the industry, including regulating prices at the retail level. The board was permitted to set retail prices at an amount sufficient to provide milk producers and dealers with a "reasonable return." [n61] The legislation's primary object was to improve the farmers' economic position. The board required milk to be sold at retail price of a minimum of nine cents per quart. Rejecting plaintiff's claim that the law violated his due process and equal protection rights, the Court held that "[i]f the laws passed are seen to have a reasonable relation to a proper legislative purpose, and are neither arbitrary nor discriminatory, the requirements of due process are satisfied. . . ." [n62]

Prior to *Nebbia*, substantive due process invalidated price restraints in all but unique circumstances. [n63] *Nebbia* signified a much more limited judicial scrutiny for economic regulation. [n46] Since *Nebbia*, courts require that the rate regulation in question only have a rational relation to a legitimate end, and not be arbitrary or impermissibly discriminatory. [n65]

Recent cases similarly articulate this deferential standard. For example, as recently as 1988 in *Dennell v. City of San Jose*, the Supreme Court stated a regulation violates due process only if it is "arbitrary, discriminatory, or demonstrably irrelevant to the policy the legislature is free to adopt." [n66] In the eyes of the Supreme Court, to withstand challenge a rate regulation need only be rationally related to any conceivable legitimate state interest. [n67] In practice, showing a violation of due process in the context of economic regulation is exceedingly difficult to make.

Importantly, the Supreme Court stated it will no longer analyze state rate regulation on substantive due process grounds. [n68] Thus, lower courts have shifted away from considering challenges to rate regulation on "substantive due process" grounds, and instead determine the validity of such regulations under the "takings clause" of the Fifth Amendment. [n69] As explained below, the current interpretation of the takings clause [n70] provides minimal protection against rate regulation. [n71]

IMPAIRMENT OF CONTRACTS

Article 1 section 10 of the United States Constitution provides that "No state shall . . . pass any . . . Law impairing the Obligation of Contracts." [n72] In 1827, however, the Supreme Court severely limited the application of this clause. In *Ogden v. Saunders*, the Court held the contracts clause applies only to existing contracts, not to the regulation of future ones. [n73]

The application of the contracts clause was further weakened in *Home Building & Loan Ass'n v. Blaisdell*, [n74] which limited the clause's application to the realm of existing contracts. *Blaisdell* involved a state law authorizing courts to extend temporarily the period of homeowner redemption from mortgage foreclosure sale. Despite the unambiguous language of the Constitution, the Court held the contracts clause limitation is "not an absolute one and is not to be read with literal exactness like a mathematical formula." [n75] The Court then applied a balancing test and sustained the legislation over a spirited dissent. [n76] The Court placed great weight on the state's use of its police power. Since *Blaisdell*, few attacks on regulation based on contracts clause grounds have succeeded. [n77]

Today, courts use the Supreme Court's three-part test to determine the constitutionality of state legislation impairing private contractual relationships. [n78] First, the reviewing court must assess the severity of the contractual impairment. [n79] The more severe the impact, the greater scrutiny the law is given. [n80] Substantial impairment may result even without a total destruction of contractual expectations. [n81] One consideration in determining substantial impairment is the extent to which reasonable expectations under the contract are disrupted. [n82]

Under the second step, if the law is found to cause severe substantial impairment, the court will assess the state's justification for the law. [n83] Regulation of existing contractual relationships must serve a "significant and legitimate" public purpose. [n84] "The requirement of a legitimate public purpose guarantees that the state is exercising its police power, rather than providing a benefit to special interests." [n85]

The final step involves determining whether the means chosen to achieve the public purpose are based "upon reasonable conditions and of a character appropriate to the public purpose justifying its adoption." [n86] Courts typically give deference to legislative judgment concerning the necessity and reasonableness of economic and social legislation which affects private contracts. [n87]

In practice, courts applying the standard articulated by the Supreme Court rarely find a law which violates the contracts clause. [n88] In fact, the First Circuit has stated that "with respect to the reasonableness and necessity of laws affecting private obligations, a very substantial if not total deference to legislative judgments is in order." [n89]

Two exceptions to this rule of judicial deference exist. The first exception involves regulations which serve to vitiate contracts between the state and private parties. [n90] The second involves regulations which retroactively adjust the obligations of contracting parties. [n91] In *United States Trust Company v. New Jersey*, [n92] the Supreme Court held the contract clause barred subsequent modification or elimination by a state of its own contractual financial obligations. The Court ruled in such circumstances, "complete deference to a legislative assessment of reasonableness and necessity is not appropriate because the state's self-interest is at stake." [n93] This case was the first Supreme Court case in nearly forty years to strike down legislation on contracts clause grounds. It appears courts will carefully scrutinize state regulation which impairs its own contractual obligations. [n94]

The second exception to deferring to state judgment involves regulations which retroactively adjust the obligations of contracting parties. In *Minnesota Ass'n of Health Care Facilities v. Minnesota Dept. of Pub. Welfare*, the court

refused to defer to the state's judgment regarding retroactive adjustment of contracts. [n95] The court was confronted with a state statute [n96] which regulated the amount **nursing homes** who participated in Medicaid could charge residents who did not receive state medical assistance. The court upheld the regulation against a contracts clause challenge to the extent that it operated prospectively; that is, fixing rates subsequent to its enactment. [n97] Part of the statute, however, required the **nursing homes** to return to residents funds collected for rates charged prior to the enactment of the legislation that were in excess of those set by the statute. [n98] The court held this part of the statute violated the contracts clause:

Because of its retroactivity, the statute imposes totally unexpected liability in **nursing homes** for charges that were permitted by law when collected. This statute goes too far because it disrupts settled and completed financial arrangements under contracts made in reliance on existing law. [n99]

Like *Minnesota Ass'n of Health Care Facilities*, other courts have found laws that unsettle settled rights can be harsh and they deserve a special scrutiny. [n100] In sum, contracts clause claims stand the best chance of success where a state modifies its own contractual obligations and where the regulation impairs contractual obligations on a retroactive basis. While there is no guarantee such claims will prevail, courts seriously scrutinize these regulations.

TAKINGS OF PRIVATE PROPERTY

What little serious court review of economic regulation has taken place since 1937, has occurred under the Constitution's takings clause. [n101] The clause, which is contained in the Fifth Amendment, provides "private property" shall not "be taken for public use, without just compensation." [n102] Takings claims have had some success where the state has appropriated land or other property. [n103] In the context of rate regulation, success has been much more limited. [n104] Moreover, the few cases involving rate regulation in the health care context have been unsuccessful. [n105]

Takings of Property

To establish a Fifth Amendment takings clause violation, the complaining party must show "property" was "taken," by the government in return for which there was not "just compensation." [n106] When the government takes a specific piece of property outright under its eminent domain powers, the state is required to compensate the owner with the fair market value for the property. [n107] When a regulation merely lessens the value of the property, however, courts look to see if there is an economically viable use left for the property. [n108] In *Penn Central Transportation Co. v. New York City*, [n109] the Court concluded application of a landmark law which resulted in a substantial devaluation of a parcel of land in New York City was not a taking and, therefore, just compensation was not required. The *Penn Central* test requires a court to analyze the character of the government action, looking first at whether the interference with property can be characterized as a physical invasion. [n110] If not, the Court must analyze the economic impact of the regulation and, particularly, the extent to which the regulation has interfered with distinct, investment-backed expectations. [n111] Under this standard, many regulations which interfere with the economic value of someone's property are constitutional.

Rate Regulation as a Taking

Regulatory takings claims most often occur in the areas of public utilities, worker's compensation, railroads, gasoline and other commodities subject to extensive regulation by the state. [n112] As pointed out above, the Supreme Court has indicated rate regulation challenges are more appropriately analyzed under the takings clause, rather than the due process clause. [n113] In cases involving rate regulation of public utilities, the Supreme Court has held that regulated rates must be "just and reasonable" to be constitutional. [n114] A rate that is so "unjust" as to be "confiscatory" constitutes a taking within the meaning of the fifth amendment. [n115] Following the Supreme Court, the First Circuit required:

regulated rates must be "just and reasonable" in order to be constitutional. To be just and reasonable, rates must

provide not only for a **company's** costs, but also for a fair return on investment. Rates which fall below this standard are "confiscatory." [n116]

Rate Regulation in the Health Care Context

Although the Supreme Court has never heard a rate regulation case involving health care, several lower courts have heard such cases. [n117] In *Minnesota Ass'n of Healthcare Facilities v. Minnesota Dep't of Pub. Welfare*, a constitutionality of a Minnesota statute was challenged. [n118] The statute limited the rates which **nursing homes** could charge residents who did not receive state medical assistance benefits as a condition of participation in the state's Medicaid program. The plaintiffs relied unsuccessfully upon theories of substantive due process, [n119] equal protection, [n120] and impairment of contract. [n121] The plaintiffs also argued that the rate limits, in combination with an inadequate level of Medicaid reimbursement from the state, resulted in a taking of their property without just compensation. [n122] In making this argument, they relied upon Supreme Court precedent in the area of regulation of utility rates, specifically the case *Bluefield Water Works and Improvement Co. v. Public Service Comm'n.* [n123]

Rejecting the application of this line of cases, the Minnesota court found that **nursing homes**, unlike public utilities, have the freedom to decide whether to remain in business. [n124] Consequently, they subject themselves voluntarily to the limits on investment returns imposed by Minnesota. The court further held that participation in the Medicaid program is also voluntary despite business realities which indicate otherwise. [n125] The allegedly voluntary nature of the **nursing home's** decision led to the court's conclusion that the takings clause did not apply. After applying the rational relationship test, the court concluded:

the Minnesota Legislature could reasonably find that differences in rates for the same **nursing home** services, depending wholly upon whether or not a resident received medical assistance, are inimical to the public welfare and thus it could properly choose to regulate the rates that **nursing homes** participating in Medicaid charged the residents who do not receive medical assistance. [n126]

Cases subsequent to *Minnesota Association* reiterate the view that government price regulation does not constitute a taking of property where the regulated group is not required to participate in the regulated industry. [n127] For example, *Whitney v. Heckler* involved a challenge to the constitutionality of a statutory freeze on what nonparticipating physicians could charge their Medicare patients. [n128] Plaintiffs argued that because they chose not to participate in the Medicare program, they could not be said to have voluntarily agreed to be bound by the regulation and, therefore, *Minnesota Association* was distinguishable. Rejecting this argument, the district court noted the plaintiffs were voluntarily treating Medicare patients even though they had the option of refusing to do so and "thus being able to raise fees to all their patients without penalty." [n129]

TOWARD A REINVIGORATED "TAKINGS" ANALYSIS

After reviewing the standards courts apply to review governmental regulation, this Article will now argue that the present day constitutional doctrine regarding the extent of state police power and the lack of restrictions on the permissible use of that power is flawed. While the constitutional legitimacy of modern jurisprudence surrounding the police power and the due process clause is questionable, the Supreme Court's cramped reading of the takings clause is clearly the most suspect. Any challenge to state rate regulation of health care providers, therefore, would stand the best chance of success by arguing that an unconstitutional taking without just compensation occurs when the state requires hospitals to sell services to the state below the prevailing market rate.

THE RENEGADE POLICEMAN

Although not explicitly mentioned in the United States Constitution, the police power of the state has long been a part of the constitutional landscape. [n130] The Supreme Court described the legitimate scope of state regulation under its inherent police power in *Lochner v. New York*. [n131] The Court explained that the state possessed:

. . . certain powers, existing in the sovereignty of each state in the Union, somewhat vaguely termed police powers, the exact description and limitation of which have not been attempted by the courts. Those powers, broadly stated and without, at present, any attempt at a more specific limitation, relate to the safety, health, morals, and general welfare of the public. [n132]

One need not quarrel with this formulation to conclude that the state's confiscation of services provided by health care providers is beyond the legitimate police power of the state. A central function of government in a representative democracy is to maintain peace and order in society. Regulations dealing with preventing physical harm to members of society and threats to public health and morals are undoubtedly within the broad power outlined in *Lochner*, as are other regulations dealing with the "general welfare" of the people. Courts have erred, however, in construing the police power as an unlimited grant of power to legislatures to act in what they perceive to be the public interest. Regulating the price a state will pay for services provided by hospitals goes far beyond any legitimate use of police power.

A Massachusetts federal district court held the purpose of rate setting is to regulate the amount of revenue generated annually by state hospitals where such regulation is designed to pressure hospitals to cut costs and increase efficiency by decreasing the rate at which hospitals can increase their revenues. [n133] However, regardless of whether the stated purpose is the true purpose of the regulation, the undeniable effect of rate setting is to allow the state to purchase health care services below the fair price. [n134] As the *Lochner* Court stated: "whether [a statute] is or is not repugnant to the Constitution of the United States must be determined from the natural effect of such statutes when put into operation, and not from their proclaimed purpose." [n135] Thus, notwithstanding the stated purpose of the rate regulation, its practical effect leads one to conclude rate setting is not a legitimate use of a state's powers.

Moreover, the rationale used by courts to uphold rate setting in the Medicaid context could logically be extended to justify rate setting for all goods and services the state purchases from private entities. Does a state have the power to force milk suppliers to sell it milk at a price below its fair market value? Could a state force public utilities to sell it utility services below fair market value? What about gasoline for state vehicles or food for state prisons? The cases strongly imply that the answers are yes. In fact, since *Lochner*, no reported case has invalidated state regulation on the ground that it exceeded the state's police power.

In each of these instances, the state may be said to be acting for the general welfare of the people. Health care providers, milk producers, utility **companies**, gas stations and all others the state could be forced to sell products or services below fair market value would have to absorb the difference between fair market value and the price paid by the state. The only free rider is the state.

Unlike later courts, [n136] the *Lochner* Court required more than a mere assertion by the legislature that a law promoted the "public health or welfare." [n137] The *Lochner* Court did not "shut [its] eyes to the fact that many of the laws of this character, while passed under what is claimed to be the police power for the purpose of **protecting** the public health or welfare, are, in reality, passed from other motives." [n138]

When a state acts as policeman, it should play by the rules in force for others, or required to do so by the courts. If other purchasers pay fair value for services provided by health care providers, then a state should not demand that it receive the same services for less. It is time for courts to once again take seriously the principle that constitutional limits to state police power do exist.

GIVING PROCESS ITS DUE

As discussed above, not since the 1930s has the Supreme Court found an economic regulation to violate the due process clause of the Constitution. The reason is simple: the standard by which the Court evaluates the validity of economic regulation under the clause has been greatly narrowed. Courts uphold economic regulation for it exists.

This point was aptly illustrated in *Williamson v. Lee Optical*. [n139] *Lee Optical* upheld, against a due process and equal protection challenge, a law requiring a written prescription from an optometrist or an ophthalmologist before an

optician could legally fit old lenses into a new frame. Justice Douglas noted while the law would create a "needless, wasteful requirement in many cases," the legislature might have concluded it was necessary to protect the public health, although there were no legislative findings to that effect. [n140]

Criticizing the decision as wrongly decided, federal judge Richard Posner stated: "a state statute that, on grounds of public health, forbids opticians to replace eyeglass frames without a prescription signed by an optometrist or ophthalmologist can have no real purpose other than to increase the income of optometrists and ophthalmologists at the expense of opticians -- and consumers." [n141] The alleged public health rationale in *Lee Optical* was a smoke screen for a law benefitting a special interest. The public health rationale promoted by the state of Massachusetts to sustain its rate-setting legislation [n142] likewise bears no real relation to the public health and is no more than a smoke screen for a regulation benefitting the state. Yet the judicial deference to legislative judgment defined in *Lee Optical* remains the present law of the land.

Soon after the Supreme Court abandoned serious review of economic regulation, it began stringently reviewing legislation impacting "fundamental" rights and interests. [n143] For example, if a state law limits free speech, race, voting or privacy, the state has the burden to demonstrate the law serves a compelling state interest. [n144] Today, there exists a "vast gulf separating judicial treatment of government regulation affecting expression and that affecting production and distribution of goods and services." [n145]

Professor Siegan, along with numerous other commentators, has argued the judicial bifurcation in the treatment of individual and economic liberties is untenable and unprincipled. [n146] The constitutional provisions safeguarding economic liberty are part of the same Bill of Rights as those safeguarding individual liberty. The provisions prohibiting impairment of contracts and takings of private property are more specific than due process or equal protection protections. Moreover, economic liberty is individual liberty; any dividing line is simply artificial.

Finally, a state's dual role as purchaser and price setter should trigger heightened due process scrutiny. In *United States Trust Co. of New York v. New Jersey*, the Supreme Court held "a state cannot refuse to meet its legitimate financial obligations simply because it would prefer to spend the money to promote the public good rather than the private welfare of its creditors." [n147] The Court required the law be "reasonable and necessary" to serve an "important" purpose and held the law in question was not necessary. [n148] Although the New Jersey case was decided under the Constitution's "impairment of contracts" clause, [n149] the same reasoning should apply under the due process clause where a state refuses to pay health care providers fair value for their services on the ground that it prefers to spend the money elsewhere. The state should be forced to show that inadequate Medicaid reimbursement rates are "necessary" to keep hospital costs under control and keep hospitals efficient. Under this test, if a less stringent alternative exists, the inadequate rates would not survive.

The Court's continuing selective application of the due process clause to certain rights while ignoring others is inexcusable. Yet, it is also true that the Constitution's specific prohibition against governmental takings without just compensation [n150] provides a more principled vehicle to invalidate regulations by the state than an amorphous "due process" clause. [n151] Also, the Supreme Court has directed lower courts to consider regulatory claims under a takings clause analysis. [n152]

REQUIRING JUST COMPENSATION -- THE STATE MEDICAID MONOPSONY

The market power of a large buyer is called monopsony power. [n153] A buyer's monopsony power is in many ways analogous to a seller's monopoly power. [n154] A monopolist uses its power to raise the price of a product it sells. [n155] At the monopoly price, a monopolist sells less, but earns a greater total profit than a competitor could earn. [n156] Alternatively, a monopsonist uses its power to lower the price it pays for services it buys. The monopsonist, however, is usually not free to choose the most advantageous combination of price and quantity. Rather, the monopsonist must offer a price high enough to purchase the quantity it needs; if the price is too low, too many providers will leave the market.

In the Medicaid reimbursement area, states act as monopsonists, using the force of the state to pay less than the competitive price for the services purchased. Rather than go out of business, health care providers continue to deal with Medicaid so long as they are able to recover their costs plus a small rate of return on recoverable capital. As one commentator has argued:

[u]ltimately, monopsony is self-defeating. Unless providers selling to Medicaid make a normal profit, no new capital will be invested in health care facilities for Medicaid patients. Thus the state will someday have to raise its price in order to maintain a source of supply. The state budget process, however, usually looks only to short-run problems, and in the short run monopsonistic rate setting benefits the state. . . . Providers can legitimately object that monopsony is not an equitable way to finance Medicaid programs. . . . [n157]

As a matter of constitutional law under the Fifth Amendment's Takings clause, [n158] a distinction should be made between industries that utilized government intervention to achieve a lofty market, or even a monopoly position, and those that did not. For example, railroads and utilities typically utilized the force of a state in obtaining land grants, exercising private rights of condemnation and utilizing public rights of way.

In sharp contrast, other forms of regulation seek to limit the profits of individual firms whose gains do not depend upon the state's exercise of the eminent domain power. Today the dominant response is to ignore the distinction and to assume rate regulation is justified as a matter of principle, without regard to how the regulated party came by its advantages. This unwillingness to pass on the merits of comprehensive economic regulation is clearly reflected in the case law: "challenges to comprehensive economic regulation are typically dismissed with the back of the hand and an invocation of the ghost of *Lochner*." [n159] Critics such as Professor Epstein feel a closer examination of such regulation is needed. [n160]

Simply put, when a state confers a benefit to a regulated entity, this benefit may closely approximate the cost to the entity of the state's rate setting at below market value. Health care providers, however, receive no such benefit to offset a state's inadequate Medicaid reimbursement. Thus, a health care provider can appropriately question why it should be forced to accept the price at which state wishes to pay for services. If the price of its services in the marketplace exceeds the state mandated price, then the provider has made a prima facie showing that it is entitled to compensation equal to the difference between what the market will bear for its services and the price the state is forcing the health care provider to accept. Otherwise the Constitution's Takings clause is mere surplusage, without the power to prevent confiscation backed by the coercive power of the state.

Why have courts not adopted this common sense view of the Takings clause? In large part the answer is political: courts do not wish to substitute their judgment for that of the legislature. [n161] Yet, such an argument allows the fox to guard the henhouse, since the state itself is the direct purchaser of health care services. The argument also ignores the Constitution's explicit prohibition of taking private property for a public purpose without just compensation.

Courts have also attempted to avoid the takings problem by ruling despite business realities, that health care providers participate in Medicaid voluntarily and thus no state taking exists. [n162] In *Minnesota Ass'n of Health Care Facilities v. Minnesota Dep't of Public Welfare* the court stated "[i]f appellants find that the reimbursement rates are insufficient, then they may either make their [facilities] more efficient and economical or terminate their relationship with Medicaid and no longer accept Medicaid recipients." [n163]

Whatever the merits of this position in other states, it is inapplicable in Massachusetts. Massachusetts hospitals must treat all patients, at least in emergency rooms, irrespective of their ability to pay. [n164] If a hospital participates in Medicaid, it may be compensated, in whole or in part, for its services. If not, the hospital receives only what the patient is able to pay, which is little or nothing in most instances. Thus, in Massachusetts, a hospital does not have the alternative of refusing to participate in any government programs in order to sell its services to the public at a fair market rate. [n165] In a very real sense, a Massachusetts hospital either accepts the state's rates or goes out of business.

CONCLUSION

Today, health care providers are guaranteed no more than a reasonable rate of return for their services, rather than what the market will bear. Beyond reasonableness, the only meaningful restriction on a state's rate setting authority is that rates can not be set retroactively. This judicial deference to a state's rate setting authority is unfair to hospitals and health care providers and should be abandoned for a more restrictive approach. A state abuses its police power and acts without affording due process when it forces private entities to sell services below their fair market value to the state. A reinvigorated application of the Constitution's explicit prohibition against government takings without just compensation would prevent this injustice. Short of this, political action represents the best hope for changing the status quo.

REFERENCE: [n2.] MASS. ANN. LAWS ch. 117, § 24A.

[n1.] MASS. ANN. LAWS ch. 111, § 25C (Law. Co-op. 1993).

[n3.] MASS. ANN. LAWS ch. 117, § 24.

[n4.] See infra note 134 and accompanying text.

[n5.] See infra note 12 and accompanying text.

[n6.] See infra notes 58-65 and accompanying text.

[n7.] See infra notes 33 and 36 and accompanying text.

[n8.] See infra notes 106-114 and 73-88 and accompanying text.

[n9.] See infra notes 123 and accompanying text.

[n10.] See infra notes 114 and accompanying text.

[n11.] See infra notes 66-67 and accompanying text.

[n12.] See infra notes 113-115 and accompanying text.

[n13.] See infra note 106 and accompanying text.

[n14.] See infra note 131 and accompanying text.

[n15.] See infra note 25 and accompanying text.

[n16.] See infra notes 33-36 and accompanying text.

[n17.] See infra note 25 and accompanying text.

[n18.] See infra notes 72-100 and accompanying text.

[n19.] See infra notes 101-111 and accompanying text.

[n20.] See infra notes 32-36 and accompanying text.

[n21.] See, e.g., THOMAS M. COOLEY, A TREATISE ON THE CONSTITUTIONAL LIMITATIONS WHICH REST UPON THE LEGISLATIVE POWER OF THE STATES OF THE AMERICAN UNION (DaCapo Press 1972)

(1868); see also ERNEST FREUND, *THE POLICE POWER, PUBLIC POLICY AND CONSTITUTIONAL RIGHTS* (Arno Press 1976) (1904); CHRISTOPHER G. TIEDEMAN, *A TREATISE ON THE LIMITATIONS OF POLICE POWER IN THE UNITED STATES* (DaCapo Press 1971) (1886).

[n22.] U.S. Const.

[n23.] JOHN E. NOWAK ET AL., *CONSTITUTIONAL LAW* 121 (1986).

[n24.] *THE FEDERALIST NO. 45*, at 238-39 (J. Madison) (Max Beloff ed., 1948).

[n25.] U.S. CONST. Amend. X. While the police power allows each state the power to regulate, it does not require any state to exercise that power in any given area. Differences in health care regulation among the states are attributable to this federalistic nature of our government rather than differences in state authority.

Massachusetts is therefore free to regulate the health care industry extensively, while regulation in other states is much less extensive. For example, Arizona, a state with minimal regulation of the health care industry, recognizes the promotion of the public health, safety, and welfare is an appropriate use of the police power. *American Federation of Labor v. American Sash & Door Co.*, 189 P.2d 912 (Ariz. 1948), *aff'd*, 335 U.S. 538 (1949); *Arizona State Liquor Bd. of Dep't of Liquor Licenses and Control v. Ali*, 550 P.2d 663 (Ariz. Ct. App. 1976). Arizona legislators evidently feel the public welfare is served by less, not more, regulation of the health care industry.

In sum, the fundamental authority to enact regulations such as those in Massachusetts does not vary from state to state. Rather, the differences lie in the varying extent to which state governments exercise their police power in the area of health care regulation.

[n26.] See *supra* note 25 and accompanying text.

[n27.] See *supra* note 25 and accompanying text.

[n28.] See *supra* note 25 and accompanying text.

[n29.] MASS. CONST. pt. 2, c. 1, § 1, art. 4.

[n30.] See, e.g., *Commonwealth v. Town of Hudson*, 52 N.E.2d 566 (Mass. 1944); *McMurdo v. Getter*, 10 N.E.2d 139 (Mass. 1937); *Commonwealth v. Libbey*, 103 N.E. 923 (Mass. 1914).

[n31.] See *supra* note 25.

[n32.] The second half of this Article argues such regulation may not be a valid exercise under the police power. See *infra* notes 130-138 and accompanying text.

[n33.] See, e.g., *Merit Oil Co. v. Director of Div. on Necessaries of Life*, 65 N.E.2d 529 (Mass. 1946); *Commonwealth v. Houtenbrink*, 126 N.E. 669 (Mass. 1920).

[n34.] See, e.g., *Marshal House, Inc. v. Rent Control Bd. of Brookline*, 358 Mass. 686, 266 N.E.2d 876 (1971); *Merit Oil*, 65 N.E.2d 529.

[n35.] At times, some Massachusetts courts have suggested a tougher standard. For example, in *M. H. Gordon & Son, Inc. v. Alcoholic Beverage Control Comm'n*, 358 N.E.2d 778, 785 (Mass. 1976), the Massachusetts Supreme Court stated that the validity of a particular law as an exercise of the police power turns on whether it "bears a real and substantial relation to the public health, safety, morals, or some other phase the general welfare." At the same time, however, the Court held it would make "all rational presumptions" in favor of the law and a law would be invalidated only when "it is in manifest excess of legislative power." Thus, while the "real and substantial" language sounds tough,

the vigor with which it is enforced is diminutive.

[n36.] See supra note 35 and accompanying text.

[n37.] See Mass. H.R. 5240 (1991).

[n38.] *Massachusetts Medical Soc'y v. Dukakis*, 815 F.2d 790 (1st Cir.), cert. denied, 484 U.S. 896 (1987).

[n39.] *Id.*

[n40.] MASS. ANN. LAWS ch. 112, § 2 (Law Co-op. 1993).

[n41.] *Massachusetts Medical Soc'y*, 815 F.2d at 791.

[n42.] *Massachusetts Nurses Ass'n v. Dukakis*, 570 F.Supp. 628 (D. Mass. 1983), *aff'd*, 726 F.2d 41 (1st Cir. 1984).

[n43.] MASS. CODE ch. 6A §§ 31 (West 1993).

[n44.] 29 U.S.C. §§ 141 (1988).

[n45.] *Massachusetts Nurses Ass'n*, 570 F. Supp. at 629-32.

[n46.] *Id.* at 632.

[n47.] *Id.* at 634.

[n48.] *Id.*

[n49.] *Id.* at 636. Consistent with the usual deference by courts to legislative judgments in the area of economic regulation, the issue of whether the regulation, rather than the free market, best accomplishes the goals of cutting costs and increasing efficiency was not addressed by the court.

[n50.] *Id.* at 638.

[n51.] *Id.* at 640.

[n52.] *Massachusetts Nurses Ass'n v. Dukakis*, 726 F.2d 41, 44 (1st Cir. 1984).

[n53.] See *York Hosp. v. Maine Health Care Fin. Comm'n*, 719 F. Supp. 1111, 1118 (D. Me. 1989); *Massachusetts Medical Soc'y v. Dukakis*, 815 F.2d 790, 791 (1st Cir.), cert. denied, 484 U.S. 896 (1987).

[n54.] U.S. CONST. amend. XIV, § 1.

[n55.] See *Algeyer v. Louisiana*, 165 U.S. 578 (1897); *Jacobson v. Massachusetts*, 197 U.S. 11 (1905); *Lochner v. New York*, 198 U.S. 45 (1905); *Tyson & Bro. United Theatre Ticket Offices v. Banton*, 273 U.S. 418 (1927).

[n56.] See *Lochner*, 198 U.S. at 45.

[n57.] *Id.*

[n58.] *Nebbia v. New York*, 291 U.S. 502 (1934).

[n59.] *West Coast Hotel v. Parrish*, 300 U.S. 379 (1937).

[n60.] 291 U.S. 502 (1934).

[n61.] Id. at 516.

[n62.] Id. at 537.

[n63.] See, e.g., *Tyson & Bro. United Theatre Ticket Offices v. Banton*, 273 U.S. 418 (1927).

[n64.] The end of serious Supreme Court scrutiny of economic and social legislation is associated with the Supreme Court's 1937 decision in *West Coast Hotel v. Parrish*, 300 U.S. 379 (1937). In upholding a minimum wage law for women, the Court reasoned the liberty protected by the Fourteenth Amendment is not individual freedom, but rather freedom to pass laws: "the liberty safeguarded is liberty in social organization, which requires the protection of law against the evils which menace the health, safety, morals, and welfare of the people." Id. at 391.

[n65.] See, e.g., *North Dakota State Bd. of Pharmacy v. Snyder's Drug Stores, Inc.*, 414 U.S. 156 (1973); *Ferguson v. Skrupa*, 372 U.S. 726, 730 (1963).

[n66.] *Pennell v. City of San Jose*, 485 U.S. 1, 11 (1988).

[n67.] *Tenoco Oil Co. v. Department of Consumer Affairs*, 876 F.2d 1013 (1st Cir. 1989).

[n68.] See *Williamson v. Lee Optical of Oklahoma*, 348 U.S. 483 (1955).

[n69.] *Duquesne Light Co. v. Barasch*, 488 U.S. 299 (1989); *Tenoco*, 876 F.2d at 1020-21.

[n70.] U.S. CONST. amend. V.

[n71.] See *infra* notes 101-111 and accompanying text.

[n72.] U.S. CONST. art. I, § 10, cl. 1.

[n73.] 25 U.S. 213 (1827).

[n74.] 290 U.S. 398 (1934).

[n75.] Id. at 428.

[n76.] Id. at 436.

[n77.] See, e.g., *East New York Sav. Bank v. Hahn*, 326 U.S. 230 (1945); *United States Trust Co. of New York v. New Jersey*, 431 U.S. 1 (1977).

[n78.] See, e.g., *NOWAK*, *supra* note 23, at 382. *Energy Reserves Group v. Kansas Power & Light*, 459 U.S. 400 (1983).

[n79.] *Energy Reserves Group*, 459 U.S. at 411.

[n80.] Id.

[n81.] Id.

[n82.] Id.

[n83.] Id. at 411-412.

[n84.] *Allied Structural Steel Co. v. Spannaus*, 438 U.S. 234 (1978).

[n85.] Energy Reserves Group, 459 U.S. at 412.

[n86.] United States Trust Co. of New York v. New Jersey, 431 U.S. 1, 22 (1977).

[n87.] Energy Reserves Group, 459 U.S. at 412-13.

[n88.] See, e.g., Exxon Corp. v. Eagerton, 462 U.S. 176 (1983); Keystone Bituminous Coal Ass'n v. DeBenedictis, 480 U.S. 470 (1987).

[n89.] Kargman v. Sullivan, 582 F.2d 131, 134 (1st Cir. 1978).

[n90.] Id.

[n91.] Id.

[n92.] United States Trust Co. v. New Jersey, 431 U.S. 1 (1976), reh'g denied, 431 U.S. 975 (1977).

[n93.] Id. at 26.

[n94.] The second half of this Article argues that similar scrutiny should apply when the state acts as both purchaser and price setter. See *infra* note 13b and accompanying text.

[n95.] Minnesota Ass'n of Health Care Facilities v. Minnesota Dep't of Pub. Welfare, 742 F.2d 442 (8th Cir. 1984), cert. denied, 469 U.S. 1215 (1985).

[n96.] Id. at 445.

[n97.] Id. at 450.

[n98.] Id.

[n99.] Id. at 451.

[n100.] Adams **Nursing Home** of Williamstown v. Mathews, 548 F.2d 1077, 1080 (1st Cir. 1977). See also, Allied Structural Steel Co. v. Spannaus, 438 U.S. 234 (1978) (law retroactively modifying payment obligations assumed by plaintiff **company** held invalid).

[n101.] COOLEY, *supra* note 21.

[n102.] Although the Fifth Amendment on its face applies only to constrain the federal government, it has been applied to the states through the Fourteenth Amendment. See, e.g., Tenoco Oil Co. v. Dep't of Consumer Affairs, 876 F.2d 1013, 1023 (1st Cir. 1989); Chicago, B. & Q. R.R. v. Chicago, 166 U.S. 226 (1897).

[n103.] See, e.g., Lucas v. South Carolina Coastal Council, U.S. 112 S. Ct. 2886 (1992).

[n104.] See *infra* notes 114-116 and accompanying text.

[n105.] See *infra* notes 117-129 and accompanying text.

[n106.] U.S. CONST. amend. V. Takings include intangible as well as tangible property. See Ruckelhaus v. Monsanto, 467 U.S. 986 (1984) (trade secrets, and other intangible property are property for purposes of takings clause).

[n107.] United States v. Reynolds, 397 U.S. 14, 25 (1970).

[n108.] *Loretto v. Teleprompter Manhattan CATV*, 458 U.S. 419, 430 (1982).

[n109.] *Penn Central Transp. Co. v. New York City*, 438 U.S. 104 (1978).

[n110.] *Id.* at 124.

[n111.] *Id.*

[n112.] See, e.g., *Penn Central Transportation v. New York*, 438 U.S. 104 (1978) (landmark regulation of railroad station); *Keystone Bituminous Coal Ass'n v. DeBenedictis*, 480 U.S. 470 (1987) (regulation of coal under the surface of land).

[n113.] See, e.g., *Duquesne Light Co. v. Barasch*, 488 U.S. 299 (1989).

[n114.] See, e.g., *Duquesne Light Co.*, 488 U.S. at 315; *Tenoco Oil Co. v. Dep't of Consumer Affairs*, 876 F.2d 1013, 1020 (1st Cir. 1989).

[n115.] *Duquesne Light Co.*, 488 U.S. at 315, *Tenoco*, 876 F.2d at 1020.

[n116.] *Tenoco*, 876 F.2d at 1020.

[n117.] See *infra* note 10b, 10c.

[n118.] *Minnesota Ass'n of Health Care Facilities v. Minnesota Dep't of Pub. Welfare*, 742 F.2d 442 (8th Cir. 1984), cert. denied, 469 U.S. 1215 (1985).

[n119.] *Id.* at 445.

[n120.] *Id.* at 447.

[n121.] *Id.* at 448.

[n122.] *Id.* at 445.

[n123.] 262 U.S. 679 (1923).

[n124.] *Minnesota Ass'n of Health Care Facilities*, 742 F.2d at 446.

[n125.] *Id.*

[n126.] *Id.* at 447.

[n127.] See *Whitney v. Heckler*, 780 F.2d 963 (11th Cir.) cert. denied, 479 U.S. 813 (1986); *American Medical Ass'n v. Bowen*, 659 F. Supp. 1143 (N.D. Tex. 1987); *Idaho Healthcare Ass'n v. Sullivan*, 716 F. Supp. 464 (D. Idaho 1989).

[n128.] 603 F. Supp. 821, 823 (N.D. Ga. 1985).

[n129.] *Id.* at 827.

[n130.] See, e.g., *Brown v. Maryland*, 25 U.S. 419, 443 (1827).

[n131.] *Lochner v. New York*, 198 U.S. 45 (1905).

[n132.] *Id.* at 53.

[n133.] *Massachusetts Nurses Ass'n v. Dukakis*, 570 F. Supp. 628 (Mass. Dist. Ct. 1983). One certainly could question whether such rate setting achieves its desired effect. Moreover, there is evidence that low levels of Medicaid reimbursement will have unintended effects -- namely, leaving the poor with few alternatives to the so-called "Medicaid Mills," i.e., low priced, low quality clinics serving only state-supported patients. Mitchell D. Raup, *Medicaid Boycotts by Healthcare Providers: A Noerr-Pennington Defense*, 69 IOWA L. REV. 1393, 1414 n.149 (1984). Today, "[m]any Medicaid patients often seek care in overcrowded hospital emergency rooms because they cannot find doctors willing to treat them." *Doctors Dropping Medicare Patients*, N.Y. Times, Apr. 12, 1992 at A1, A16.

[n134.] Additionally, it is quite likely that rather than making hospitals more efficient, such pervasive regulation has the opposite effect. One of the tragedies of modern jurisprudence is that courts will not take a fresh look and determine whether the asserted purpose will meet the desired objective. See Part I, *supra*. Rather, the regulation need only be rationally related to a legitimate end.

[n135.] *Lochner*, 198 U.S. at 64.

[n136.] See, e.g., *Pennell v. City of San Jose*, 485 U.S. 1, 11 (1988).

[n137.] *Lochner*, 198 U.S. at 53.

[n138.] *Id.* at 64.

[n139.] 348 U.S. 483 (1955).

[n140.] *Id.* at 487.

[n141.] RICHARD A. POSNER, *ECONOMIC ANALYSIS OF LAW* 271 (1972).

[n142.] MASS. GEN. LAWS ANN. ch. 6A, § 31 (West 1993).

[n143.] See, e.g., *Skinner v. Oklahoma*, 316 U.S. 535 (1942) (upholding procreation as a fundamental right).

[n144.] See, e.g., *Kramer v. Union Free School District*, 395 U.S. 621 (1969) (analysis of compelling state interest in the context of voting). See also *Griswold v. Connecticut*, 381 U.S. 479 (1965) (fundamental right to privacy).

[n145.] BERNARD H. SIEGAN, *ECONOMIC LIBERTIES AND THE CONSTITUTION* (1980).

[n146.] See, e.g., RICHARD A. EPSTEIN, *PRIVATE PROPERTY AND THE POWER OF EMINENT DOMAIN* (1985); Houle, *Eminent Domain, Police Power and Business Regulation: Economic Liberty and the Constitution*, 92 W. VA. L. REV. 51 (1989); Philips, *Another Look at Economic Substantive Due Process*, 1987 WISC. L. REV. 265.

[n147.] 431 U.S. 1, 28-29 (1977).

[n148.] *Id.* at 29.

[n149.] *Id.* at 17.

[n150.] U.S. CONST. Amend. V.

[n151.] *Id.*

[n152.] See *Duquesne Light Co. v. Barasch*, 488 U.S. 299 (1989).

[n153.] Mitchell D. Raup, *Medicaid Boycotts by Healthcare Providers: A Noerr-Pennington Defense*, 69 IOWA L. REV. 1393, 1396 (1984).

[n154.] Id.

[n155.] Id.

[n156.] Id.

[n157.] Id. at 1396-7.

[n158.] U.S. CONST. Amend. V ("... nor shall private property be taken for public use, without just compensation").

[n159.] RICHARD A. EPSTEIN, PRIVATE PROPERTY AND THE POWER OF EMINENT DOMAIN (1985).

[n160.] Id.

[n161.] See, e.g., *Williamson v. Lee Optical of Oklahoma*, 348 U.S. 483 (1955).

[n162.] See, e.g., *Minnesota Ass'n of Health Care Facilities v. Minnesota Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir, 1984).

[n163.] Id.

[n164.] MASS. GEN. LAWS ANN. ch. 111, § 51D (West 1993).

[n165.] The Eighth Circuit Court of Appeals has noted that a provider could "choose" to go out of business altogether. This so-called "choice," however, is "the type of Hobson's choice that could scarcely be called voluntary." *Liberty Mutual Ins. Co. v. Janes*, 586 A.2d 536 (R.I. 1991). It should have no impact on the question of whether a compensable taking has occurred. #LS930830SP# #LS930902LEufishmx# #LS931105SP# #LS931105LEuholls#

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TITLE: NOTES AND COMMENTS: Section 525(a) of the Bankruptcy Code Plainly Does Not Apply to Medicare Provider Agreements

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TEXT:

ABSTRACT: Section 525(a) of the Bankruptcy Code prevents government entities from discriminating against debtors based on the debtor's bankruptcy filing. This Article analyzes how this provision is applied to healthcare providers who file for bankruptcy. Some commentators have expressed concerns that because of Section 525, the federal government is unable to deny a bankrupt provider a new Medicare provider agreement due to the debtor's failure to pay debts discharged during bankruptcy. This Article, however, argues that Section 525 does not apply to a provider agreements because it is not a "license, permit, charter, franchise, or other similar grant" as defined by the statute. Therefore, the author concludes that debtor healthcare providers should not be allowed back into the Medicare program without first paying their statutorily required debts.

Section 525(a) of the Bankruptcy Code n1 has the lofty goal of preventing debtors from being discriminated against by government entities because of the debtor's bankruptcy filing and thus thwarting the debtor's chance for the fresh start a bankruptcy filing is meant to provide. n2 In recent years, the onslaught of bankruptcy filings by healthcare providers, n3 including hospitals and **nursing homes**, has raised the concern of whether the federal government is able to deny a bankrupt healthcare provider a new Medicare provider agreement due to the debtor's failure to pay debts discharged during bankruptcy. This question is important because Medicare recipients often comprise a large portion of a debtor's patients. n4 Thus, losing the provider agreement, and the ability to serve these patients, can represent a significant decrease in revenue. On the other hand, if the Department of Health and Human Services ("DHHS") is forced to enter into provider agreements with delinquent providers, it hurts the already precariously funded future of Medicare and perversely rewards those providers who have been terminated from the program.

n1 11 U.S.C. § 525(a)(2001).

n2 *Perez v. Campbell*, 402 U.S. 637, 648 (1971) ("This Court on numerous occasions has stated that 'one of the primary purposes of the Bankruptcy Act' is to give debtors 'a new opportunity in life and a clear field for future effort, unhampered by the pressure and discouragement of pre-existing debt.'") (quoting *Local Loan Co. v. Hunt*, 292 U.S. 234, 244 (1934)); *Norton v. Tennessee Dep't of Safety*, 867 F.2d 313, 316 (6th Cir. 1989) (Section 525 was "designed to prevent governmental units from frustrating the fresh start policy of the Code by discriminating against persons who have been debtors under the Code or the prior Bankruptcy Act.").

n3 See generally Christopher O'Leary, *Healthcare Defaults Threaten Commercial Mortgage-Backed Securities Sector, Too*, INVESTMENT DEALER'S DIG., Feb. 21, 2000 (stating that about 10% of the Nation's **nursing home** facilities are run by **companies** in bankruptcy); Ann Donahue, *Crisis In Health Care: Financial Pressures Are Ripping System Apart*, L.A. BUS. J., May 17, 1999 (stating that "numerous health maintenance organizations--both for-profit and non-profit--are in financial trouble, as profit margins shrink and competition increases").

n4 James T. Marcus & John F. Young, *Anti-Discrimination Provisions--Do They Have Any Real Meaning?*, 17 AM. BANKR. INST. J. 14, 14 (1988) (noting that "an increasing portion of health care provider revenues are derived from participation in the Medicare and Medicaid programs").

The determination of whether Section 525 applies in this situation hinges upon whether a provider agreement is a "license, permit, charter, franchise or other similar grant" within the meaning of the statute. Due to a conflict between the legislative history and the statutory language, courts have reached different conclusions regarding the section's reach. This Article begins by providing some background of Section 525 and Medicare and then examines the different approaches courts have taken in looking at this issue. It concludes that Section 525 does not apply to provider agreements because under the appropriate plain meaning interpretation, a Medicare provider agreement is not a "license, permit, charter, franchise or other similar grant." Thus, debtor healthcare providers should be treated just like their nondebtor counterparts and not be allowed back into the Medicare program without first paying their statutorily required debts. n5

n5 If it is important to the debtor's reorganization that it have a Medicare provider agreement in place, then it can simply seek permission from the bankruptcy court for relief from the stay to pay the outstanding debts.

I. Medicare Provider Agreements

The Medicare program was established in 1965 n6 as an insurance program to provide healthcare benefits for people over age sixty-five and for the disabled. n7 As of 1997, Medicare insured thirty-two million senior citizens, n8 and in 1999 it was the fourth largest federal program, falling behind only Social Security, defense, and interest on the national debt. n9 Medicare's purpose is to benefit the elderly, needy, blind, and disabled n10 and it is intended to benefit the provider only to the extent necessary to ensure high-quality care. n11

n6 See Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 291.

n7 *Id.*

n8 Lewis D. Solomon & Tricia Asaro, *Community-Based Health Care: A Legal and Policy Analysis*, 24 FORDHAM URB. L.J. 235, 236 (1997).

n9 See Timothy Stoltzfus Jost, *Governing Medicare*, 51 ADMIN. L. REV. 39, 40 (1999).

n10 S. REP. NO. 98-404, (1965), *reprinted in* 1965 U.S.C.C.A.N. 305, 305.

n11 See *Fischer v. United States*, 529 U.S. 667, 675 (2000).

Medicare is governed by the Health Care Financing Administration ("HCFA")--a division of DHHS. Medicare consists of three parts: A, B, and C. Part A covers institutional services such as hospital, hospice, and **nursing home** care, while Part B covers the services of physicians and other health professionals, diagnostic tests, and other specific services and supplies. n12 Part C was added as part of the Balanced Budget Act of 1997 to give beneficiaries more options in health insurance choices than were given in parts A and B. n13

n12 42 U.S.C. §§ 1395d,k (2001).

n13 See Balanced Budget Act of 1997, Pub. L. No. 105-33, § 1851(a), 111 Stat. 276, 276.

Part A services are the type this Article addresses. In order to render services reimbursable under Medicare Part A, a healthcare provider must enter into a provider agreement with HCFA. n14 Courts have treated provider agreements as either executory contracts or statutory agreements. In *University Medical Center v. Sullivan*, the Third Circuit held that a provider agreement is an executory contract for purposes of bankruptcy. n15 This approach more fully accords with the rights and obligations of the parties. Therefore, for purposes of this Article, a provider agreement is treated as an executory contract. Even if one were to treat the provider agreement as a statutory right, n16 the analysis would be the same because even though it is a statutorily created relationship, it still is not a "license, permit, charter, franchise or other similar grant."

n14 42 U.S.C. § 1395cc (2000).

n15 *University Med. Ctr. v. Sullivan*, 973 F.2d 1065, 1075 (3d Cir. 1992) (holding that a "Medicare provider agreement easily fits within" the Code's definition of "executory contract"). See *Hollander v. Brezenoff*, 787 F.2d 834, 838 (2d Cir. 1986) (stating in dicta that a Medicare provider agreement might be construed as a contract if it obligated DHHS to assume non-statutorily required duties); *In re Heffernan Mem'l Hosp. Dist.*, 192 B.R. 228, 231 (Bankr. S.D. Cal. 1996) (holding that a Medicare provider agreement is a contract); *Blue Cross v. Monsour Med. Ctr.*, 11 B.R. 1014, 1018 (Bankr. W.D. Pa. 1981) (accord).

n16 *Memorial Hosp. v. Heckler*, 706 F.2d 1130, 1136 (11th Cir. 1983) (holding that a Medicare provider agreement creates a statutory, not a contractual, right); *Maximum Care Home Health Agency v. HCFA*, No. 3-97-CV-1451-R, 1998 WL 901642, at *5 (N.D. Tex. 1998) (holding that a Medicare provider agreement is "not a contract in the traditional sense"); *Germantown Hosp. & Med. Ctr. v. Heckler*, 590 F. Supp. 24, 30-31 (E.D. Pa. 1984) (holding that a provider agreement creates a statutory, not a contractual right).

While a provider agreement is in effect, the healthcare provider will be reimbursed periodically on an estimated basis for the services it provides to eligible recipients. These payments are subject to a year-end adjustment after an audit determines the precise amount of reimbursements due the provider. n17 The inexactness of the payment system results in frequent under or overpayments.

n17 42 U.S.C. § 1395g (2000); see generally *United States v. Consumer Health Servs.*, 108 F.3d 390, 392 (D.C. Cir. 1997).

Under the statutory framework, a provider agreement remains in effect unless one of the following occurs: (1) it is voluntarily terminated by the provider; n18 or (2) it is terminated by HCFA after a determination that the provider is not complying with the statutory obligations of the agreement, that it is no longer meeting the conditions of participation, n19 that it has failed to supply information necessary to make payments, or that it has refused to permit fiscal examinations. n20 Prior to a provider obtaining a new provider agreement, it must fulfill certain obligations. These include showing that it has corrected the problem that resulted in HCFA's terminating its previous provider agreement, and paying any outstanding debts, such as overpayments from prior years or fines owed to HCFA. n21 This Article addresses what happens when a provider in bankruptcy seeks to obtain a new provider agreement without paying its outstanding debts or fines. In particular: Does a Medicare provider agreement fall under Section 525, thus preventing HCFA from using the outstanding financial obligation to bar the debtor from the program?

n18 42 U.S.C. § 1395cc(b)(1) (2000).

n19 *Id.* § 1395f.

n20 *Id.* § 1395cc(b)(2).

n21 42 C.F.R. § 489.57 (2001).

II. History of Section 525

Section 525 is a codification of the Supreme Court's ruling in *Perez v. Campbell*. n22 *Perez* involved a husband and wife who had received a discharge in bankruptcy. n23 Included among the discharged debts was a judgment for an automobile accident. n24 Under the Arizona Motor Vehicle Safety Responsibility Act, the couple was denied new driver's licenses because of failure to pay the discharged judgment. n25 In *Perez*, the Supreme Court struck down the Arizona statute under the Supremacy Clause n26 holding that it conflicted with the "fresh start" provisions of the federal bankruptcy laws. n27

n22 402 U.S. 637 (1971). *See* S. REP. NO. 95-989, at 81 (1978), *reprinted in* 1978 U.S.C.C.A.N. 5787, 5867; *Saunders v. Reehar*, 105 B.R. 781, 787 (Bankr. E.D. Pa. 1989) ("all courts have recognized (based upon legislative history) that the congressional intent in enacting § 525(a) was to codify. . . *Perez v. Campbell*").

n23 *Perez*, 402 U.S. at 638-39.

n24 *Id.*

n25 *Id.* at 643.

n26 U.S. CONST. art. VI, § 1, cl. 2.

n27 402 U.S. at 656.

In 1978, as part of the Bankruptcy Reform Act, Congress enacted Section 525(a), which states in pertinent part:

a governmental unit may not deny, revoke, suspend, or refuse to renew a license, permit, charter, franchise or other similar grant to, . . . solely because such bankrupt or debtor is or has been a debtor under this title or a bankrupt or debtor under the Bankruptcy Act, has been insolvent before the commencement of the case under this title, or during the case but before the debtor is granted or denied a discharge, or has not paid a debt that is dischargeable in the case under this title or that was discharged under the Bankruptcy Act. n28

n28 11 U.S.C. § 525(a) (2001).

The legislative history of Section 525 shows that Congress tried to strike a balance between **protecting** the government interest against debtors who failed to repay debts discharged in bankruptcy and barring any discrimination that prevented the debtors from having a meaningful fresh start. n29 The original version of Section 525 offered very broad protection to debtors and had the stated goal that no one be "subjected to discriminatory treatment because he, or any person with whom he is or has been associated, is or has been a debtor or has failed to pay a debt discharged in a case under the Act." n30 After the above language created great controversy, Congress ultimately enacted the narrower

language cited above. However, "the scars from the debate which had ensued over the original draft found their way into the legislative history and thereby affected the consistency of decisions to come." n31 Importantly, in enacting Section 525, Congress did not prohibit the consideration of factors such as future financial responsibility of the debtors. n32 It also recognized the interrelationship between the anti-discrimination provisions and the anti-reaffirmation provisions of the Bankruptcy Act. n33

n29 H.R. REP. NO. 95-595, at 366-67 (1977); S. REP. NO. 95-989, at 81 (1978), *reprinted in* 1978 U.S.C.C.A.N. 5787, 5867.

n30 *See* H.R. DOC. NO. 93-137, pt. II, at 143-44 (1973).

n31 Dana C. Siragusa, *In re Bacon: The Extent of A Debtor-Tenant's Right In Public Housing Under § 525(a) of the Anti-Discrimination Clause*, 15 BANKR. DEV. J. 555, 559 (1999).

n32 H.R. REP. NO. 95-595, at 366-67 (1977); S. REP. NO. 95-989, at 81 (1978), *reprinted in* 1978 U.S.C.C.A.N. 5787, 5867.

n33 *Id.*

Because the legislative history provides support for both an expansive reading of Section 525 n34 and a narrow application, n35 courts have, not surprisingly, adopted their own various, and often conflicting, interpretations.

n34 The House Report stated: "The doctrine is a developing doctrine, and its precise and ultimate contours are not yet clear. More case law will undoubtedly develop the extent of the discrimination that is contrary to bankruptcy policy." H.R. REP. NO. 95-595, at 165 (1977).

n35 H.R. REP. NO. 95-595, at 366-67 (1977), *reprinted in* 1978 U.S.C.C.A.N. 5963, 6322-23.

III. Provider Agreements Do Not Fall Under Section 525

Importantly, Section 525 does not include government contracts in its list of covered instruments. In addition, the Bankruptcy Code does not define what is meant by a "license, permit, charter, franchise, or other similar grant." The general view of courts, however, is that Section 525 is meant to prevent the government from denying a debtor the ability to earn its livelihood by denying the very license, permit, or charter necessary to earn that livelihood. Under the appropriate plain meaning interpretation, it is clear that a provider agreement, which is a government contract, does not fall within Section 525's enumerated categories. Thus, it does not prevent a bankrupt healthcare provider from earning its living as a healthcare provider. Rather, a provider agreement is more similar to a credit relationship, which Congress expressly excluded from Section 525, than to a "license, permit, charter or other similar grant."

A. Under a Plain Meaning Interpretation, Section 525 Does Not Apply to Provider Agreements

Although the Supreme Court has not addressed this particular section, Court precedent favors a plain meaning interpretation of Bankruptcy Code provisions. n36 In *United States v. Ron Pair Enterprise, Inc.*, n37 the Court noted that Congress spent nearly a decade drafting the Code and that "as long as the statutory scheme is coherent and consistent, there generally is no need for a court to inquire beyond the plain language of the statute." n38 The Court then held that where the language of the Code is clear, "the sole function of the courts is to enforce it according to its terms." n39 In general, "the Court has been remarkably consistent in deciding Bankruptcy Code cases in that, almost without exception, it has used a textualist approach for statutory interpretation." n40

n36 Joseph A. Guzinski, *Policy Problems and "Plain Meaning": An Examination of Some Recent Decisions Under 11 U.S.C. § 525(A)*, 15 AM. BANKR. INST. J. 10 (1996) ("Recent Supreme Court bankruptcy decisions emphasize the language of the statute over considerations of legislative history, policy or other tools that traditionally have been relied upon to illuminate the meaning of statutory language.").

n37 489 U.S. 235, 240 (1989).

n38 *Id.* at 240-41.

n39 *Id.* at 241 (quoting *Caminetti v. United States*, 242 U.S. 470, 485 (1917)).

n40 Adam James Wiensch, Note, *The Supreme Court, Textualism and the Treatment of Pre-Bankruptcy Code Law*, 79 GEO. L.J. 1831, 1832 (1991).

Congress could have drafted Section 525 to include government contracts, but it did not. Therefore, under a plain meaning approach, Medicare provider agreements do not fall under the scope of Section 525.

Nevertheless, some courts have applied Section 525(a) to other types of government contracts. In *Exquisito Services, Inc. v. United States (In re Exquisito Services, Inc.)*, the Fifth Circuit held that Section 525 should be construed narrowly in conjunction with the Air Force's failure to renew an 8(a) n41 business's food service contract. n42 Examining the legislative history, the Fifth Circuit noted that as originally written, Section 525 extended to all discrimination and to all parties. n43 After extensive hearings and the opportunity for public comment, Congress narrowed the provision to apply only to "discrimination by the government in some enumerated functions." n44 The court noted the number of courts that had applied a broad reading of Section 525 and found that the better approach was to apply a narrow interpretation and focus on the specific language. n45 The court then adopted a "narrow construction approach" and examined "the character of the relationship between the parties" to determine whether it fell within one of Section 525's enumerated categories. n46 Ultimately, the *Exquisito* court found that due to the special goals of an 8(a) contract in encouraging minority businesses, n47 an 8(a) contract was similar to a franchise and that Section 525 applied. Judge E. Grady Jolly wrote a strong dissent in which he argued that, regardless of the special nature of the 8(a) contracts, "government contracts simply cannot be forced to fit in to the statutory language of Section 525 without judicially amending the statute." n48 A provider agreement does not have the policy goals of encouraging minority businesses. Thus, it is different from an 8(a) contract and cannot be likened to a franchise. n49 Moreover, Judge Jolly correctly noted in his dissent how inappropriate it is to contort Section 525's language to include government contracts. n50

n41 See Small Business Act § 8(a), 15 U.S.C. § 637(a)(1) (2000).

n42 823 F.2d 151, 154 (5th Cir. 1987).

n43 *Id.* at 153.

n44 *Id.*

n45 *Id.*

n46 *Id.* at 154.

n47 *Id.*

n48 *Exquisito*, 823 F.2d at 155.

n49 *Id.* at 155-56.

n50 *Id.*

Despite Section 525's narrow language, some courts have incorrectly applied a more liberal interpretation to find that it applies to government contracts. n51 In *Marine Electric Railway Products Division, Inc. v. New York City Transit Authority*, n52 the court applied a broad reading to find that Section 525 prevented the New York City Transit Authority ("NYCTA") from declining to contract with a manufacturer of electrical equipment solely because of that manufacturer's status as a debtor. This finding, however, is dicta because the court dismissed the motion on other grounds. n53 Furthermore, the contract involved in *Marine Electric* was a fee for services contract; n54 it did not involve prospective payments subject to a later reconciliation as the Medicare program does. Thus, the NYCTA was not faced with the prospect of making overpayments to a **company** that was not fiscally responsible. In addition, the NYCTA admitted that the sole reason it did not select the debtor for the contract award was the debtor's status as a bankrupt. n55 It did not involve the debtor's failure to repay the NYCTA any outstanding fines or overpayments, as is often the case in Medicare cases.

n51 *In re Psychotherapy and Counseling Ctr., Inc.*, 195 B.R. 522, 533-534 (Bankr. D.C. 1996) (stating that HHS's exclusion of debtor from Medicare based on its failure to pay outstanding debt to Medicare potentially violated § 525(a)); *In re Rusnak*, 184 B.R. 459, 467 (Bankr. E.D. Pa. 1995) (questioning whether Debtor's access to Medicare falls under meaning of § 525); *In re St. Mary Hosp.*, 89 B.R. 503, 513 (Bankr. E.D. Pa. 1988), *vacated*, see *University Med. Ctr. v. Sullivan*, 973 F.2d 1065, 1071 n.6 (3d Cir. 1992) (noting that *St. Mary* was vacated after settlement).

n52 17 B.R. 845, 853 (Bankr. E.D. N.Y. 1982)

n53 *Id.* at 856.

n54 *Id.* at 847.

n55 *Id.*

Similarly, in *Coleman American Moving Services, Inc. v. Tullos*, n56 the court found that Section 525 applied to a moving and storage contractor's bid on a contract with the Air Force. Here, the court focused on the term "employment" to find that the Air Force had violated Section 525 by finding the debtor to be "non-responsible" and thus not eligible for an award due to its bankruptcy filing. n57 This case predates most of the Supreme Court precedent urging a narrow interpretation of the Code, and improperly applies an expansive reading of Section 525. Furthermore, it also dealt with a fee for services contract by which the debtor was contracting directly with the Air Force for services provided to the Air Force, n58 as opposed to the Medicare situation in which the government is reimbursing the debtor for services provided to private citizens.

n56 8 B.R. 379, 383 (Bankr. D. Kan. 1980).

n57 *Id.*

n58 *Id.* at 380.

Another important distinction that separates Medicare provider agreements from the above government contracts is that a provider agreement is treated as an executory contract in bankruptcy. This means that a provider with a current provider agreement who wishes to stay in the program must cure any outstanding financial obligations. n59 To allow a debtor to obtain a new provider agreement without paying its statutorily required debts would put it in a better position than a debtor who entered bankruptcy with a provider agreement in place. n60 This would create the perverse incentive of rewarding healthcare providers whose provider agreements were terminated prior to bankruptcy because of substandard care or failure to comply with the program policies. It also creates the irresponsible incentive to have providers terminate their provider agreement prior to filing for bankruptcy so that they could be let back into the program post-petition, without having to pay any outstanding overpayments or debts.

n59 11 U.S.C. § 365(b)(1) (2000).

n60 WILLIAM L. NORTON, JR., *NORTON BANKRUPTCY LAW AND PRACTICE*, § 50:2, n.9 (2d ed. 2000) ("Although there is a split in authority, the better view is that the antidiscrimination provisions in Code § 525(a) cannot control over Code § 365(b)(1), which generally requires that a debtor wishing to assume an executory contract or unexpired lease must cure certain defaults and provide adequate assurance of future performance under the contract or lease.").

A similar situation was addressed in *Housing Authority v. James (In re James)*, where the court held that a public housing authority could evict a tenant whose lease was terminated for nonpayment of rent prior to the petition date and was not required to enter into a new lease with the tenant. n61 The court concluded that:

To rule in favor of debtor on this matter would pervert § 525(a) by turning it into a sword rather than a shield. Debtor would be treated preferentially in comparison to other public housing tenants who pay their rent and to others who do not but who fail to file for bankruptcy. Such an outcome goes far beyond providing debtor with a "fresh start." n62

n61 198 B.R. 885, 888 (Bankr. W.D. Pa. 1996).

n62 *Id.* at 889.

In a Medicare situation, granting debtors readmission to the program without having them cure their debts would have the unfair result that facilities which provide high quality care must pay their Medicare debts to participate in the Medicare program post-confirmation, while facilities that provide substandard care and are terminated from the program may participate without paying their debts.

B. Section 525 Does Not Apply to Provider Agreements Because a Provider Agreement Is Not a Prerequisite for Operating a Healthcare Facility

In addition to the exclusion of government contracts from the litany of instruments included in Section 525, Medicare provider agreements also are not "other similar grants" to the instruments listed. In general, courts have applied Section 525 to instruments without which the debtor would be unable to earn its livelihood. Some clear-cut examples of a government entity denying a debtor something necessary to earn his or her livelihood include a real estate license for a realtor, n63 a liquor license for a liquor storeowner, n64 or a contracting license for a contractor. n65 DHHS' refusal to issue a healthcare provider a new Medicare provider agreement, however, does not prevent that provider from operating a healthcare facility.

n63 *Shade v. Fasse (In re Fasse)*, 40 B.R. 198 (Bankr. D. Colo. 1984).

n64 *In re Mason*, 18 B.R. 817 (Bankr. W.D. Tenn. 1982); *Anderson v. Mississippi State Tax Comm'n (In re Anderson)*, 15 B.R. 399 (Bankr. S.D. Miss. 1981); *In re Maley*, 9 B.R. 832 (Bankr. W.D. N.Y. 1981).

n65 *Fintel v. State (In re Fintel)*, 10 B.R. 50 (Bankr. D. Or. 1981).

In *In re Watts*, n66 the Third Circuit applied a plain meaning approach and held that Section 525 is meant to limit government action only insofar as the government acts as a gatekeeper in determining who may pursue certain livelihoods. n67 The Third Circuit stated that "indeed, it seems perfectly clear that the items enumerated are in the nature of indicia of authority from a governmental unit to the authorized person to pursue some endeavor. Thus, a 'similar grant' should be given the same meaning." n68

n66 876 F.2d 1090 (3d Cir. 1989).

n67 *Id.* at 1094.

n68 *Id.*

In *Watts*, the court held that Section 525 did not apply to the debtor's participation in a mortgage assistance program. The *Watts* court rejected the debtor's invitation to construe Section 525 broadly to maximize the debtor's "fresh start." Instead, the court held that Section 525 is limited to specific transactions and concluded that the mortgage assistance program was not sufficiently similar to a "grant" to fall within the section. n69 The court noted that "the fresh start policy does not require the State to insulate a debtor from any and all adverse consequences of a bankruptcy filing." n70 The Supreme Court expressed similar sentiments in *NLRB v. Bildisco & Bildisco*, n71 saying that a "debtor-in-possession is not relieved of all obligations under [a non-bankruptcy statute] simply by filing a petition for bankruptcy." n72

n69 *Id.*

n70 *Id.* See *Toth v. Michigan State Hous. Dev. Auth.*, 136 F.3d 477, 479-80 (6th Cir. 1984).

n71 465 U.S. 513, 534 (1984).

n72 *Id.*

To engage in the business of operating a healthcare facility, a healthcare provider must first obtain a license from the state. n73 If the healthcare provider wishes to provide services to Medicare beneficiaries and be reimbursed for such services by the state, it also must enter into a Medicare provider agreement with the state. n74 If the healthcare provider also wants to provide services to Medicare beneficiaries and be reimbursed by the federal government for such services, it must enter into a Medicare provider agreement with DHHS. n75 A provider licensed by the state enters into only one agreement with the federal government prior to serving Medicare beneficiaries--the provider agreement. DHHS does not engage in any type of licensing, meaning that if the facility is licensed by the state and not excluded or debarred, DHHS may enter into a provider agreement with it.

n73 Each state has its own licensing laws. *See, e.g.*, ARK. CODE ANN. § 20-9-213 (2001); CAL. HEALTH & SAFETY CODE § 1253 (2001); 210 ILL. COMP. STAT. ANN. 45/3-109 (2000); N.H. REV. STAT. ANN. § 420-A:4 (1999).

n74 42 U.S.C. § 1396a(a)(27)(2001); 42 C.F.R. § 431.107(2001).

n75 42 U.S.C. § 1395cc (2000).

Thus, because the facility is licensed by the state, a Medicare provider agreement is not similar to a "license, permit, charter or franchise." As noted above, it has been held that a provider agreement is a contract for purposes of bankruptcy. n76 Although it could be argued that a "license" or a "permit" is a form of contract, there is a fundamental difference between a license and a contract or permit. A license or permit is a unilateral requirement imposed by the government for purposes of **protecting** a public interest, for example, the dispensing of alcohol or the proper sale of a home. A contract is an agreement between two or more parties whereby each receives consideration from the other by agreeing to do or not to do a particular thing. n77 By holding that a provider agreement is an executory contract, the Third Circuit adopted the definition of executory contract as an agreement for which performance is to some extent due on both sides. n78 This creates a bilateral relationship. A license or permit cannot be executory because performance cannot be due on both sides. Once issued, the government's duty is complete. The licensee or permit holder then is able to perform a service for which the public will reimburse it (such as the sale of alcohol). n79 This arrangement is quite different from the circumstances of a Medicare provider agreement, under which the government will pay the provider for services performed. Although the government can revoke or restrict the license, neither activity can be described as a bargained-for promise for the benefit of the licensee.

n76 *University Med. Ctr. v. Sullivan*, 973 F.2d 1065, 1075 (3d Cir. 1992).

n77 BLACK'S LAW DICTIONARY 318 (7th ed. 1999).

n78 *University Med. Ctr.*, 973 F.2d at 1075

n79 *Exquisito*, 823 F.2d at 155 (Jolly, J., dissenting).

Moreover, only state licensure provides the "gatekeeping" function described in *Watts*, because without a state license a healthcare facility cannot operate on any level. By entering into provider agreements, HCFA is not deciding who can or cannot engage in any particular profession, merely who HCFA will contract with to reimburse for providing healthcare services to certain categories of patients. The only difference between a facility with a provider agreement and one without is that the former will be reimbursed by HCFA for services properly rendered to Medicare beneficiaries at that facility while the other will have to look to private insurance **companies**, state Medicaid programs, or the patients themselves for payment. Although it is true that without a provider agreement a facility cannot be reimbursed for services rendered to Medicare beneficiaries, the same can be said for every federal contract. n80

n80 See the following cases for the general proposition that a third party must have privity of contract with the Federal Government to seek compensation from it: *Erickson Air Crane Co. v. United States*, 731 F.2d 810,813 (Fed. Cir. 1984); *United States v. Johnson Controls, Inc.*, 713 F.2d 1541, 1550-51 (Fed. Cir. 1983); *Eubanks v. United States*, 25 Fed. Cl. 131, 137 (1992); *Orchards v. United States*, 4 Cl. Ct. 601, 607 (1984).

In fact, the credit agreements excluded by Congress and denied by the courts would be "licenses," because without such agreements the debtors could not operate as profitably as their competitors. The Sixth Circuit noted in *Toth v. Michigan State Housing Development Authority*, "the items enumerated in the statute--licenses, permits, charters, and franchises--are benefits conferred by government that are unrelated to the extension of credit. They reveal that the target

of § 525(a) is government's role as a gatekeeper in determining who may pursue certain livelihoods." n81 The *Toth* court held that the Michigan State Housing Development Authority did not violate Section 525 when it denied plaintiff's home improvement loan solely because she had received a discharge in bankruptcy three years ago. n82 Medicare provider agreements simply do not provide the gatekeeping function of the instruments to which Section 525 has been applied and, thus, it does not apply to them.

n81 136 F.3d at 480; *accord* *Watts*, 876 F.2d at 1094.

n82 *Toth*, 136 F.3d at 480.

C. Section 525 Does Not Apply to Provider Agreements Because the Relationship Between HCFA and a Provider Requires HCFA to Take Financial Risk

Section 525 also does not apply to provider agreements because the relationship between HCFA and a provider is akin to the credit relationships to which Section 525 was held inapplicable in *Watts* and *Toth*. In enacting Section 525, Congress expressly excluded relationships requiring financial risk from its purview. As explained by the *Watts* court, Congress' decision to limit the section's application to specific types of licenses and grants was driven by concerns that a broader rule might prohibit lenders from denying credit based upon a debtor's past credit history, which would be unfair to the lender. n83 The *Watts* court also relied upon *In re Goldrich*, in which the Second Circuit held that a credit guarantee is not a license, permit, franchise, or grant. n84 The *Goldrich* court held it would be improper to stretch Section 525 "so far beyond its plain terms" to encompass extensions of credit by government entities. n85 The Medicare program operates by making estimated payments to providers, subject to a later reconciliation, including collection of prior overpayments. n86 When HCFA overpays the provider, it relies upon the financial condition and responsibility of that provider to return the unearned payments to the Medicare Trust Fund. The return of these overpayments is critical, since by some estimates the Medicare Part A trust fund will run out of funding in the next ten years. n87 Because of the uncertainty associated with these payments, it is important that HCFA be assured that new providers are able to repay their debts. HCFA does so, in part, by requiring the payment of past debts as a condition precedent to re-entry into the program. HCFA should not be forced to do business with an entity that does not meet the financial and regulatory requirements for participation. n88

n83 *Watts*, 876 F.2d at 1094, n.3.

n84 *Id.* at 1094 (citing *In re Goldrich*, 771 F.2d 28, 30 (2d Cir. 1985), *superseded by statute*, 11 U.S.C. § 525(c)(2001)); *see* *United States v. Cleasby* (*In re Cleasby*), 139 B.R. 897, 900 (Bankr. W.D. Wis. 1992)(holding that § 525 does not apply to loans).

n85 771 F.2d at 29.

n86 42 U.S.C. § 1395g(a) (2000).

n87 *See* Robert Pear, '98 Medicare Growth Slowest Since Program Began in '65, N.Y. TIMES, Jan. 12, 1999, at A1.

n88 42 C.F.R. § 489.57 (2001); *see* B.F. Goodrich Employees Federal Credit Union v. Patterson (*In re Patterson*), 967 F.2d 505, 514 (11th Cir. 1992) (noting that § 525 does not "abrogate[] the general proposition that a creditor should not be forced to do business with a debtor").

IV. Conclusion

Section 525 does not apply to provider agreements because provider agreements do not fall under, and are not similar to, any of the enumerated categories in the statute. Rather, Medicare provider agreements are executory contracts more like a credit relationship exposing HCFA to financial risk, which Congress expressly excluded from the reach of Section 525. Therefore, healthcare providers who file for bankruptcy should be required to pay their statutory obligations to DHHS, just like their non-bankrupt counterparts, before being issued a new provider agreement.

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LENGTH: 17803 words**TITLE:** ARTICLE: Healthcare Fraud and Quality of Care: A Patient-Centered Approach**AUTHOR:** Joan H. Krause *

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TEXT:

ABSTRACT: This Article explores the intersection between quality of care and healthcare fraud by examining the extent to which quality-related fraud settlements benefit patients. The author argues that, although the protection of beneficiary health and welfare often is invoked by the federal government as one of the reasons for undertaking anti-fraud efforts, such considerations do not appear to play a large role in many of the settlements that are negotiated. While returning funds to the federal Treasury helps to ensure that the federal healthcare programs remain solvent and continue to serve beneficiaries in the aggregate, it may not adequately address harm to individual patients. Thus, the author concludes it may be time to explore new models of fraud settlements that can provide adequate compensation to the patients who may have suffered harm.

I'd suggest to you that the bigger issues going forward are not the issues of billing for services not rendered; the bigger issues are what is happening to the patients. . . . That's what the jury is going to focus on, that's what the fraud statutes are basically designed to protect, the victims of the fraud. . . . n1

n1 James Sheehan, *Biotech Fraud: Reality or Fantasy?*, 2 HOUS. J. HEALTH L. & POL'Y 11, 20, 26 (2002).

When it comes to ensuring quality care in the federal healthcare programs, patients and the federal government would seem to be natural allies. Just as substandard care endangers patient welfare, it diverts limited program funds and diminishes program integrity. It is not surprising, then, that an increasing number of civil, criminal, and administrative healthcare fraud initiatives undertaken by the Department of Justice (DOJ) and the Department of Health and Human Services (DHHS) Office of the Inspector General (OIG) focus on quality of care problems, and that patient protection increasingly is invoked as a core goal of these efforts.

Yet the relationship between healthcare fraud and patient protection is more complicated than it might first appear. While it is true that neither program integrity nor patient welfare is served by healthcare providers n2 who engage in quality-related fraud, there is an inherent tension between these natural allies in one very practical respect: what to do

with the recovered funds. This dilemma reflects the fact that quality-related fraud involves two distinct victims: the patients whose care is affected and the federal program that pays for that care. In that context, it is unclear whether recovered funds should be used primarily to remedy injuries to patients or to remedy financial losses suffered by the federal Treasury.

ⁿ² In the federal healthcare program context, the term "provider" technically refers to institutional entities such as hospitals, home health agencies, and **nursing homes**. 42 U.S.C. § 1395x(u) (2004) (defining "provider of services"). Drawing on government guidance to the healthcare industry, however, this Article will use the term "healthcare provider" more broadly to encompass both individual healthcare professionals and institutional entities. See DEPT OF HEALTH & HUMAN SERVS., OFF. OF INSPECTOR GEN., SPECIAL ADVISORY BULLETIN: PRACTICES OF BUSINESS CONSULTANTS 1 n.1 (July 2001) (using term to include "providers, suppliers, and practitioners that provide items or services payable in whole or in part by a Federal health care program"), available at www.oig.hhs.gov/fraud/docs/alertsandbulletins/consultants.pdf (last visited Mar. 30, 2004).

This Article argues that while the protection of beneficiary health and welfare frequently is espoused by the federal government as a reason for undertaking healthcare fraud efforts, such considerations do not play a significant role in the resolution of these disputes. The reasons for this inconsistency are complex. The problem exists, in part, because federal statutes commonly invoked against healthcare fraud do not provide a direct mechanism for channeling compensation to injured individuals. Additionally, identifying the potential victims of large-scale healthcare fraud, such as schemes involving nationally marketed prescription drugs, may pose significant logistical obstacles. Moreover, there is a danger of conflating the federal government's role as a defrauded *payor* in these cases with its more amorphous power as the *protector* of its citizenry. As quality-related fraud cases become more common, however, it will be necessary to expand our views of healthcare fraud recoveries. This Article argues that we should explore new models that provide adequate compensation to beneficiaries who suffered any type of harm due to healthcare fraud--be that harm physical, financial, or otherwise.

I. Quality-Related Healthcare Fraud

Despite the change in presidential administrations in 2001, it is clear that healthcare fraud remains a top federal law enforcement priority. Since the mid-1990s, Congress has significantly increased the funding available to the federal agencies with jurisdiction over healthcare fraud and has vastly increased the number of federal fraud laws that apply to healthcare. ⁿ³ These efforts have paid off: The DOJ recovered \$ 1.7 billion in healthcare fraud prosecutions and settlements in fiscal year 2003. ⁿ⁴ Bolstered by this success, federal and state agencies continue to pursue and negotiate massive settlements with individuals and entities accused of health-related fraud. The targets of these investigations have expanded beyond patent falsification of billing documents to encompass a much broader array of fraudulent activities, including those related to substandard care.

ⁿ³ See, e.g., Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, § 201 (codified at 42 U.S.C. § 1320a-7c.), §§ 241-247 (codified in scattered portions of 18 U.S.C.), 110 Stat. 1937, 1992-1996, 2016-2018 (establishing a "Fraud and Abuse Control Program" to coordinate federal, state, and local healthcare fraud enforcement efforts).

ⁿ⁴ Press Release, Dep't of Justice, Justice Dept. Civil Fraud Recoveries Total \$ 2.1 Billion for FY 2003: False Claims Act Recoveries Exceed \$ 12 Billion Since 1986 (Nov. 10, 2003), available at www.usdoj.gov/opa/pr/2003/November/03_civ_613.htm (last visited Mar. 30, 2004) [hereinafter Justice Dept. Civil Fraud Recoveries Total \$ 2.1 Billion for FY 2003].

At the federal level, healthcare fraud is actionable under a variety of criminal, civil, and administrative provisions. Some of these laws--such as the Medicare and Medicaid Anti-Kickback Statute, the "Stark Law" prohibition on physician self-referrals, and the provisions governing exclusion from the federal healthcare pro-grams--specifically target improper healthcare activities. ⁿ⁵ Others, such as the civil and criminal false claims prohibitions, ⁿ⁶ apply more broadly to entities that do business with the federal government. Healthcare fraud also may be prosecuted under general federal criminal statutes, such as mail and wire fraud, conspiracy, and the Racketeer Influenced and Corrupt

Organizations Act (RICO), which prohibit improper conduct more broadly regardless of the industry in which it occurs.
n7

n5 See 42 U.S.C. § 1320a-7 (2004) (exclusion from federal healthcare programs); 42 U.S.C. § 1320a-7a (2004) (civil monetary penalties applicable to federal healthcare programs); 42 U.S.C. § 1320a-7b(b) (2004) (Medicare & Medicaid Anti-Kickback Statute); 42 U.S.C. § 1395nn (2004) (limitations on physician self-referrals).

n6 See 18 U.S.C. §§ 286-287 (2004) (criminal false claims provisions); 31 U.S.C. §§ 3729-3733 (Civil False Claims Act).

n7 See 18 U.S.C. §§ 1341, 1343, 1346 (2004) (mail and wire fraud); 18 U.S.C. §§ 1961-1962 (2004) (RICO). RICO provides for both criminal and civil causes of action. *Id.* § 1964 (setting forth civil remedies).

The current centerpiece of the government's war on healthcare fraud is the Civil False Claims Act (FCA), a Civil War-era statute that prohibits the knowing submission of false or fraudulent claims to the federal government. n8 Although a wide range of fraudulent activities fall within the statutory prohibitions, the most commonly invoked cause of action applies when: (1) a defendant presents (or causes to be presented) n9 a claim for payment or approval; (2) the claim is false or fraudulent; and (3) the defendant's acts are undertaken "knowingly." n10 The statutory definition of "knowingly" incorporates "deliberate ignorance" and "reckless disregard of the truth or falsity," as well as "actual knowledge." n11 Violators are liable for a civil penalty of \$ 5,500 to \$ 11,000 per claim, plus three times the amount of damages sustained by the government--making the law a powerful addition to the federal anti-fraud arsenal. n12

n8 31 U.S.C. §§ 3729-3733 (2004). The law was enacted in 1863 in response to reports of "rampant fraud" perpetrated on the United States military during the Civil War. See S. REP. NO. 99-345, at 8 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5273 (noting history of False Claims Act).

n9 "Cause to be presented" liability applies where the person responsible for the falsity does not actually submit the claim, but rather directs others (who may not know of the falsity) to do so. See, e.g., *United States v. Mackby*, 261 F.3d 821, 828 (9th Cir. 2001) (holding that a lay clinic owner caused false claims to be submitted by instructing his office staff to bill for physical therapy services using the billing number of a physician who was not involved in the care).

n10 31 U.S.C. § 3729(a)(1) (2004). For other prohibited acts, see, e.g., *id.* § 3729(a)(2) (prohibiting the use of false records or statements to get a false or fraudulent claim paid or approved); *id.* § 3729(a)(3) (prohibiting conspiracies "to defraud the Government by getting a false or fraudulent claim allowed or paid"); *id.* § 3729(a)(7) (prohibiting reverse false claims in which false records or statements are used "to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government").

n11 See *id.* § 3729(b). An actionable "claim" includes "any request or demand . . . for money or property" if any portion thereof comes from the federal government. *Id.* § 3729(c).

n12 See 31 U.S.C. § 3729(a)(7) (2004) (setting forth statutory penalties and treble damages); 28 C.F.R. § 85.3(a)(9) (2004) (increasing statutory penalties by 10% for inflation).

The unique nature of the FCA derives from its *qui tam* provision, which permits private "whistleblowers" who sue on the government's behalf to retain fifteen to thirty percent of the proceeds of the suit. n13 The *qui tam* provision creates a powerful incentive for private parties, known as "relators," to police their neighbors in the healthcare market. Since 1986, when amendments modernized the FCA and made it more lucrative to pursue *qui tam* actions, the number of healthcare FCA suits has grown exponentially. Healthcare *qui tam* suits now eclipse those in other areas of government contracting, including the defense industry. n14 This powerful law is invoked not only by federal prosecutors, but also by competitors, employees, and even patients and their families--making the FCA a significant threat to healthcare providers who receive payment from the federal healthcare programs. n15 Recent settlements in the

hundreds of millions of dollars attest to the FCA's powerful effect on the healthcare industry. n16

n13 *See* 31 U.S.C. §§ 3730(b), 3730(d) (2004) (noting that a private person who brings a civil action may potentially receive 15 to 30% of the proceeds of the suit).

n14 By 1998, 61% of the *qui tam* cases filed involved the federal healthcare programs, compared to only 12% in 1987. *See* Fried Frank Harris Shriver & Jacobsen, *Qui Tam FCA Statistics*, at www.ffhsj.com/quitam/fcastats.htm (last visited Mar. 30, 2003).

n15 *See, e.g.*, *United States ex rel. Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001) (alleging that relator's former employer, a pulmonology physician practice, submitted fraudulent Medicare claims for spirometry tests); *United States ex rel. Showell v. Philadelphia AFL, CIO Hosp. Ass'n*, 2000 U.S. Dist. LEXIS 4960, at *1 (E.D. Pa. Apr. 18, 2000) (alleging that hospital submitted false claims in connection with care of the relator's mother), *aff'd*, 275 F.3d 38 (3d Cir. 2001).

n16 *See, e.g.*, Press Release, Dep't of Justice, TAP Pharmaceutical Products, Inc. and Seven Others Charged with Health Care Crimes; **Company** Agrees to Pay \$ 875 Million to Settle Charges (Oct. 3, 2001), at www.usdoj.gov/opa/pr/2001/October/513civ.htm (last visited Mar. 30, 2004) (describing largest healthcare fraud settlement to date) [hereinafter Dep't of Justice, TAP Pharmaceutical Products, Inc.].

Historically, healthcare FCA cases have involved misrepresentation of the services for which payment was requested. For example, liability has been imposed on healthcare providers who submitted claims for services never rendered, such as when a physician billed for a patient he did not actually treat. n17 Similarly, liability has attached to claims for services that were not provided as indicated on the bill, such as when a more expensive procedure was billed in place of the less expensive service rendered--a practice known as "upcoding." n18 But over time, federal prosecutors and *qui tam* relators have sought to extend this powerful law to encompass broader categories of improper activities that involve the federal healthcare programs.

n17 *See, e.g.*, *Peterson v. Weinberger*, 508 F.2d 45, 47-48 (5th Cir. 1975) (imposing liability on a physician who submitted bills to Medicare for physical therapy services that were not performed).

n18 *See, e.g.*, *United States v. Halper*, 490 U.S. 435, 437 (1989) (imposing liability on a defendant who submitted bills for services reimbursed at \$ 12 when the services he actually provided entitled him to only \$ 3), *abrogated on other grounds by Hudson v. United States*, 522 U.S. 93 (1997).

Recent cases have sought to style regulatory noncompliance, rather than billing misrepresentations, as actionable falsity or fraud. In such cases legitimate healthcare services may be rendered to patients, but the claimant allegedly violates an underlying program requirement in connection with the services. For example, the relator in *United States ex rel. Pogue v. American Healthcorp, Inc.* n19 alleged that the defendant hospitals and physicians submitted claims for services furnished pursuant to patient referrals made in violation of the Medicare & Medicaid Anti-Kickback Statute and the Stark Law. n20 The relator argued that because compliance with these anti-referral laws was a prerequisite for participation in Medicare and Medicaid, claims submitted in violation of these laws were by definition false and fraudulent. n21 In other words, the regulatory noncompliance arguably fell within the FCA's prohibition because the government would not have paid the defendants for their services had it known of the illegal referrals. The district court found these allegations sufficient to withstand a motion to dismiss, but did not rule on the underlying merits. n22

n19 *United States ex rel. Pogue v. American Healthcorp, Inc.*, 914 F. Supp. 1507 (M.D. Tenn. 1996).

n20 *See id.* at 1513 (denying defendants' motion to dismiss); 42 U.S.C. § 1320a-7b(b) (2004) (Anti-Kickback Statute); 42 U.S.C. § 1395nn (2004) (Stark Law).

n21 *Pogue*, 914 F. Supp. at 1513. The district court initially rejected *Pogue's* theory, *see* *United States ex rel. Pogue v. American Healthcorp, Inc.*, No. 3-94-0515, 1995 WL 626514, at *6 (M.D. Tenn. Sept. 14, 1995), but later reconsidered. *Pogue*, 914 F. Supp. at 1513 (granting motion to reconsider).

n22 *Pogue*, 914 F. Supp. 1507 (denying defendants' motion to dismiss).

These newer healthcare FCA cases precede under two distinct theories of liability: "tainted claims" and "false certifications." n23 Tainted claims arise when a defendant provides false information or violates a legal requirement in the course of negotiating a government contract, thus *per se* "tainting" all subsequent claims under the contract. n24 This theory of "fraud-in-the-inducement" arose in government contracting cases in which the defendant used false information to procure the contract. n25 In the healthcare context, the tainted claims approach encompasses not only providers who use false information to obtain approval to *participate* in the federal healthcare programs, but also regulatory violations that arise *during* the provider's subsequent participation in the program, such as the prohibited referrals alleged in *Pogue*. n26 While a number of district courts have found this theory of FCA liability credible when ruling on motions to dismiss, the Fifth Circuit has rejected the *per se* approach to healthcare fraud, holding "that claims for services rendered in violation of a statute do not necessarily constitute false or fraudulent claims under the FCA." n27

n23 For a detailed discussion of the history and application of these theories, see Joan H. Krause, "*Promises to Keep: Health Care Providers and the Civil False Claims Act*," 23 CARDOZO L. REV. 1363, 1372-81, 1391-99 (2002) [hereinafter Krause, "*Promises to Keep*"]; Joan H. Krause, *Health Care Providers and the Public Fisc: Paradigms of Government Harm Under the Civil False Claims Act*, 36 GA. L. REV. 121, 170-81 (2001) [hereinafter Krause, *Health Care Providers and the Public Fisc*].

n24 Krause, "*Promises to Keep*," *supra* note 23, at 1393.

n25 *See, e.g.,* *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 787-88 (4th Cir. 1999) (describing "fraud-in-the-inducement" cases).

n26 *See Pogue*, 914 F. Supp. 1507 (basing FCA suit on alleged violations of Anti-Kickback Statute and Stark Law); S. REP. NO. 99-345, at 10 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5275 (noting that "all Medicare claims submitted by or on behalf of a physician who is ineligible to participate in the program" are actionable under the FCA); Lisa Michelle Phelps, Note, *Calling Off the Bounty Hunters: Discrediting the Use of Alleged Anti-Kickback Violations to Support Civil False Claims Actions*, 51 VAND. L. REV. 1003, 1005 (1998) (describing "anti-kick-back-based tainted claims").

n27 *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997). *See United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1020 (7th Cir. 1999) (holding that "the FCA is not an appropriate vehicle for policing technical compliance with administrative regulations."); Krause, "*Promises to Keep*," *supra* note 23, at 1393-96 (discussing tainted claims).

Rather than hinge FCA liability on an expansion of the traditional fraud-in-the-inducement theory, other courts focus on false *certifications* of compliance with the legal requirements that are prerequisites to receiving government payment. Federal prosecutors and *qui tam* relators have argued that participation in Medicare and Medicaid entails an implied certification that the claimant will abide by all relevant program requirements. n28 The implied certification theory has not been persuasive when the alleged violations are not clearly linked to the payment decision. n29 Nonetheless, when an *explicit* certification of compliance is required before the government will make payment, or where the misrepresentation lies at the "heart" or "core" of the defendant's agreement with the government, false representations clearly implicate the FCA. n30

n28 In *Pogue*, for example, the relator argued that the defendants had implicitly certified their compliance with the federal anti-referral statutes. Thus, by requesting payment for medical services rendered in violation of these statutes, the defendants allegedly submitted false and fraudulent claims. *Pogue*, 914 F. Supp. at 1509.

n29 *See, e.g., United States ex rel. Mikes v. Straus*, 84 F. Supp. 2d 427, 435 (S.D.N.Y. 1999) (finding implied certification theory not applicable unless "the claimant's adherence to the relevant statutory or regulatory mandates lies at the core of its agreement with the Government"); *Luckey v. Baxter Healthcare Corp.*, 2 F. Supp. 2d 1034, 1045 (N.D. Ill. 1998) (finding there to be "no evidence that [defendant's] practice violated the heart of its agreement with the government").

n30 *Mikes*, 84 F. Supp. 2d at 435; *Luckey*, 2 F. Supp. 2d at 1045. As the Ninth Circuit has noted, "violations of laws, rules, or regulations alone do not create a cause of action under the FCA. It is the false *certification* of compliance which creates liability when certification is a prerequisite to obtaining a government benefit." *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996) (emphasis in original) (citations omitted). *See Thompson*, 125 F.3d at 902 (noting that "where the government has conditioned payment of a claim upon a claimant's certification of compliance with, for example, a statute or regulation, a claimant submits a false or fraudulent claim when he or she falsely certifies compliance with that statute or regulation"); Krause, "*Promises to Keep*," *supra* note 23, at 1396-99 (discussing false certifications).

While the tainted claims approach is largely confined to suits alleging violations of the anti-kickback and Stark laws, false certification has been used to reach allegations concerning the quality of care in institutions participating in the federal healthcare programs. This theory was first publicized in *United States ex rel. Aranda v. Community Psychiatric Centers*, in which a psychiatric hospital was accused of failing to provide Medicaid patients with the "reasonably safe environment" required by federal law. n31 The government invoked the implied certification theory, arguing that by submitting bills for services rendered to patients, the hospital implicitly certified that it was in compliance with all relevant program quality criteria. n32 The district court agreed that this could be a viable theory of FCA liability, noting that the Medicaid law and regulations mandated compliance with certain quality standards. n33

n31 *United States ex rel. Aranda v. Cmty. Psychiatric Ctr.*, 945 F. Supp. 1485, 1487-88 (W.D. Okla. 1996) (alleging that environment within the psychiatric center was not "reasonably safe" because understaffing placed patients in danger of physical injury and sexual abuse).

n32 *Id.* at 1487.

n33 *Id.* at 1488. Because the opinion arose on a motion to dismiss, the court did not have occasion to address whether the plaintiff ultimately would have prevailed on the merits.

In many ways, these institutional quality of care cases have more in common with traditional false claims than with the modern anti-referral cases. At core, the government's focus is not on a regulatory violation *per se*, but rather on the paradigm false claim: a bill for care that was not rendered. The Medicare and Medicaid statutes impose broad quality obligations on participating institutions, such as **nursing homes**. Thus, it is not surprising that quality-related FCA theories have had the greatest impact in the long term care industry. In *United States v. NHC Healthcare Corp.*, for example, the government argued that a **nursing home** "was so severely understaffed that it could not possibly have administered all of the care it was obligated to perform" for its federal healthcare program patients. n34 The court explained that a violation of the FCA could be found if "patients were not provided the quality of care which promotes the maintenance and the enhancement of the quality of life," as required by the Medicare and Medicaid regulations. n35 In a later proceeding, the court found that "the standard of care [was] indeed at the heart of the agreement" and denied the defendant's motion for summary judgment. n36 The idea that systemic substandard care violates the "heart" of a federally funded **nursing home's** obligations has proven extremely successful in subsequent cases. Beginning with a 1996 case against a Philadelphia **nursing home** operator and management **company**, federal prosecutors have used this theory as the basis for negotiating a number of high-profile settlements with **nursing homes** accused of billing the government for "inadequate" care. n37

n34 *United States v. NHC Healthcare Corp.*, 115 F. Supp. 2d 1149, 1153 (W.D. Mo. 2000).

n35 *Id.*

n36 *United States v. NHC Healthcare Corp.*, 163 F. Supp. 2d 1051, 1055 (W.D. Mo. 2001).

n37 *See, e.g.*, David R. Hoffman, *The Role of the Federal Government in Ensuring Quality of Care in Long-Term Care Facilities*, 6 ANNALS HEALTH L. 147 (1997) (detailing the prosecuting attorney's discussion of *United States v. GMS Management-Tucker, Inc.*, No. 96-1271 (E.D. Pa., settled Feb. 21, 1996)).

Outside the institutional context, however, the quality-based certification theory has met with mixed success. In several cases, relators have alleged violations of technical and scientific requirements pertaining to the federal healthcare programs, such as laboratory testing or medical equipment calibration standards. n38 In *United States ex rel. Mikes v. Straus*, for example, the Second Circuit affirmed the dismissal of a physician relator's suit, which was premised on her ex-employer's submission of bills for pulmonary function tests performed on equipment that allegedly had not been properly calibrated. n39 Although affirming the validity of "implied certification" in the abstract, the court found that payment was not expressly conditioned on compliance with the proffered calibration standards. n40 The relator similarly failed to establish that claims were submitted for "worthless services" because the defendants "proffered ample evidence . . . that they held a good faith belief that their spirometry tests were of medical value." n41 Hence, the defendants lacked the requisite knowledge of falsity under the FCA.

n38 *See, e.g.*, *Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730, 730 (7th Cir. 1999) (rejecting FCA allegations based on disagreement as to proper testing procedures for blood plasma samples).

n39 *Straus*, 274 F.3d at 692-93.

n40 *Id.* at 700-03 (holding that "implied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies expressly states the provider must comply in order to be paid.").

n41 *Id.* at 704. *See Luckey*, 183 F.3d at 732 (rejecting the "equation of ineffective testing with no testing, followed by the proposition that a battle of experts in litigation determines whether testing is 'effective.'"). *Cf. United States ex rel. Lee v. Smithkline Beecham, Inc.*, 245 F.3d 1048, 1050, 1053-54 (9th Cir. 2001) (acknowledging that "in an appropriate case, knowingly billing for worthless services . . . may be actionable," and holding that relator should have been granted leave to amend his suit alleging that a laboratory falsified results of tests on control samples).

There may be several reasons why the institutional quality-of-care cases have fared better than those alleging violations of technical quality-related testing and calibration standards. One such reason is jurisprudential: while both types of quality cases are styled as implicit or explicit false certifications, the essence of the institutional allegations is that the government has paid for services that were not rendered. Thus, these cases allege a paradigmatic false claim and fit squarely within the rich history of government contracting FCA cases. n42 Moreover, by characterizing *patients* as the direct victims of the fraud--rather than a faceless federal agency--these cases generate significantly more sympathy from jurors and the general public. n43 As one commentator has noted:

This theory, which focuses on the patient as a victim of the fraudulent provider, allows proof of a sad truth: the health care provider, by virtue of expertise and status, is able to commit fraud by frightening the ill and trusting patient into parting with money, or more. n44

n42 *See NHC Healthcare Corp.*, 163 F.Supp. 2d at 1055 (noting that "defendants are being sued because they allegedly failed to provide the services that they billed for," an approach that obviated the need to prove false certification); Krause, "*Promises to Keep*," *supra* note 23, at 1402-06 (situating institutional quality cases within traditional FCA jurisprudence).

n43 *See* ROBERT FABRIKANT ET AL., HEALTH CARE FRAUD: ENFORCEMENT & COMPLIANCE § 1.04[2], at 1-25 (2003)

("In circumstances where it is possible and appropriate to include the patient as a victim in the theory of the case, prosecutors may gain substantial leverage in negotiating or trying claims of health care fraud.")

n44 Pamela H. Bucy, *Fraud by Fright: White Collar Crime by Health Care Providers*, 67 N.C. L. REV. 855, 937 (1989).

The combination of an established theory of FCA liability (which appeals to judges), with a sympathetic victim (which appeals to jurors), has given federal prosecutors and *qui tam* relators significant leverage in these disputes--a fact that is both acknowledged and lamented by many in the healthcare industry. n45

n45 See, e.g., Michael E. Clark, *Whether the False Claims Act is a Proper Legal Tool for the Government to Use for Improving the Quality of Care in Long-Term Care Facilities*, 15 HEALTH LAW. 1, at 12, 16 (Sept. 2002) (arguing that "even though the judicial system can be used to force compliance with government edicts, the effectiveness of this method is debatable since the results can be haphazard and counterproductive, as when providers decide that they will no longer participate in programs that impose too many regulations for too little money); Krause, *"Promises to Keep"*, *supra* note 23, at 1394-96, 1398-99, 1401-03 (analyzing criticism of various quality-related FCA theories); Krause, *Health Care Providers and the Public Fisc*, *supra* note 23, at 202-12 (discussing need for the healthcare industry to perceive enforcement agenda as legitimate).

II. The Relationship Between Fraud and Harm

It is clear that healthcare fraud leads to substantial financial losses for the federal healthcare programs. A recent audit estimated that the Medicare program paid out \$ 11.6 billion in improper claims in fiscal year 2003 alone, an error rate of 5.8%. n46 Given ongoing concerns over the solvency of the Medicare program, particularly once the "Baby Boomers" become eligible for benefits, healthcare fraud recoveries may provide a means to offset escalating program costs without raising taxes or reducing the scope of benefits. n47 Nevertheless, it is important to remember that the federal government is not the only entity that is affected by fraudulent activities. Healthcare fraud also causes significant harm to *patients*--be it physical harm, financial harm, or less tangible forms of interference with patient interests. While the current focus on returning funds to the federal Treasury helps to assure that the federal healthcare programs remain solvent and continue to benefit patients in the *aggregate*, it does not directly address harm to *individual* beneficiaries.

n46 Press Release, Ctrs. for Medicare and Medicaid Servs., CMS Announces Medicare Improper Payments Rate for 2003 (Nov. 14, 2003), *available at* www.cms.gov/media/press/release.asp?Counter=905 (last visited Mar. 30, 2004).

n47 See, e.g., OFF. OF MANAGEMENT AND BUDGET, MID-SESSION REVIEW: MEDICARE TRUST FUNDS, (projecting Medicare shortfalls through 2011), *available at* www.whitehouse.gov/omb/budget/fy2002/msr03.html (last visited Mar. 30, 2004).

A. Physical Injury

At times, beneficiaries suffer direct physical injury as the result of fraudulent activities, such as when unnecessary medical procedures are performed solely for the purposes of obtaining payment from the federal healthcare programs. In *United States v. Laughlin*, an obstetrician/gynecologist was convicted of multiple counts of Medicaid fraud and mail fraud based on a series of fraudulent billings, including double billings. n48 In one instance, the defendant performed a tubal ligation four weeks after delivering a patient's baby by caesarian section. n49 While this procedure enabled the doctor to bill for two surgical procedures rather than one, it also posed a risk of serious harm to a patient who had not yet healed from her previous surgery. n50 Similarly, in *United States ex rel. Kneepkins v. Gambro Healthcare Inc.*, a laboratory **company** was accused of drawing additional blood samples from patients for unnecessary tests, despite being aware that the procedures "would provide no medical or economic benefit (other than to the Lab's bottom line) and would subject sick patients to needless and intrusive withdrawal of additional blood, with the attendant (albeit incremental) medical risks." n51

n48 *United States v. Laughlin*, 26 F.3d 1523, 1530-31 (10th Cir. 1994).

n49 *Id.* at 1530.

n50 *Id.* at 1530-31. Despite the recent emphasis on cases involving physical harm, these types of allegations are not new. *See, e.g.*, *United States v. Talbott*, 590 F.2d 192, 194 (6th Cir. 1978) (affirming conspiracy and mail fraud convictions of dentists based on allegations, *inter alia*, "that root canal procedures were performed on teeth that should have been extracted as well as on healthy teeth; that some procedures billed as root canals were at best pulpotomies; and that in certain instances teeth were filled for no apparent reason while obvious cavities went untreated").

n51 *United States ex rel. Kneepkins v. Gambro Healthcare Inc.*, 115 F. Supp. 2d 35, 42 (D. Mass. 2000).

Even if the unnecessary services do not in themselves pose any risk to patients, courts have recognized that harm may occur if patients rely on useless treatments and delay seeking medically necessary care. In *United States v. Vivit*, a physician was convicted of mail fraud based on the provision of unnecessary services, which included physical therapy performed by his unlicensed office personnel. n52 Acknowledging that some patients relied on the physician to treat their serious medical conditions, the court noted, "by failing to examine such patients properly, Vivit created a risk that, had these patients suffered serious injuries, their injuries would remain untreated." n53

n52 *United States v. Vivit*, 214 F.3d 908, 911 (7th Cir. 2000).

n53 *Id.* at 922. *See also* *United States v. Greene*, 17 Fed. Appx. 722, 2001 WL 1019497, at *1 (9th Cir. Sept. 4, 2001) (defendant's sale of fraudulent HIV kits "posed a substantial threat to public health because he purported to provide reliable HIV screening when in fact there was no sensible basis for the test 'results' he sent to customers," leading to at least one customer "who unwittingly put a new partner at risk.").

A theory of direct physical harm also underlies the recent **nursing home** settlements, in which the government has alleged that understaffed facilities pose serious threats to patient health (as well as submitting fraudulent bills for care). n54 The United States Attorney for the Eastern District of Pennsylvania has assumed the lead in these cases, beginning with a 1996 case against a Philadelphia **nursing home** operator and management **company**. n55 Although the nursing facilities have not admitted any liability in these proceedings, common elements of the settlements include the payment of civil penalties, the development of specific training and oversight procedures for problem areas, quality monitoring by outside entities, and the adoption of a corporate compliance program. n56

n54 *See, e.g.*, Hoffman, *supra* note 37, at 152-53 (describing patient injuries that gave rise to *GMS Management-Tucker nursing home* settlement).

n55 *See id.* (discussing prosecuting attorney's views of case); Settlement Agreement between United States and Ashton Hall Nursing and Rehabilitation Center (Nov. 7, 2000), at www.usdoj.gov/usao/pae/Nursing/ashton.pdf (last visited Mar. 30, 2004) (describing terms of settlement); Consent Order and Judgment, *United States v. Chester Care Ctr. et al.*, Civ. A. No. 98-CV-139, (E.D. Pa., Jan. 1998) (describing terms of settlement), available at www.usdoj.gov/usao/pae/Nursing/chester3.pdf (last visited Mar. 30, 2004).

n56 *See* Hoffman, *supra* note 37, at 154-56 (explaining initial settlement).

B. Financial Injury

It is equally clear that, even in the absence of physical injury, fraudulent activities can cause *financial* harm to patients. Recent investigations in the prescription drug industry illustrate this on a grand scale. In October 2001, TAP Pharmaceutical Products (TAP) agreed to pay a record \$ 875 million to settle a variety of civil and criminal fraud

allegations stemming from the sale of its cancer drug, Lupron. n57 TAP allegedly inflated the prices it reported to the drug pricing publications on which Medicare contractors base their reimbursement rates, thus assuring that reimbursement would remain artificially high. n58 By "marketing the spread" between the discounted prices paid by its physician customers and the artificially high rate at which Medicare reimbursed the product, TAP was accused of offering its customers a financial inducement to prescribe Lupron in violation of the Anti-Kickback Statute, and causing customers to submit false claims under the FCA. n59 Plaintiffs in a subsequent private suit against TAP alleged that while the actual cost of Lupron *dropped* from \$ 340 to \$ 207 between 1993 and 1999, the published AWP *increased* from \$ 418.75 to \$ 623.79. n60 As the court in that case noted, "defendants repeatedly assert that . . . AWP was a 'sticker price' and never intended to reflect the drug's true average wholesale price. . . . *There is a difference between a sticker price and a sucker price.*" n61

n57 See Dept of Justice, TAP Pharmaceutical Products Inc., *supra* note 16.

n58 *Id.* Under then-current law, physicians generally were reimbursed on the lower of (i) their actual charges or (ii) 95% of the "Average Wholesale Price" (AWP) of the drug. See 42 U.S.C. §§ 1395u(o)(1), 13951(a)(1)(S) (2004); 42 C.F.R. § 405.517(b) (2004). Neither the law nor regulations provided a definition of "AWP"; rather, the Medicare contractors performed their own calculations based on the information in drug pricing publications. See John K. Iglehart, *Medicare and Drug Pricing*, 348 NEW ENGL. J. MED. 1590, 1591 (2003). This reimbursement methodology was changed as part of the Medicare reform legislation enacted in December 2003. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 303, 117 Stat. 2066, 2233 (2003) ("Payment Reform for Current Outpatient Drugs and Biologicals").

n59 See Dept of Justice, TAP Pharmaceutical Products Inc., *supra* note 16.

n60 See *In re Lupron Mktg. & Sales Practices Litig.*, 295 F. Supp. 2d 148 at 159, & n.8 (D. Mass. 2003).

n61 *Id.* at 168 n.19 (emphasis added).

Moreover, the Medicare program was not the only victim of this pricing fraud: Medicare beneficiaries are required to pay a twenty percent co-payment for such drugs. n62 As noted in the Conference Report accompanying the 2003 Medicare reform legislation, "in addition to the financial toll on the U.S. Treasury, these large spreads also affect Medicare beneficiaries, who are often required to pay dramatically inflated co-payments for the drugs they receive." n63 Following the TAP settlement, which resolved only the state and federal government claims against the **company**, a consortium of patients, health plans, and state attorneys general filed a series of civil actions against the **company** seeking damages and injunctive relief. n64

n62 See 42 U.S.C. § 13951(a) (setting forth 80/20 split).

n63 H.R. CONF. REP. NO. 108-391, at H12030 (2003) (reporting OIG estimate "that if Medicare had paid reimbursements equal to widely available wholesale prices, beneficiaries would have paid \$ 175 million less in coinsurance" each year).

n64 See, e.g., *In re Lupron Mktg. & Sales Practices Litig.*, 295 F. Supp. 2d 148 (consolidated suit against TAP by consortium of patients and health plans).

Allegations of this type, however, are not limited to TAP. A number of the major drug manufacturers are under investigation for similar pricing activities. n65 The potential impact on beneficiaries has been illustrated by the Centers for Medicare & Medicaid Services (CMS), which reported that the "spread" for some drugs is so large that the patient's twenty percent Medicare co-payment is greater than the *total* price paid by the physician who purchased the drug. n66 If these allegations are true, the potential harm to patients is staggering. Virtually every federal healthcare program

beneficiary who received these drugs on an outpatient basis, as well as every privately insured patient whose insurer based its own payment structure on the inflated AWP, might have a compensable injury.

n65 *See, e.g., Complaint for Injunctive Relief, Damages, Restitution, Disgorgement, Forfeiture, Civil Penalties and Other Relief, State of Nevada v. Abbott Laboratories Inc.* (2d Jud. Dist. Ct., Jan. 17, 2002), at ag.state.nv.us/agpress/2002/02_0117a.pdf (last visited Mar. 30, 2003) (consumer protection action brought by Nevada Attorney General against numerous drug **companies** "on behalf of persons in Nevada including thousands of patients who have paid inflated charges for medications"); *TAP Pharmaceuticals, Bristol-Myers Squibb Targets of Federal Marketing, Pricing Probe*, 4 HEALTH CARE FRAUD REP. (BNA) 207 (Oct. 17, 2001).

n66 *See Ctrs. for Medicare and Medicaid Servs., Medicare Program; Payment Reform for Part B Drugs*, 68 Fed. Reg. 50,428, 50,430 (proposed Aug. 20, 2003) (to be codified at 42 C.F.R. pt. 405) (proposing to revise Medicare drug reimbursement methodology).

C. Intangible Injuries to Patient Interests

In other circumstances, the harm to patients is less tangible. Healthcare fraud, for example, may involve a provider's misuse of patient information to gain reimbursement for services that were not performed. In some cases, the provider renders legitimate services to the patient, but also charges for additional services the patient did not receive. In *United States v. Sidhu*, for example, a physician billed the federal healthcare programs for biofeedback services, despite the fact that patients "never saw [the] biofeedback machine, and [the provider] generally just talked to the patient, performing more of a counseling role." n67 In other cases, the provider may have no interaction with the patient at all--which may be the basic point of the scheme. n68 In *Sidhu*, the physician was also accused of billing for psychotherapy on dates when he was out of town and, in one case, for "a patient who was no longer living." n69 Given the current interest in healthcare privacy, the misappropriation of sensitive patient medical information for personal financial gain appears to be particularly offensive. n70

n67 130 F.3d 644, 648-49 (5th Cir. 1997).

n68 *See U.S. GEN. ACCOUNTING OFF., HEALTH CARE FRAUD: SCHEMES COMMITTED BY CAREER CRIMINALS AND ORGANIZED CRIMINAL GROUPS AND IMPACT ON CONSUMERS AND LEGITIMATE HEALTH CARE PROVIDERS*, B-283695, at 8-9 (Oct. 5, 1999) (discussing fraudulent use of beneficiary information that was stolen, illegally purchased, or otherwise obtained) [hereinafter GEN. ACCOUNTING OFF., HEALTH CARE FRAUD].

n69 *Sidhu*, 130 F.3d at 647.

n70 *See, e.g., 45 C.F.R. pts. 160, 164* (2004) (containing new privacy standards for "protected health information").

In many of these cases the primary harm appears to be to the federal Treasury, such as when Medicare pays for services supposedly rendered to a deceased patient. When fraudulent bills are generated in a living patient's name, however, there is significant potential for interference with the patient's ability to obtain services in the future. Similar to private insurers, many Medicare-covered services have annual or lifetime limits. For example, Medicare Part A coverage of inpatient hospital services is limited to ninety days per spell of illness, plus sixty lifetime reserve days. n71 Similarly, skilled nursing care is limited to one hundred days per spell of illness. n72 If fraudulent bills are submitted under a beneficiary's name, little or no coverage may be available when the patient legitimately requires care in the future. In one reported case, a psychiatrist was accused of submitting false bills for daily therapy for hospitalized patients. n73 The court noted:

[Patients] were often admitted to the hospital needlessly or their stays in the hospital were extended beyond what was necessary and their insurance **companies** were billed for treatment not given. Further, the patients' treatment benefits were often exhausted by the time of their discharge. In some cases, patient

benefits were exhausted for a life-time; therefore, any future treatment needs would not be covered under their current policy. n74

n71 42 U.S.C. § 1395d(a)(1) (2004).

n72 *Id.* § 1395d(a)(2).

n73 *United States v. Burgos*, 137 F.3d 841, 842 (5th Cir. 1998).

n74 *Id.* at 844.

The reality of this result was underscored by a General Accounting Office (GAO) report on organized criminal healthcare schemes, which concluded that beneficiaries "unknowingly risk exhaustion of their insurance benefits, due to false information included in the claims that use their names." n75

n75 GEN. ACCOUNTING OFF., HEALTH CARE FRAUD, *supra* note 68, at 4.

Even when future coverage is not at risk, fraud may affect a patient's healthcare *choices*, including the choice of caregiver. Managed care organizations (MCOs) that serve the Medicaid program, for example, have been accused of purchasing the names of potential enrollees, making fraudulent representations to prospective enrollees, and offering improper inducements for patients to enroll in their plans. n76 Without accurate information, however, patients are unable to make a responsible choice between managed care and traditional fee-for-service Medicaid options. n77 Moreover, when these misrepresentations rise to the level of coercion, they may interfere with patient autonomy and dignity rights. On occasion, Medicaid patients have reported threats by marketers who warn that they will lose their coverage if they do not immediately enroll in an MCO for their care. n78 Similarly, in one particularly egregious anti-kickback case, a chemical dependency program for pregnant women paid illegal remunerations for referrals of patients from a federally funded research project designed to advise pregnant women about drug abuse treatment options. n79 More disturbing than the obvious payment for referrals was the fact that the illegal arrangement directly interfered with the counseling the women received. At trial, several women testified that they were threatened with the loss of their children if they did not receive treatment for their addictions from this particular chemical dependency program. n80 Thus, even if there is no threat of immediate physical or financial injury, fraudulent activities may interfere with a patient's dignitary right to make healthcare choices free from coercion.

n76 See Sharon L. Davies & Timothy Stoltzfus Jost, *Managed Care: Placebo or Wonder Drug for Health Care Fraud and Abuse?* 31 GA. L. REV. 373, 387-89 (1997) (summarizing recent investigations into Medicaid managed care marketing practices).

n77 Cf. Joan H. Krause, *Reconceptualizing Informed Consent in an Era of Health Care Cost Containment*, 85 IOWA L. REV. 261, 281-92 (1999) (analyzing autonomy concerns raised by managed care).

n78 Davies & Jost, *supra* note 76, at 389 (describing abuses in New York).

n79 *United States v. Starks*, 157 F.3d 833, 836 (11th Cir. 1998).

n80 *Id.* at 837.

While all of these harms may result from fraudulent activities, they differ in key respects. In some schemes, such as those involving the misappropriation of patient information to generate false bills for care, patient harm is largely incidental to the fraud. In other words, the fraud is complete when the bill is submitted, regardless of whether the bill is paid, whether the fraud is detected, or whether the patient suffers any repercussions. In other cases, by contrast, healthcare fraud appears almost incidental to patient harm. If a **nursing home** commits malpractice by mistreating a resident, the patient harm is complete. In contrast, fraud does not occur until the institution submits a *bill* for its services--and, most likely, only if the allegations are systemic and the services are so inadequate as to be equivalent to no care at all. n81

n81 *See, e.g., NHC Healthcare Corp.*, 163 F. Supp. 2d at 1055 ("Defendants are not being sued simply for violating the standard of care Rather, Defendants are being sued because they allegedly failed to provide the services that they billed for."); *id.* at 1055 n.3 (distinguishing malpractice from FCA liability).

While cases in the former category implicate the FCA from the beginning, those in the latter category only do so if the activities are part of an ongoing problem. Furthermore, they are likely to be attractive enforcement targets only when other quality improvement mechanisms fail. Thus, the first category invokes the government's authority as a defrauded *payor*, while the second implicates the government's role as the *protector* of vulnerable program beneficiaries--a theme that runs through many of the quality-of-care cases.

III. Patient Harm and Fraud Enforcement: The Rhetoric

The laws and regulations prohibiting healthcare fraud are drafted to apply to a wide variety of anticipated, and perhaps unanticipated, activities. Several provisions explicitly consider patient harm when assessing the necessity and severity of sanctions. Federal prosecutors have liberally drawn on these laws, developing a "rhetoric of patient protection" that underlies recent healthcare fraud investigations.

A. Legal Recognition of Patient Harm

The potential for patient harm is recognized by a variety of laws and regulations governing healthcare fraud as a factor relevant to both the imposition and the amount of sanctions. For example, the "health care fraud" crime created by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) imposes progressively longer terms of imprisonment on persons convicted of defrauding a healthcare benefit program if patient harm occurs. Depending on the level of physical harm caused, imprisonment ranges from a base term of no more than ten years, to no more than twenty years if the activity "results in serious bodily injury," to "any term of years or for life" if death results. n82 Similarly, in assessing the length of time a provider will face mandatory exclusion from the federal healthcare programs, the fact that the acts "had a significant adverse physical, mental, or financial impact on one or more program beneficiaries or other individuals" is an aggravating factor weighing in favor of a more lengthy exclusion period. n83 Where the fraud itself is likely to have an impact on beneficiary health--such as when an MCO fails to furnish medically necessary items and services to its enrollees--the fact that the denial "had or could have had a serious adverse effect" is particularly relevant to the length of exclusion. n84

n82 18 U.S.C. § 1347 (2004).

n83 42 C.F.R. § 1001.102(b)(3) (2004). Similar factors are taken into account when the government has discretion to exclude under the permissive exclusion authority. *See, e.g., id.* § 1001.201(b)(2)(iii) (permissive exclusion based on convictions for program or healthcare fraud); *id.* § 1001.401(c)(2)(ii) (permissive exclusion based on convictions for controlled substances); *id.* § 1001.501(b)(1) (permissive exclusion based on license revocation or suspension); *id.* § 1001.601(b)(2)(i) (permissive exclusion based on exclusion or suspension from federal or state healthcare program); *id.* § 1001.701(d)(2)(ii) (permissive exclusion based on excessive claims or provision of unnecessary/substandard services); *id.* § 1001.951(b)(1)(ii) (permissive exclusion based on frauds and kickbacks).

n84 42 C.F.R. § 1001.801(c)(2)(iii) (2004).

The severity of actual or potential harm to patients also is relevant in determining the amount of civil monetary penalties (CMPs) to be imposed in administrative proceedings within DHHS. The fact that "false or misleading information resulted in harm to the patient, a premature discharge or a need for additional services or subsequent hospital admission" is an aggravating circumstance warranting higher penalties. n85 Similarly, when a healthcare provider "dumps" an unwanted patient in violation of the Emergency Medical Treatment and Labor Act (EMTALA), n86 aggravating circumstances include whether the "violation(s) occurred with regard to an individual who presented . . . a medical condition that was clearly an emergency," and whether "an individual was severely harmed or died as a result, directly or indirectly," of the violation. n87

n85 *Id.* § 1003.106(b)(1)(iv).

n86 42 U.S.C. § 1395dd (2004).

n87 42 C.F.R. §§ 1003.106(d)(2), (d)(6)(ii).

Physical harm, however, is not the only type of injury relevant to punishment under the fraud laws. In determining the appropriate length of a permissible exclusion, aggravating factors include the fact that the actions "had a significant financial impact on program beneficiaries or other individuals." n88 Similarly, physicians who knowingly and willfully bill Medicare patients for excessive charges are subject to CMPs, n89 as are MCOs that impose excessive premiums on their enrollees. n90 It is clear, then, that the federal laws and regulations governing healthcare fraud acknowledge both physical and financial harm to patients as factors relevant to the necessity and severity of sanctions.

n88 *Id.* § 1001.201(b)(2)(i).

n89 *See* 42 U.S.C. § 1395u(j)(1)(A) (2004) (stating prohibition); *id.* § 1395u(j)(2) (setting forth exclusion and CMP authorities). *See also* Entry of Consent Decree, *United States v. Corson*, No. 93-CV-3637, 1993 WL 332268, at *4 (E.D. Pa. July 12, 1993) (alleging that physician caused the submission of false or fraudulent claims for excessive charges).

n90 *See* 42 U.S.C. § 1395mm(i)(6) (2004) (stating prohibition and listing penalties).

B. Patient Protection Rhetoric

Not surprisingly, federal prosecutors have drawn on these provisions to develop a "rhetoric of patient protection" in healthcare cases, advancing the protection of program beneficiaries as a key reason for undertaking fraud investigations. This rhetorical commitment to **protecting** patients is apparent both in agency guidance and in public statements made by OIG and DOJ personnel.

One of the clearest statements regarding the importance of patient protection came in the OIG's *Compliance Program Guidance for Nursing Facilities*, published in March 2000. n91 The OIG has issued a series of such guidances, each designed to assist healthcare providers in a particular sector of the industry in establishing voluntary compliance programs. n92 While adherence is not mandatory, the guidances are useful for illuminating what OIG believes to be the key fraud issues for each sector. Given ongoing concern over the quality of care in **nursing homes**, as illustrated by the Philadelphia-area FCA settlements, it is not surprising that patient protection plays a prominent role in the government's advice to these entities.

n91 Dep't of Health and Human Servs., Off. of Inspector Gen., Publication of the OIG Compliance Program Guidance for Nursing Facilities, 65 Fed. Reg. 14,289 (Mar. 16, 2000).

n92 See Joan H. Krause, *A Conceptual Model of Health Care Fraud Enforcement*, 12 J.L. & POLICY 55, 95-98 (describing history and effect of guidances).

In the *Compliance Program Guidance for Nursing Facilities*, the OIG made clear that risk of physical harm to patients is a key consideration when a potential compliance problem has been identified, even if there is no harm to the government.

In fact, there may be instances where there is no readily identifiable monetary loss, but corrective actions are still necessary to protect the integrity of the applicable program and its beneficiaries, *e.g.*, where failure to comply with the facility's policies and procedures results in *inadequate or inappropriate care being furnished to a facility resident*. n93

n93 Publication of the OIG Compliance Program, Guidance for Nursing Facilities, 65 Fed. Reg. at 14,303 n.108 (emphasis added).

Additionally, the OIG advised that misconduct having "a significant adverse impact on the quality of care provided to residents" should be considered serious enough to warrant immediate government notification, regardless of whether the **nursing home** has finished its internal compliance investigation. n94 Similar emphasis is present in the *Compliance Program Guidance for Hospices*, which identifies "under-utilization" and "knowingly billing for inadequate or substandard care" as key areas of concern for hospices. n95

n94 *Id.* at 14,304 n.114.

n95 Dep't of Health and Human Servs., Off. of Inspector Gen., Publication of the OIG Compliance Program, Guidance for Hospices, 64 Fed. Reg. 54,031, 54,035-36 (Oct. 5, 1999).

The potential for patient harm also pervades the OIG's responses to comments received from the public regarding proposed healthcare fraud regulations. For example, since 1982, the Medicare program has required oversight by peer review organizations (PROs, renamed "quality improvement organizations" or QIOs), to ensure that Medicare services are medically necessary, are provided economically and efficiently, and meet accepted standards of quality. n96 Healthcare providers who fail to meet these standards are subject to exclusion or to CMPs up to \$ 10,000 for each medically unnecessary or improper treatment. n97 In revising the procedures for sanctioning providers who do not meet these professionally recognized standards of care, the OIG declined to limit the harshest penalties to those situations in which a patient already has suffered harm. n98 Instead, the OIG has stated "that a gross and flagrant violation includes those situations where a patient is placed in danger or in a high-risk situation, whether or not the patient is harmed." n99

n96 See 42 U.S.C. § 1320c-3 (2004) (setting forth functions of PROs); Dep't of Health and Human Servs., Ctrs. for Medicare and Medicaid Servs., Office of Inspector General--Health Care; Medicare & Medicaid Programs; Peer Review Organizations: Name and Other Changes--Technical Amendments, 67 Fed. Reg. 36,539 (May 24, 2002) (to be codified at 42 C.F.R. Chapters IV, V) (changing name to "quality improvement organizations").

n97 42 U.S.C. §§ 1320c-5(a)(2)-(3), 1320c-5(b)(2)-(3) (2004).

n98 Dep't of Health and Human Servs., Off. of Inspector Gen., Health Care Programs: Fraud and Abuse; Revisions to the PRO Sanctions Process, 60 Fed. Reg. 63,634, 63,636 (Dec. 12, 1995) (to be codified at 42 C.F.R. pt. 1004).

n99 *Id.* Similarly, in responding to comments regarding the CMP for retaining an ownership or control interest in an entity while excluded, the OIG stated, "where we have deemed a particular provider unfit to participate in the Medicare and other Federal health care programs . . . we believe that, ordinarily, immediate exclusion will protect . . . program beneficiaries." Dep't of Health and Human Servs., Off. of Inspector Gen., Health Care Programs: Fraud and Abuse; Revised OIG Civil Money Penalties Resulting From Public Law 104-191, 65 Fed. Reg. 24,400, 24,403 (Apr. 26, 2000) (to be codified at 42 C.F.R. pts. 1001, 1003, 1005, 1006).

Similar concerns have been echoed in the DOJ's general statements pertaining to corporate misconduct. In January 2003, Deputy Attorney General Larry D. Thompson issued a memorandum to United States Attorneys setting forth the *Principles of Federal Prosecution of Business Organizations*. n100 In the memorandum, the Deputy Attorney General identified the "risk of harm to the public" as a factor to consider in deciding whether to prosecute. n101 Thus, whether the fraud investigation is led by the OIG or the DOJ, the potential for harm to patients is likely to be an important factor in the severity of the sanctions imposed.

n100 Memorandum from Larry D. Thompson, Deputy Attorney General, to Heads of Department Components, United States Attorneys, re: Principles of Federal Prosecution of Business Organizations (Jan. 20, 2003), at www.usdoj.gov/dag/cftf/business_organizations.pdf (last visited Mar. 30, 2004).

n101 *Id.* at 3.

Patient protection rhetoric also pervades public statements made by OIG personnel and federal prosecutors, both at conferences and in the media. In a press release announcing a \$ 355 million settlement concerning AstraZeneca Pharmaceuticals' drug pricing and marketing activities, for example, Food and Drug Administration Commissioner Mark B. McClellan stated that the "FDA will not tolerate criminal conduct that exploits patients," and Associate Attorney General Robert D. McCallum, Jr., promised "to protect and preserve the health of our elderly, our poor, our military, and its dependents." n102 Similarly, the Chief of the OIG's Industry Guidance Branch stressed in 2000 that the OIG would pursue quality of care cases "where there is actual patient harm and where alleged harm is a result of systemic . . . problems." n103 The rhetoric of patient protection is thus a powerful component of the government's war on healthcare fraud.

n102 Press Release, Dep't of Justice, AstraZeneca Pharmaceuticals LP Pleads Guilty to Healthcare Crime; **Company** Agrees to Pay \$ 355 Million to Settle Charges (June 20, 2003), at www.usdoj.gov/opa/pr/2003/June/03_civ_371.htm (last visited Mar. 30, 2004).

n103 *Increased Focus on Program Exclusions, Quality of Care, Civil Remedies Seen*, 4 Health Care Fraud Rep. (BNA) 75, 76 (2000).

IV. Patient Harm and Fraud Enforcement: The Reality

Despite references to patient harm in many of the healthcare fraud laws and regulations, and in spite of the clear commitment to patient protection found in public statements by government officials, it is not clear whether patients actually benefit from the resolution of these cases. This result is somewhat counterintuitive--if patients are harmed by healthcare fraud, one logically might expect healthcare fraud recoveries to make them whole. For a variety of reasons, however, this does not appear to be a priority. The strictly controlled disposition of monies recovered from healthcare fraud investigations, combined with both logistical and philosophical objections to diverting these funds to individual patients, makes patient benefit difficult to achieve under current law.

A. Lack of Benefits to Patients

While patient protection rhetoric permeates the healthcare fraud debate, it is not always consistent with the terms of the resulting settlements. For example, one prosecutor characterized the Philadelphia **nursing home** cases by saying "the entire idea that the [defendant] is providing care to these people is a fraud . . . they're being denied the value of that payment they made for that patient" under the federal healthcare programs. n104 This "total value" approach to FCA

liability historically was reserved for situations in which the government received absolutely *nothing* of value in return for its payment. n105 In other words, liability under this theory results when the goods or services, as received, are so substandard as to have no real value to the government at all. n106 This logic has obvious attraction in the **nursing home** context, where the facilities have been characterized as providing such substandard, neglectful, and downright harmful care to their residents that the facilities may as well not have provided care at all.

n104 *Philadelphia Prosecutor Calculates Damages in Quality of Care Cases*, 2 Health Care Fraud Rep. (BNA) 928-29 (1998) (quoting James Sheehan, Assistant U.S. Attorney for the Eastern District of Pennsylvania).

n105 See Krause, "*Promises to Keep*", *supra* note 23, at 1405-06 (questioning application of "total value" approach to damages in quality-related FCA cases).

n106 JOHN T. BOESE, CIVIL FALSE CLAIMS AND QUI TAM ACTIONS 3-33 to 3-34 (Supp. 2001).

The force of this argument, however, is severely undercut by the manner in which these cases have been resolved. Despite powerful patient protection rhetoric, the majority of **nursing home** defendants have entered into settlements that permit them to continue serving Medicare and Medicaid beneficiaries. They are, however, subject to stricter quality oversight, including the development of targeted training procedures, third-party quality monitoring, and the adoption of a corporate compliance program. n107 The willingness to allow these facilities to continue to participate in the federal healthcare programs seems to contradict the idea that the government is receiving *nothing* of value from them, and suggests that care of *some* value, albeit perhaps minimal, is being rendered. A cynic might conclude that apparently the care is bad enough that the government should get its money back, but not bad enough that the facilities should be barred from treating additional program patients.

n107 See, e.g., Hoffman, *supra* note 37, at 154-55 (describing terms of *GMS Management-Tucker* settlement).

Moreover, it is extremely interesting to trace what is done with the money from federal healthcare fraud recoveries. In a Medicare FCA case, for example, a portion of the proceeds may be awarded to the *qui tam* relator(s) (if any) who initiated the suit. n108 The majority of the remaining funds are deposited into the perennially near-insolvent Medicare Part A Trust Fund (Medicare Trust Fund). n109 In accordance with HIPAA, however, a significant portion of this money is available for appropriation back to the "Health Care Fraud and Abuse Control Account" (Control Account), which funds future healthcare fraud inspections, investigations, and prosecutions undertaken by the DOJ and the OIG. n110 Distributions from the Control Account are controlled by the Secretary of DHHS and the Attorney General, who jointly certify the amounts necessary to fund anti-fraud programs each year within broad ranges established by Congress. n111 These procedures also apply to criminal fines and forfeitures recovered from healthcare fraud prosecutions, as well as to CMPs and other civil assessments collected. n112

n108 See 31 U.S.C. § 3730(d) (2004) (discussing the range of awards for *qui tam* plaintiffs); 42 U.S.C. § 1395i(k)(2)(C)(iv) (2004) (exempting funds awarded to relator from amounts allocated to Medicare Trust Fund under HIPAA).

n109 See 42 U.S.C. § 1395i(k)(2)(C)(iv) (authorizing the transfer of penalties and damages obtained in healthcare FCA cases to the Medicare Trust Fund).

n110 See *id.* § 1395i(k)(3) (describing appropriations to the Health Care Fraud and Abuse Control Account).

n111 See *id.* § 1395i(k)(3)(A)(i) (setting out the maximum amounts available to DHHS and DOJ). In fiscal year 2002, the DHHS

Secretary and the Attorney General certified \$ 209 million as necessary for healthcare anti-fraud efforts; DHHS received approximately \$ 150 million, and DOJ received approximately \$ 50 million. *See* DEPT OF HEALTH AND HUMAN SERVS. & DEPT OF JUSTICE, HEALTH CARE FRAUD & ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2002 3-4 (Sept. 2003), *available at* www.usdoj.gov/dag/pubdoc/hcfacreport2002.htm (last visited Mar. 30, 2004).

n112 *See* 42 U.S.C. § 1395i(k)(2)(C) (2004) (setting forth Medicare Trust Fund transfer provisions). *See also* 18 U.S.C. § 24 (2004) (defining "federal health care offense" to include, *inter alia*, conspiracies, mail fraud, and wire fraud if related to a healthcare benefit program).

The fact that the OIG and the DOJ ultimately receive some benefit from the fraud recoveries they obtain has given rise to allegations that HIPAA established a "bounty system" for the federal anti-fraud agencies, albeit an attenuated one. Professor Dayna Bowen Matthew has argued that these financial incentives affect prosecutorial discretion, noting that while "public prosecutors do not have a direct personal interest in funds deposited into the Control Account from their prosecutorial efforts, . . . they do have an interest in the size of the Control Account as a measure of their professional success and as a source of financing for future professional endeavors." n113 The government, in turn, has vehemently denied the existence of such bounties, arguing that the HIPAA-mandated enforcement efforts have "a stable source of funding under HIPAA" and that "all recovered monies are returned to the Medicare Trust Funds." n114 While the precise nature of the government's stake in healthcare fraud recoveries may not be critical to the patient protection debate, it nonetheless is troubling. For purposes of this discussion, the concern is that the money from healthcare fraud recoveries goes to the Medicare Trust Fund, to any relator(s) who initiated the suit, and to the federal agencies that investigate and prosecute healthcare fraud--but not directly to remedy the harm suffered by the patients in whose names, at least figuratively, the investigations are mounted.

n113 Dayna Bowen Matthew, *Tainted Prosecution of Tainted Claims: The Law, Economics, and Ethics of Fighting Medical Fraud Under the Civil False Claims Act*, 76 IND. L.J. 525, 580 n.319 (2001). A similar result occurs under the Affirmative Civil Enforcement (ACE) program, under which a percentage of the civil fraud recoveries obtained by the U.S. Attorneys Offices are available to fund future collection efforts. *See, e.g.*, Civil Division, *at* www.usdoj.gov/civil/ (last visited Mar. 30, 2004).

n114 HEALTH CARE FINANCING ADMINISTRATION, THE MEDICARE INTEGRITY PROGRAM: PAY IT RIGHT! 11 (Mar. 2001), *available at* www.cms.hhs.gov/providers/psc/mip.pdf (last visited Mar. 30, 2004) (addressing the funding of the Medicare Integrity Program, which requires DHHS to enter into contracts with outside entities to audit various aspects of the Medicare program). Of course, given the reallocation of many such dollars back to the Control Account, these arguments appear somewhat disingenuous.

A few of the healthcare anti-fraud authorities do in fact provide for a return of money to injured patients. For example, a physician who does not participate in the Medicare program cannot charge Medicare patients more than 115% of the Medicare-approved charge. n115 A physician who violates this provision is subject to exclusion and CMPs. The Secretary of DHHS is authorized to use a portion of the funds collected to "make a payment to a beneficiary . . . in the nature of restitution for amounts paid by such beneficiary to such physician which was determined to be . . . excessive." n116

n115 42 U.S.C. § 1395w-4(g)(2)(c) (2004) (defining the "limiting charge").

n116 *Id.* § 1395u(j)(4). *See supra* note 89 and accompanying text (explaining penalties). The portion of FCA recoveries awarded for restitution is exempt from allocation to the Trust Fund, thus preventing a direct conflict between the needs of victims and the financial goals of federal prosecutors. *See* 42 U.S.C. § 1395i(k)(2)(C)(iv) (2004) (exempting restitution amounts from transfer to the Control Account).

Even broader authority supports restitution when healthcare fraud is pursued under criminal statutes such as health care fraud or mail/wire fraud. n117 In "offenses against property" under Title 18 of the United States Code, as well as cases "in which an identifiable victim or victims has suffered a physical injury or pecuniary loss," restitution to the victim is a mandatory component of sentencing. n118 In other cases, including healthcare fraud offenses under Title 42

(such as a criminal violation of the Anti-Kickback Statute), n119 restitution may be ordered as a part of a plea bargain, as a condition of probation, or a condition of supervised release. n120 The expenses subject to restitution are defined broadly to include not only financial losses but also the costs of necessary medical care, including psychiatric, psychological, and certain "nonmedical care and treatment." n121

n117 See 18 U.S.C. §§ 1341, 1343, 1346-47 (2004) (defining mail, wire, and health care fraud).

n118 18 U.S.C. §§ 3663A(c)(1)(A)(ii), 3663A(c)(1)(B) (2004) (listing crimes for which restitution must be ordered); UNITED STATES SENTENCING GUIDELINES MANUAL § 5E1.1 (2003) (providing for restitution under the federal Sentencing Guidelines). See also *id.* § 8B1.1 (restitution for corporate defendants). Mandatory restitution does not apply to offenses against property, however, if "the number of victims is so large as to make restitution impracticable; or [] determining complex issues of fact related to the cause or amount of the victim's losses would complicate or prolong the sentencing process to a degree that the need to provide restitution to any victim is outweighed by the burden on the sentencing process." 18 U.S.C. § 3663A(c)(3). See also UNITED STATES SENTENCING GUIDELINES MANUAL § 5E1.1(B)(2).

n119 42 U.S.C. § 1320a-7b(b) (2004).

n120 See 18 U.S.C. § 3556 (2004) (order of restitution); *id.* § 3563 (conditions of probation); *id.* § 3583 (conditions of supervised release after imprisonment); *id.* § 3663 (discretionary restitution authority).

n121 *Id.* §§ 3663(b)(2), 3663A(b)(2). In certain drug offenses in which there is no identifiable victim, restitution "based on the amount of public harm caused by the offense" is paid to the state agencies that administer crime victim assistance and federal substance abuse block grants. *Id.* § 3663(c); UNITED STATES SENTENCING GUIDELINES MANUAL § 5E1.1(d).

The Federal Sentencing Guidelines also permit an increase in offense level, and hence a more severe sentence, if the crime involves a vulnerable victim, the abuse of a position of trust, or the use of a special skill. Upward departures in sentences also exist for crimes in which death, physical injury, or extreme psychological injury results. n122 Moreover, as a policy matter, the DOJ has made clear its commitment to restitution in healthcare fraud crimes, stating that "victims of health care fraud have a right to receive restitution as part of the federal criminal law enforcement process" and agreeing to share the information needed to expedite this process with private health plans. n123 Thus, in healthcare fraud cases brought under the criminal authorities, restitution likely will be an available remedy. Unfortunately, the majority of healthcare fraud cases involve civil and administrative causes of action that do not independently provide for restitution. As a result, most healthcare fraud recoveries are destined for the Medicare Trust Fund and the Control Account, rather than for the individual victims of the fraud.

n122 See UNITED STATES SENTENCING GUIDELINES MANUAL §§ 3A1.1, 3B1.3, 5K2.1-2.3.

n123 Memorandum from the Attorney General, to All United States Attorneys, All Assistant United States Attorneys, the Assistant Attorney Generals for the Criminal and Civil Divisions, All Trial Attorneys re: The Sharing of Information on Health Care Fraud With Private Health Plans (Oct. 9, 1998), reprinted at 2 Health Care Fraud Rep. (BNA) 847, 848 (1998), available at www.usdoj.gov/ag/readingroom/hcarefraud.htm (last visited Mar. 30, 2004).

B. Impediments to Patient Recovery

In short, it appears that the patient protection rhetoric that drives many healthcare fraud investigations may not be worth much to the *patients* themselves, at least in terms of direct compensation for harm suffered. There are a number of practical and legal impediments to structuring federal healthcare fraud recoveries to include a patient compensation component. Moreover, any attempt to use part of these recoveries to compensate patients, even indirectly, generates a debate over the proper role of the federal government in healthcare fraud cases: in carrying out its anti-fraud agenda,

does the government act primarily as a *payor* or as a *protector*?

1. Existing Benefits to Patients

As a preliminary matter, it is not quite accurate to say that healthcare fraud recoveries provide no benefit to federal healthcare program beneficiaries. In fact, beneficiaries *do* benefit from the resolution of these cases, both in terms of the *quality* and the *security* of their healthcare coverage. When quality-related cases are settled, as in the **nursing home** FCA cases, the settlement is likely to include provisions directly related to improving the quality of the care rendered. n124 The groundbreaking consent order in *United States v. GMS Management-Tucker, Inc.*, for example, required, *inter alia*: the implementation of a nutritional monitoring and quality assessment program; the implementation of a corporate compliance program; training of all staff on nutrition and wound care, as well as on the requirements of the compliance program; and careful monitoring by the U.S. Attorney's Office, including reporting of all nutritionally compromised or at-risk residents for at least one year. n125 Assuming such provisions function as intended, they should improve the quality of care provided to residents of the facility. They will not, however, compensate those residents who already have suffered harm, particularly those no longer living.

n124 These conditions may be specified either in the Settlement Agreement/Consent Order entered into with DOJ, or in a Corporate Integrity Agreement (CIA) entered into with OIG. Defendants often enter into CIAs in return for the OIG's agreement not to seek permissive exclusion. CIAs typically function as mandated compliance programs, requiring the defendant to institute a compliance structure as well as training, auditing, and investigational procedures, all under strict OIG oversight. *See* Krause, *supra* note 92, at 96.

n125 *See* *United States v. Tucker House II, Inc.*, Civ. A. No. 96-1271 (Consent Orders, E.D. Pa., Feb. 1996), *available at* www.usdoj.gov/usao/pae/Nursing/tucker.pdf and www.usdoj.gov/usao/pae/Nursing/gms3.pdf (last visited Mar. 30, 2004); Hoffman, *supra* note 37, at 155 (describing elements of consent order).

Moreover, healthcare fraud recoveries play a role in extending the solvency of the Medicare Trust Fund, which in turn permits the program to provide care to future beneficiaries--as well as continuing to care for beneficiaries who suffer fraud-related injuries. In 2002, Medicare spending amounted to \$ 252.2 billion. n126 According to the most recent projections by the Medicare Payment Advisory Commission (MEDPAC), the Medicare Trust Fund will become insolvent in 2026, and costs are expected to exceed tax revenues as soon as 2013. n127 While the \$ 1.7 billion recovered in fiscal year 2003 as a result of civil healthcare fraud actions is not enough to stave off program insolvency, its effects are not insignificant. n128 Thus, at least in some small way, fraud recoveries increase the likelihood that the Medicare program will be able to provide care for the evergrowing number of beneficiaries--a benefit not only to current and future beneficiaries, but also to the future generations of taxpayers who likely will be called upon to shoulder an increasing portion of the program's finances. Once again, however, the protection of beneficiary entitlement in the *aggregate* is not the same thing as compensating *individual* beneficiaries who have been harmed by fraudulent activities.

n126 *See* MEDICARE PAYMENT ADVISORY COMM'N, A DATA BOOK: HEALTHCARE SPENDING AND THE MEDICARE PROGRAM 56 (June 2003) (explaining solvency projections), *available at* www.medpac.gov/publications/congressional_reports/Jun03DataBook_Entire_Report_links.pdf (last visited Mar. 30, 2004).

n127 *Id.* at 59.

n128 *See* Justice Dept. Civil Fraud Recoveries Total \$ 2.1 Billion for FY 2003, *supra* note 4.

2. Logistical Concerns and Legal Limitations

Moreover, as a practical matter, there are a number of logistical barriers to compensating patients as the victims of

healthcare fraud. One crucial issue is that of *causation*, proving that the defendant's fraudulent activities were the cause of the patient's harm and the government's financial loss. In the **nursing home** FCA cases, for example, defendants frequently contest responsibility for their residents' physical conditions, arguing that any deterioration is due to the residents' advanced age and underlying medical diagnoses. n129 If these allegations were brought in the medical malpractice context, causation would be a crucial aspect of the plaintiff's case. n130 In the FCA context, however, the need to prove causation for individual injuries is largely obviated by the government's "substandard care" approach, which alleges that the facility failed *overall* to provide the level of services for which it was paid. n131 Without such individualized proof, however, there may be no clear way to compensate individual victims.

n129 See, e.g., *NHC Health Care Corp.*, 163 F. Supp. 2d at 1053-54 (disputing whether residents' conditions were caused by inadequate care or by underlying medical impairments).

n130 See, e.g., *Herskovits v. Group Health Coop.*, 664 P.2d 474, 475 (Wash. 1983) (alleging that decedent would have died from lung cancer even if the defendant had diagnosed his condition earlier).

n131 See *NHC Health Care Corp.*, 163 F. Supp. 2d at 1055 (describing theory of liability). See also *supra* notes 34-45 and accompanying text.

Furthermore, once the alleged fraud extends beyond a single institution, the logistical problems increase exponentially. If the fraudulent activities are national in scope, it might be difficult, perhaps impossible, for the government even to *identify* all the potential victims, let alone to compensate them appropriately. For example, the DOJ recently intervened in a *qui tam* suit against a pharmacy benefits manager, Medco Health Solutions, for fraudulent activities in connection with its mail-order prescription drug business. The complaint alleges a fraudulent scheme spanning eight years, during which time the **company** had facilities located in twelve states, operating under more than thirteen subsidiaries, and serving almost all the federal healthcare programs. n132 Even in the age of computerized records, identifying all the patients potentially harmed by such a scheme would appear to be a daunting task. An even greater problem is likely to arise in trying to identify every person--whether covered under a federal healthcare program, enrolled in a private MCO or insurance plan, or paying out-of-pocket--who was disadvantaged by the manner in which a drug **company** priced its products over a multi-year period, and calculating how much each person was harmed. n133 At some point, the resources required to identify the potential victims may exceed the expected return, especially if individual awards are likely to be small.

n132 See Amended Complaint, *United States et al. v. Merck-Medco Managed Care, L.L.C.*, Case No. 00-CV-737 (E.D. Pa., filed Dec. 9, 2003) (copy on file with author).

n133 According to one federal prosecutor, feasibility issues have prevented patient compensation from being pursued in several cases. Personal conversation with Michelle Zingaro, Assistant United States Attorney, Southern District of Texas (Feb. 26, 2002). However, other federal prosecutors report having used this approach successfully. Personal conversation with James G. Sheehan, Associate United States Attorney, Eastern District of Pennsylvania (June 6, 2003).

On occasion, federal prosecutors have undertaken large-scale efforts to return money to beneficiaries. The most prominent example is the "72-Hour Window Project," a national initiative designed to investigate whether hospitals submitted separate Medicare bills for outpatient services (usually laboratory tests) provided within seventy-two hours of an inpatient admission. These services, by law, are included in Medicare's lump-sum hospital inpatient payment. n134 As a result, patients were improperly charged a portion of the outpatient fee, rather than solely the deductible or co-payments applicable to their inpatient stays. As a condition of settling these allegations, the hospitals were required to reimburse patients for the additional co-payments and deductibles improperly collected. n135 Because each hospital was audited for a limited universe of claims, it was possible to identify both the patient victims and the dollar amounts

by which they were overcharged. Where both the allegations and the scope of the potential harm are more amorphous, however, this strategy may not prove feasible.

n134 See GEN. ACCOUNTING OFF., MEDICARE: APPLICATION OF THE FALSE CLAIMS ACT TO HOSPITAL BILLING PRACTICES, GAO/HEHS-98-195, at 3 (July 1998) (describing initiative) [hereinafter GEN. ACCOUNTING OFF., MEDICARE]; 42 C.F.R. § 412.2(c)(5) (2004) (defining certain preadmission services as included within inpatient prospective payment).

n135 GEN. ACCOUNTING OFF., MEDICARE, *supra* note 134, at 9 (describing settlements). See, e.g., United States v. Mississippi Baptist Med. Ctr. (Settlement Agreement Oct. 10, 1999), at P10, *reprinted in* Compliance Rep. (CCH) P130,318 (requiring hospital to refund copayments and deductibles to patients). Anecdotal evidence exists of similar restitution efforts, albeit on a small scale. See, e.g., News Release, Attorney General Bob Butterworth, Humana Medical Plan to Refund \$ 800,000 to Settle Allegations (Feb. 16, 2000) (requiring Medicare HMO to refund money to beneficiaries who were overcharged for hearing aids), *available at* myfloridalegal.com/newsrel.nsf/newsreleases/AAECA64080033E5085256887004AC291?OpenDocument (last visited Mar. 30, 2004).

Of course, such concerns are by no means limited to healthcare. In the antitrust and consumer protection arenas, for example, we have devised workable remedies in cases involving large numbers of potential victims, even where it is difficult to identify all injuries and where individual recovery is likely to be small. In many cases, courts have used the equitable doctrine of *cy pres* to place recoveries into "consumer trust funds" to be used for general consumer protection/education purposes. n136 As one commentator explains, the doctrine is attractive in cases in which:

(1) the class of consumers represented is large and practically unidentifiable; (2) the individual damage suffered by each consumer is relatively small; (3) there are no creative alternatives to provide value directly to consumers; and (4) the recipients who will most likely benefit, albeit indirectly, are the consumers in whose name the original action is brought. n137

n136 Historically, the doctrine of *cy pres* permitted a court to avoid invalidation of a charitable trust when the testator's conditions could not all be satisfied. As the California Supreme Court explained, "where compliance with the literal terms of a charitable trust became impossible, the funds would be put to 'the next best use,' in accord with the dominant charitable purposes of the donor." *California v. Levi Strauss & Co.*, 715 P.2d 564, 570 (Cal. 1986). For a discussion of the *cy pres* doctrine in the antitrust and consumer protection contexts, see, e.g., Susan Beth Farmer, *More Lessons from the Laboratories: Cy Pres Distributions in Parens Patriae Antitrust Actions Brought By State Attorneys General*, 68 FORD. L. REV. 361 (1999).

n137 Farmer, *supra* note 136, at 365 (setting forth factors relevant to *cy pres* remedies in *parens patriae* antitrust actions).

The *cy pres* doctrine has permitted a wide range of awards that are able to reach a large pool of potential victims, at least indirectly. For example, in a class action suit against Toshiba based on the sale of allegedly defective computers, a district court in Texas ordered that funds remaining after the plaintiffs' individual claims were exhausted be distributed to a charity, which would use the funds to purchase computers for distribution to "schools, churches, nonprofit organizations, libraries, hospitals, and the poor." n138 Other courts have been willing to go further, invoking the doctrine to guide disbursement of the *entire* settlement amount, rather than just the remainder, in cases in which the goal of compensating individual class members appears to be impossible due to the size of the class and the small amount of each award. n139

n138 *Shaw v. Toshiba Amer. Info. Sys., Inc.*, 91 F. Supp. 2d 942, 981 (E.D. Tex. 2000).

n139 Compare *id.* (distributing remainder) with *New York v. Reebok Int'l Ltd.*, 96 F.3d 44, 49 (2d Cir. 1996) (approving broader distribution "because of the unlikelihood of there being any significant 'net monetary relief' for individual claimants if an attempt were made to distribute the settlement proceeds among them," due to the large number of claimants and the minimal injury suffered per purchase). See

Farmer, *supra* note 136, at 403-05 (advocating broad use of *cy pres* approaches rather than "direct restitution" under certain circumstances).

Admittedly, these actions differ from healthcare fraud cases in significant respects. Perhaps the primary difference is the government's role. In consumer protection or *parens patriae* antitrust actions, the states bring suit on behalf of their injured citizens. n140 In healthcare fraud prosecutions, however, the federal government acts first and foremost as a defrauded *payor*, exercising its own right to recover; indeed, in a *qui tam* suit it is the *relator* who brings suit on behalf of the *government*, not vice versa. Nonetheless, these disbursement options may represent the "next best use" of settlement funds because they both serve broad consumer protection goals and deter improper behavior by forcing defendants to disgorge ill-gotten gains. As such, they address many of the same issues seen in healthcare fraud cases, and might provide a fruitful alternative for future compensation efforts.

n140 See Farmer, *supra* note 136, at 362 (describing *parens patriae* power under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, Pub. L. No. 94-435, 90 Stat. 1383 (1976)).

Moreover, the federal government's ability to structure more creative forms of recovery in healthcare fraud cases may be limited by the underlying statutes. As noted earlier, HIPAA mandated that virtually all monies recovered in healthcare fraud cases--which encompass criminal healthcare fraud offenses as well as CMPs, FCA awards, and other civil assessments--be returned to the Medicare Trust Fund and subject to transfer to the Control Account. n141 Although restitution may be required under the Federal Sentencing Guidelines, these provisions only apply to defendants who are convicted of a federal *crime*. n142 Where the allegations are resolved in the *civil* context, as frequently is the case, no comparable provision facilitates, let alone mandates, similar restitution to injured victims. n143 Unless the case can be styled under one of the federal statutes permitting more creative disbursement mechanisms, such as the antitrust provisions, there appear to be few avenues available under current law.

n141 See *supra* notes 108-12 and accompanying text.

n142 See UNITED STATES SENTENCING GUIDELINES MANUAL § 5E1.1 (restitution provisions for individual defendants); *id.* § 8B1.1 (restitution provisions for organizations).

n143 The Civil Injunction Statute, which permits the Attorney General to commence a civil action to enjoin a defendant from committing a healthcare offense, authorizes the court to "take such . . . action, as is warranted to prevent a continuing and substantial injury to the United States or to any person or class of persons for whose protection the action is brought." 18 U.S.C. § 1345 (2004). One prosecutor has suggested that this statute provides the basis for broad civil remedies, which could include some form of restitution to injured victims. See Conversation with James G. Sheehan, *supra* note 133. See also United States of America et al. v. Merck-Medco Managed Care, L.L.C., Case No. 00-CV-737 (requesting an injunction against fraud) (copy on file with Author). However, there do not appear to be any reported cases invoking the statute in this manner. Cf. U.S. v. Corson, No. 93-CV-3637, 1993 WL 332268, at *1 (requiring physician, under 18 U.S.C. § 1345, to reimburse Medicare beneficiaries who were overcharged for his services).

The limited options available to federal prosecutors can be starkly contrasted with the broad consumer protection remedies available to state attorneys general, who have crafted innovative healthcare fraud settlements that target--with almost poetic elegance--the disadvantaged patient populations. For example, the Massachusetts Attorney General has negotiated settlements with drug and medical device manufacturers accused of illegally excluding Medicare and Medicaid patients from their product promotions, usually in an attempt to avoid liability under the Anti-Kickback Statute. As part of these settlements, the defendant **companies** agree to donate free products to indigent patients in the state. n144 These settlements clearly confer a financial benefit on the state and local governments, which might otherwise purchase these products for state-funded healthcare programs and public hospitals. But more importantly, these settlements impose sanctions that are well-tailored to the harm alleged, making the products available to the underprivileged population that initially was deprived of them. This represents a much more holistic approach to remedying the effects of fraud, conferring an advantage on those who were disadvantaged--if not the exact victims, then

patients who are similarly situated. By so doing, it brings us closer to the goal, in the immortal words of Gilbert and Sullivan, of "letting the punishment fit the crime." n145 The lack of a solid legal basis for similar efforts in the federal healthcare fraud context may, in the long run, be a significant impediment to true patient protection.

n144 See, e.g., Press Release; Novo Nordisk, Novo Nordisk and Massachusetts Extend NovoPen 1.5 Delivery System Promotion to Medicaid Patients (Mar. 19, 1997) (announcing **company's** agreement to provide hundreds of free insulin delivery systems to indigent and Medicaid patients at certain hospitals in the state) (copy on file with Author); Press Release, Commonwealth of Massachusetts Office of the Attorney General, N.J. Pharmaceutical Corporation Settles with Attorney General: 21,000 Nitroglycerin Patches to be Distributed Free to Public (May 21, 1993) (describing settlement with Schering Corporation, which agreed to distribute free Nitro-Dur patches to public hospitals in the state) (copy on file with author).

n145 W.S. Gilbert, *The Mikado, or The Town of Titipu*, in THE BEST KNOWN WORKS OF W.S. GILBERT 143-44 (1932).

3. The Federal Government: Payor or Protector?

Current mandates aside, asking the federal government to be more creative in disbursing the money recovered from healthcare fraud investigations risks conflating the government's role as the federal healthcare program *payor* with its role as the *protector* of program beneficiaries. As Professor William Sage has noted, "[a] central, unresolved question is whether the principal purpose of fraud and abuse law is to protect financial integrity or patient welfare." n146 At present, fraud recoveries appear to fall squarely into the former category, for rather obvious reasons. Recovered funds are directed to the Medicare Trust Fund because it is the Medicare Trust Fund that improperly *paid* for these services. Replenishing the Medicare Trust Fund is appropriate to the extent these funds were expended on care that should not have been reimbursed under program rules, and to the extent injured patients likely will incur additional costs for treatment. Thus, the focus on healthcare fraud is largely one of *program integrity and solvency*, rather than an attempt to invoke a general police power to improve the overall quality of medical care. n147

n146 William M. Sage, *Fraud and Abuse Law*, 282 J.A.M.A. 1179, 1180 (1999).

n147 Technically, it is the states that wield the "police power" to protect the health of their citizens, as well as the *parens patriae* power to protect disadvantaged citizens. The federal government's authority to regulate public health is derived, on the other hand, from specific powers enumerated in the Constitution, such as the powers to tax, spend, and regulate interstate commerce. See LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 34-55 (2000) (analyzing state and federal public health authorities).

From the payor perspective, patient compensation may not be a primary goal. Indeed, to the extent redirecting a portion of recoveries to patients necessarily would reduce the total funds returned to federal coffers, patient compensation appears inconsistent with the current legal mandate to use this money to bolster the financial integrity of the federal healthcare programs. n148 On the other hand, current law already permits a portion of these funds to be diverted to private use by awarding up to thirty percent of the proceeds to *qui tam* relators in FCA cases. n149 If one recognizes the need to reward those persons who bring fraudulent conduct to the government's attention, often at great personal sacrifice, n150 it is not illogical similarly to compensate the people who are *directly* harmed by that conduct. This recognition, however, clearly would require amendments to the current law governing the disposition of healthcare fraud recoveries.

n148 See *supra* notes 108-12 (explaining disposition of funds recovered in healthcare fraud suits).

n149 31 U.S.C. §§ 3730(b), 3730(d) (2004)

n150 See, e.g., Pamela H. Bucy, *Information as a Commodity in the Regulatory World*, 39 Hous. L. REV. 905, 915-17 (2002) (explaining the sacrifices made by whistle-blowing "insiders").

Moreover, patients are not wholly without recompense if the federal government declines to engage in more creative efforts to disburse fraud recoveries. Several legal mechanisms exist at the state level to redress direct patient harm, including the tort system and, increasingly, the consumer protection laws. n151 The federal government, however, clearly must assume some level of responsibility for the quality of care provided in its healthcare programs. As mentioned, beginning in 1982, the Medicare program has required peer review to ensure that Medicare services are medically necessary, are provided economically and efficiently, and meet accepted standards of quality. n152 Failure to meet these standards subjects healthcare providers to exclusion and CMPs. n153 Of course, the duty to protect the *general* quality of care provided to program beneficiaries does not mandate *individual* recompense for injured patients, particularly not at the expense of the funds needed to maintain program-wide vigilance. Yet if federal prosecutors were so inclined, these provisions might be used as a justification for broader efforts to redress patient harm. In summary, while compensating patients who have been harmed by healthcare fraud would bring current practice more in line with current rhetoric, it likely would create a conflict between the federal government's dual roles as payor and protector, and clearly would require significant amendments to current law.

n151 See, e.g., W. PAGE KEETON ET AL., PROSSER & KEETON ON TORTS § 1 at 5-6 (5th ed. 1984) (describing tort law as a body of law which is directed toward the compensation of individuals, rather than the public, for losses which they have suffered within the scope of their legally recognized interests); see also Lee Ann Bundren, *State Consumer Fraud Legislation Applied to the Health Care Industry: Are Health Care Professionals Being "Consumed"?*, 16 J. LEG. MED. 133, 144--53 (1995) (discussing use of consumer fraud laws in the healthcare context).

n152 See 42 U.S.C. § 1320c-3 (2004) (setting forth functions of peer review organizations); *supra* note 96 and accompanying text.

n153 42 U.S.C. § 1320c-5(a)(2)-(3) (2004); *Straus*, 274 F.3d at 701 (analyzing quality of care requirements imposed by this section); GOSTIN, *supra* note 147, at 39 (noting use of federal spending power to mandate quality standards for Medicare and Medicaid).

V. Conclusion

As this Article has argued, while the protection of beneficiary health and welfare is espoused by the federal government as one of the main reasons for pursuing healthcare fraud investigations, patient compensation is not currently a significant component of healthcare fraud recovery. This is due, in large part, to the mandated disposition of recovered funds under current law. It also results from both logistical concerns and deep-seated ambivalence over whether the fraud laws primarily are designed to aid patients or to protect the public fisc. Outside of the federal healthcare programs, however, both state and federal agencies have been able to use other legal doctrines to recoup funds in cases involving similarly large numbers of victims, and to put the funds to an approved "next best" public use if compensation of individual victims is impossible. As quality-related fraud cases become more common, it may be necessary to explore whether these models of recovery can be adapted to the federal healthcare fraud context.

Already, there are encouraging signs. In October 2003, the United States Attorney's Office for the Western District of Michigan entered into an innovative settlement with United Memorial Healthcare Association (UMH) in a case involving potential harm to patients. n154 The hospital pled guilty to one count of mail fraud in connection with a longstanding investigation into fraudulent bills submitted by one of its physicians, who was convicted of performing medically unnecessary procedures on patients at a UMH pain clinic. As a condition of the plea, UMH was required to pay a fine of over \$ 1 million and "to affiliate" itself with another healthcare entity. Pursuant to this process, Spectrum Health subsequently became the owner of UMH. n155

n154 Press Release, U.S. Attorneys Office, W. Dist. of Mich., Matching Fund Program to Provide Indigent Medical Care (Oct. 6,

2003) (attaching Matching Fund Agreement), *available at* www.usdoj.gov/usao/miw/press/UMHFunds.html (last visited Mar. 30, 2004) [hereinafter Matching Fund Agreement].

n155 *Id.*

In an interesting procedural turn, the plea was deferred by the presiding judge, permitting the government to petition for a "remission" of the fine. n156 Using the flexibility afforded by the remissions statute, the United States Attorney's Office agreed to match up to \$ 500,000 of the criminal fine. The money was designated for a specific patient-directed purpose: funding Spectrum's "Healthier Communities" program, which provides healthcare and health education services to disadvantaged individuals in the hospital's service area. n157 In essence, the agreement allowed UMH to pay only half its fine but directed those funds, plus an equal amount of government funds, specifically to improve indigent health in the community. While this strategy did not attempt to compensate any of the *individual* patients who may have been harmed by the unnecessary services, it did accomplish an important health-related goal by extending healthcare services to a disadvantaged patient community. As such, it reasonably could be described as one of the "next best uses" of the settlement funds, particularly compared to returning the money *en masse* to the Medicare Trust Fund.

n156 18 U.S.C. § 3573 (2004) (permitting judge to modify or remit an unpaid fine or assessment); Personal conversation with Glenn Martin, Assistant U.S. Attorney, Western District of Michigan (Nov. 6, 2003).

n157 Matching Fund Agreement, *supra* note 154.

As this Article demonstrates, while injured patients and the federal government have much in common when it comes to healthcare fraud, at some point their interests may diverge. Nevertheless, as demonstrated by the (admittedly convoluted) UMH settlement, federal prosecutors who possess the will can indeed craft patient-friendly options even under current law. It remains to be seen whether the federal government more broadly is willing to take the next logical step by bringing its actions in line with its patient protection rhetoric, and directing a portion of program recoveries to compensate patients injured by the fraud.

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SUMMARY: ABSTRACT: Within healthcare institutions, leadership is an essential driver of expectations, performance, and culture. Yet boards of directors traditionally played a limited role in overseeing healthcare quality, providing final approval of credentialing decisions but deferring to the medical staff to set standards for the institution. Case law and standards provide little guidance for board performance in overseeing quality of care. Recent developments--the availability of comparative quality data, public reporting, and financial incentives for higher quality--have transformed expectations for board oversight. Enforcement of fraud and abuse laws based on poor quality of care, as well as federal standards for board oversight of healthcare quality and compliance, have set higher standards for board conduct. This article examines the emerging paradigm for board oversight of healthcare quality, and recommends how boards should proceed to meet their responsibilities in an era of comparative quality measures and transparency.

TITLE: Changing Expectations for Board Oversight of Healthcare Quality: The Emerging Paradigm

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TEXT:**Introduction**

Healthcare quality depends on leadership as an essential driver of expectations, performance, and culture. Yet the broad concepts of fiduciary duty convey little guidance about how boards should undertake this responsibility. Traditionally, board oversight of quality focused on approval of credentialing decisions--often a pro forma approval of

judgments made by the medical staff.

Recent developments in quality improvement and measurement, as well as changes in regulatory oversight, have established strong financial incentives for boards to carry out their responsibilities on quality effectively. Rapid changes in the quality arena--the availability of comparative quality data, public reporting on quality measures, and pay-for-performance--all bring heightened attention and financial pressure to improve quality. The development of "never events" as markers of patient safety creates a well-delineated floor for board oversight. The stakes for increased transparency and public measures of substandard performance also have been raised by mounting compliance enforcement linking poor quality to false claims, generating the possibility of substantial financial penalties.

This article examines emerging trends in healthcare quality and the implications of these changes for board oversight. For an explicit roadmap, boards can now look to guidelines from the federal government for board actions on quality and compliance; state oversight of healthcare delivery; and corporate integrity and deferred prosecution agreements in the healthcare arena. The article assesses the expectations for board oversight of quality that have emerged in the wake of the transformation in healthcare measurement and improvement. It compares the quality oversight responsibilities of boards of healthcare providers with those of parent boards of health systems and examines the available empiric data on board activities to oversee quality. The article concludes by recommending steps boards should take to fulfill their responsibilities in an era of comparative quality measures and transparency.

The Transformation of Quality Measurement and Improvement

Traditionally, the performance of individual physicians was the primary basis for understanding and evaluating quality. Until the 1990s, responsibility for overseeing the quality of care in hospitals rested primarily with the medical staff, which functioned through a committee structure largely independent of the board of directors and management. Through credentialing, peer review of serious errors, and a medical staff committee structure, physicians engaged in a largely self-regulated process to oversee quality of care. Consistent with this focus on individual practitioners as the locus of healthcare quality, boards of directors had the authority to grant final approval of credentialing decisions; however, in practice, substantive evaluation of physicians occurred for the most part at the medical staff level. By and large, the processes to improve care were retrospective and episodic, focusing on post-hoc analysis of serious events to understand errors made in individual cases. The roles of the board, medical staff, and executive management often were coordinated poorly to serve quality goals, with the medical staff dominating quality oversight by virtue of both its professional knowledge and perspective that quality standards were solely the provenance of medical expertise. n1

n1 Legal commentators have criticized the weakness of what has been called the "three-legged stool" of oversight for quality, with responsibility and accountability divided between the medical staff, executive management, and the board. See John D. Blum, *Feng Shui and the Restructuring of the Hospital Corporation: A Call for Change in the Face of the Medical Error Epidemic*, 14 HEALTH-MATRIX: J. L.-MED. 5 (2004); Thomas Greaney, *New Governance Norms and Quality of Care in Nonprofit Hospitals*, 14 ANNALS HEALTH L. 421, 422 (2005); Richard Johnson, *Revisiting "the Wobbly Three Legged Stool."* 4 HEALTH CARE MGMT. REV. 15 (1979); Brian M. Peters & Jonathan Z. Cohen, *Board Quality Oversight: A "Real World" Systemic Compliance Model*, 14TH ANNUAL HEALTH LAW INST. (Mar. 2008); John P. Marren et al., *The Hospital Board at Risk and the Need to Restructure the Relationship with the Medical Staff: Bylaws, Peer Review and Related Solutions*, 12 ANNALS HEALTH L. 179 (2003).

Historically, the Joint Commission on Accreditation of Health Care Organizations (JCAHO, now the Joint Commission) was the primary external arbiter of hospital quality, apart from malpractice actions. n2 Both the federal and state governments rely on accreditation by the Joint Commission to evaluate the quality of hospital care. n3 Only a handful of states, such as New York, have conducted their own surveys. n4 Criticized in the past for emphasizing administrative procedures more than clinical processes and outcomes, n5 the Joint Commission changed its survey process in 2004 to include additional measures of clinical quality. n6 Although accreditation decisions became publicly available in 1996, survey scores are not publicly released. n7

n2 The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) shortened its name to "the Joint Commission" in 2007. See The Joint Commission, *The Joint Commission Launches New Brand Identity* (2007), available at www.jointcommission.org/AboutUs/brand.htm.

n3 The Centers for Medicare and Medicaid Services (CMS) approved the Joint Commission survey as the mechanism to grant hospitals certification to participate in and receive funds under the Medicare Program. 42 U.S.C. § 1395bb(a), (b), and § 1395x(e); 42 C.F.R. § 488.5. In 2009, the Joint Commission's categories for accreditation were changed; they are now provisional accreditation, conditional accreditation, preliminary denial of accreditation, denial of accreditation, and preliminary accreditation. Joint Commission, *Joint Commission Fact Sheets: Accreditation Process Overview*, available at www.jointcommission.org/AboutUs/Fact_Sheets/overview_qa.htm; Joint Commission, *Facts About Quality Check(R) and Quality Reports*, available at www.jointcommission.org/QualityCheck/06_qc_facts.htm.

n4 For example, Joint Commission hospital accreditation is not recognized by New Jersey, Oklahoma (except for hospital-based outpatient mental health services), Pennsylvania, and Wisconsin. *States Recognizing Accreditation/ Certification by the Joint Commission* (Feb. 27, 2009), available at www.jointcommission.org/NR/rdonlyres/C6A3B227-564E-46E3-A1D8-6CBF5DA6BEE5/0/9_07deeming.pdf. See also State of New Jersey Dept. of Health and Human Services, *Oversight of Acute Care Health Care Facilities*, available at <http://www.state.nj.us/health/healthfacilities/hospfines/hfines.shtml>.

n5 Molly Coye, *No Toyotas in Health Care: Why Medical Care Has Not Evolved to Meet Patients' Needs*, 20 HEALTH AFF. 44, 47 (2001) [hereinafter Coye, *No Toyotas in Health Care*].

n6 Donald M. Berwick & Troyen A. Brennan, *New Rules: Regulation, Markets, and the Quality of American Health Care* 39 (1995) [hereinafter Berwick & Brennan, *New Rules*]. In 2009, the Joint Commission will release an update to the Accreditation Requirements as part of its Standards Improvement Initiative (SII). *Joint Commission Fact Sheets: Accreditation Process Overview*, available at www.jointcommission.org/AboutUs/Fact_Sheets/overview_qa.htm. SII will focus on scores for specific activities that directly affect patient health and safety. *Standards: Facts about Joint Commission Accreditation Standards*, available at www.jointcommission.org/Standards/facts_about_accreditation_standards.htm.

n7 Communication with Joint Commission Communications Office, 3/5/09. The most current accreditation decision for an organization is available on Quality Check, the Joint Commission's website, and accreditation histories can be obtained by writing or calling the Joint Commission. *Facts about the Public Information Policy*, available at www.jointcommission.org/AboutUs/Fact_Sheets/08_pip.htm.

In fact, transparency in quality of care did not exist until recently--it ran counter to the ethos of a profession accustomed to self-regulation and peer review confidentiality. Boards of directors could receive internal reports of patient deaths or serious events, but lacked systematic data to evaluate quality. Although malpractice cases escalated in the 1970s and 80s, they provided limited insight into quality of care. By the early 1990s, studies had begun to show that malpractice actions were closer to a lottery than a fair, equitable way to reimburse patients for medical harm; the number of actions brought grossly underrepresented the rate of medical injury, and patients who did sue often lacked a valid claim. n8 Data on the exceptionally high rate of medical errors leading to patient death or serious injury began to emerge in the 1990s, and confirmed that malpractice actions covered only a small fraction of instances of patient harm from malpractice. n9 The number of disciplinary actions by state governments, like malpractice cases, encompassed a small subset of physician malpractice. n10

n8 R. Localio et al., *Relation Between Malpractice Claims and Adverse Events Due to Negligence: Results of the Harvard Medical Practice Study*, 325 NEW ENG. J. MED 245 (1991) (explaining that malpractice claims are only a rough measure of identifying and remedying specific problems, and malpractice claims are not very useful as an indicator of the quality of care). One study showed that 98 percent of all adverse events due to negligence did not result in malpractice claims, and thus, the fraction of medical negligence that leads to claims is probably under 2 percent.

n9 The Institute of Medicine report, *To Err is Human: Building a Safer Health System*, was a watershed in public recognition of the extraordinarily high rate of preventable medical errors, and the toll of those errors on morbidity and mortality of patients across the economic and healthcare spectrum. INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (Linda T. Kohn, et al, eds. 2000) [hereinafter *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM*].

n10 *Id.* A study in the 1990s by the Public Citizen Research Group found that there were only approximately three thousand disciplinary actions each year (among 584,900 medical doctors), and fewer than 10 percent of those were for negligent or poor-quality care.

The science of quality measurement and improvement first emerged in the 1970s as an organized field, prompted by government and private payor concerns about the cost of care and studies showing wide regional variation in utilization of healthcare procedures unrelated to population needs. n11 Seeking to reduce the high rate of medical errors, researchers sought to apply the model of continuous quality improvement developed by industry to the processes of healthcare delivery. n12 In this evolving understanding of quality, systems of care--not individual practitioner error--were both the cause of many serious adverse events and the potential solution for prevention. Quality experts and researchers developed measures of processes and outcomes of care designed to evaluate the treatment provided to individual patients, as well as the systems of care within hospitals, health plans, and other providers. n13

n11 Prominent healthcare quality researchers noted that healthcare quality problems could be classified into three categories: underuse, overuse, and misuse, with widespread errors in all three categories. Mark Chassin & Robert Gavin, *The Urgent Need to Improve Health Care Quality*, 280 JAMA 1000, 1002 (1998) [hereinafter Chassin & Gavin, *The Urgent Need to Improve Health Care Quality*].

n12 Berwick & Brennan, *New Rules*, at 113-18.

n13 *Id.* at 115.

Comparative measures as a precursor to transparency

As early as the 1990s, private payors, including large employers such as General Electric, regional business coalitions, and government purchasers, sought to drive payment based on quality, or "pay-for-performance." n14 However, public and private payors lacked sufficient market share and access to comparative measures across hospitals, health plans, and other providers necessary to effect change. As noted by commentators, the business case for quality was weak; hospitals and other providers were not rewarded for higher performance or investment in quality, outside of capitated systems that could capture some of the savings. n15 Moreover, providers were not penalized for poor performance. n16

n14 Tracy Miller & Sheila Leatherman, *The National Quality Forum: A "Me-Too" or a Breakthrough in Quality Measurement and Reporting?*, 18 HEALTH AFF. 233 (1999) [hereinafter Miller & Leatherman, *The National Quality Forum*]. In the absence of data on quality, businesses relied on volume of procedures as a placeholder. Coxe, *No Toyotas in Health Care*; Fraser et al., *The Pursuit of Quality by Business Coalitions: A National Survey*, 18 HEALTH AFF. 158 (1999). Private health plans also used quality data as a basis for choosing which providers would serve in their networks. N.A. Hanchack et al., *U.S. Healthcare's Quality-Based Compensation Model*, 17 HEALTH CARE FINANCING REV. 143 (1996).

n15 Sheila Leatherman et al., *The Business Case for Quality: Case Studies and an Analysis*, 22 HEALTH AFF. 17 (2003).

n16 Berwick & Brennan, *New Rules*, at 49; see also Inst. of Med., *Rewarding Provider Performance: Aligning Incentives in Medicare* (Pathways to Quality Health Care Series) 33 (2006).

In 2000, the National Quality Forum (NQF) was created as part of a concerted strategy by public and private payors to coordinate purchasing power to generate publicly available, reliable measures as a basis to improve quality, create public transparency, and enable market choice by purchasers and consumers. n17 Over the past eight years, this coordinated effort, combined with advances in quality measurement and improvement, has generated comparative measures across three interrelated dimensions of healthcare quality: patient safety, quality improvement, and patient satisfaction. n18

n17 Miller & Leatherman, *The National Quality Forum*.

n18 The two most important concepts in the evaluation of measurement are validity (or accuracy) and reliability. Many challenges still exist, including the need for risk adjustment to account for differences in patient conditions, reliability of reporting across institutions, and the validity of measures to capture quality. *See* Coye, *No Toyotas in Health Care*. However, recent studies demonstrate that challenges remain in accurately measuring hospital quality. *See* Timothy Bhattacharyya, *Measuring the Report Card: The Validity of Pay-for-Performance Metrics in Orthopedic Surgery*, 28 HEALTH AFF. 526 (2009).

Patient safety

By the mid 1990s, empirical studies showing the frequency of patient deaths and serious harm caused by medical error had generated public alarm about the safety of medical practice. The land-mark 1999 report by the Institute of Medicine, *To Err is Human*, attributed approximately 44,000 to 98,000 deaths each year to medical errors. Medication errors alone accounted for 7,000 deaths a year. n19 Studies issued before and after the report reinforced the notion of a healthcare system fraught with risk for patients. Studies showed widespread errors, high rates of inappropriate treatment that posed risks to patients, and undertreatment that led to patient harm. n20 Studies of medical errors spurred development of patient safety protocols by specialty societies, hospitals, and quality improvement experts, but did not generate data showing widespread improvement. n21 By 2002, the NQF had developed a list of "never" events that should not occur, such as operation on the wrong patient, operation on the wrong site or limb, and death or serious disability associated with a medication error. The list was updated in 2006. n22 On April 30, 2008, The Centers for Medicare and Medicaid Services (CMS) announced that Medicare would not pay for certain conditions acquired during the hospital stay, effective October 1, 2008. n23 In the wake of the CMS policy decision not to pay for hospital-acquired conditions, private plans embraced the same approach. n24

n19 TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM.

n20 *See, e.g.*, Elise C. Becher and Mark R. Chassin, *Improving Quality, Minimizing Error: Making it Happen*, 20 HEALTH AFF. 68 (2001). For example, studies found that medication errors caused about 10 preventable injuries--one-fifth of which were life-threatening--to hospitalized patients per week at each of two large urban teaching hospitals (D.W. Bates et al., *Incidence of Adverse Drug Events and Potential Adverse Drug Events*, 274 JAMA 29 (1995)); twenty-four million Americans inappropriately received antibiotics for colds and other upper respiratory viral infections (R. Gonzales et al., *Antibiotic Prescribing for Adults with Colds, Upper Respiratory Tract Infections, and Bronchitis by Ambulatory Care Physicians*, 278 JAMA 901 (1997)); A.C. Nyquist et al., *Antibiotic Prescribing for Children with Colds, Upper Respiratory Tract Infections, and Bronchitis*, 279 JAMA 875 (1998); and in a group of seven managed care plans, 16 percent of hysterectomies performed were inappropriate (S.J. Bernstein et al., *The Appropriateness of Hysterectomy*, 269 JAMA 2398 (1993)).

n21 In response to data showing prevalent medical errors, progress did occur in specific hospitals that undertook targeted improvement initiatives. *See, e.g.*, Sharon Silow-Carroll et al., *Hospital Quality Improvement: Strategies and Lessons from U.S. Hospitals*, The Commonwealth Fund (April 2007). *See also* Yosef D. Dlugacz et al., *The Quality Handbook for Health Care Organizations: A Manager's Guide to Tools and Programs* (2004); Chassin & Gavin, *The Urgent Need to Improve Health Care Quality*, at 1001 ("A few health plans, hospitals, and integrated delivery systems have made impressive efforts to improve their quality of care, and a number of successes in improving quality for specific patient groups have been documented."). However, Chassin and Gavin note that "many... institutions have made little, if any, effort to improve...."

n22 National Quality Forum, *Serious Reportable Events Transparency & Accountability are Critical to Reducing Medical Errors*, available at www.qualityforum.org/projects/completed/sre/fact-sheet.asp. The National Quality Forum (NQF) uses a consensus process with broad provider and public input to develop its measures. National Quality Forum, *Members*, available at www.qualityforum.org/pdf/list_of_members.pdf; *see also* National Quality Forum, *Serious Reportable Events Transparency & Accountability are Critical to Reducing Medical Errors*, available at www.qualityforum.org/projects/completed/sre/fact-sheet.asp.

n23 73 Fed. Reg. 23,547-52. The final regulation is available at 42 U.S.C. § 1395ww(d)(4)(D)(ii)(1); *See also* CMS, *Hospital-Acquired Conditions (Present on Admission Indicator): Overview*, available at www.cms.hhs.gov/HospitalAcqCond/01_Overview.asp. The events for which CMS limits Medicare reimbursement are not the same as the National Quality Forum's 28 never events, although there is overlap between the two lists. Some states have decided not to reimburse for never events: In 2008, for example, Massachusetts determined that

state-sponsored insurance programs would no longer pay for serious reportable events. Mass. Health Care Quality and Cost Council, *HCQCC Update: Patient Safety* (2008), available at www.mass.gov/lhqcc/docs/announcement/update_09182008.pdf. According to CMS, seven states have submitted plans to amend the state Medicaid program to restrict payment for selected adverse events. DHHS OIG, *ADVERSE EVENTS IN HOSPITALS: STATE REPORTING SYSTEMS iv* (Dec. 2008), available at www.oig.hhs.gov/oei/reports/oei-06-07-00471.pdf.

n24 For example, Cigna HealthCare announced on April 17, 2008 that it would no longer reimburse for these avoidable events when permitted under its hospital contracts. Mike Mitka, *Public, Private Insurers Refusing to Pay Hospitals for Costs of Avoidable Errors*, 299 *JAMA* 2495, 2495 (2008).

Quality improvement measures

The decision by CMS not to pay for hospital-acquired conditions followed its initial pay-for-performance initiative based on quality of care measures for five conditions:

1. heart attack,
2. heart failure,
3. pneumonia,
4. coronary artery bypass graft, and
5. hip and knee replacements. n25

n25 Press Release, CMS, Medicare Pay-for-Performance Demonstration Shows Significant Quality of Care Improvement at Participating Hospitals (May 3, 2005), available at www.cms.hhs.gov/apps/media/press/release.asp?Counter=1441&intNumPerPage=10&checkDate=&checkKey=2&srchType=2&numDays=0&srchOpt=0&srchL

In 2000, CMS reported in the *Journal of the American Medical Association* on national measures of hospital quality of care for these conditions by region, informing hospitals confidentially of their own scores compared to regional and national rates of performance. n26 CMS reported that care for Medicare fee-for-service plan beneficiaries "improved substantially" between 1998-1999 and 2000-2001, but the agency still called for further improvement.

n26 Stephen F. Jencks et al., *Quality of Medical Care Delivered to Medicare Beneficiaries: A Profile at State and National Levels*, 284 *JAMA* 1670 (2000). See also Stephen F. Jencks et al., *Change in the Quality of Care Delivered to Medicare Beneficiaries, 1998-1999 to 2000-2001*, 289 *JAMA* 305 (2003).

Patient satisfaction

The third dimension of quality measurement and reporting advanced by researchers, private organizations, and the federal government relates to patient satisfaction. n27 Patient satisfaction measures assess the patient's experience of care, seeking to capture broad considerations of whether patients and their families are treated with dignity and respect and whether care is patient-centered, i.e., engineered to meet patients' personal needs and values. While hundreds of patient satisfaction measures had been available from private vendors and **companies**, in 1995 CMS launched the Consumer Assessment of Healthcare Providers and Systems Program (CAHPS) initiative to develop a standard set of publicly reported, valid measures that would permit comparison across institutions. Available now on the CMS website, the measures evaluate eighteen key aspects of the hospital experience, including:

- . communication with nurses and doctors;

- . responsiveness of hospital staff;
- . cleanliness and quietness of the hospital environment;
- . pain management;
- . communication about medicines;
- . discharge information;
- . overall rating; and
- . recommendation of the hospital. n28

n27 CMS, *Hospital Quality Initiatives: HCAHPS: Patients' Perspectives of Care Survey*, available at www.hcahpsonline.org/home.aspx. See also Picker Inst., *About Picker Institute*, available at www.pickerinstitute.org/about/about.html.

n28 CMS, *HCAHPS Fact Sheet (CAHPS(R) Hospital Survey)* (Mar. 2008), available at www.cms.hhs.gov/HospitalQualityInits/Downloads/HospitalHCAHPSFactSheet200807.pdf [hereinafter *HCAHPS Fact Sheet*]. Similar patient satisfaction measures also have been developed for **nursing home** care.

Moving to transparency and pay-for-performance

The transparency of quality data has become instrumental in the evolution of pay-for-performance programs and quality improvement generally, with clear implications for board duties and accountability to public authorities. n29 Beginning in 2003, CMS offered hospitals a financial incentive to report quality and safety data. n30 In 2005, CMS established the Hospital Compare website, providing quality data to spur hospital improvement and promote consumer choice based on quality. n31 The Hospital Compare website provides comparative data from the Hospital Quality Initiative n32 and voluntarily submitted data on patient satisfaction from the Hospital CAHPS initiative. n33 Starting in July 2007, hospitals that collected and submitted CAHPS data to CMS were rewarded, and those that failed to do so were penalized. n34

n29 Studies have confirmed that publicly reported measures have led to quality improvement. See Peter K. Lindenauer et al., *Public Reporting and Pay for Performance in Hospital Quality Improvement*, 356 NEW ENG. J. MED. 486 (2007); Constance Fung et al., *Systemic Review: The Evidence that Publishing Patient Care Performance Data Improves Quality of Care*, 148 ANN. INTERN. MED. 111 (2008); Judith Hibbard et al., *Does Publicizing Hospital Performance Stimulate Quality Improvement Efforts?* 22 HEALTH AFF. 94 (2003) (making quality information public results in increased quality improvement efforts). See also Mark Chassin, *Achieving and Sustaining Improved Quality: Lessons from New York State and Cardiac Surgery*, 21 HEALTH AFF. 40 (2002); But see Mark Chassin et al., *Benefits and Hazards of Reporting Medical Outcomes Publicly*, 334 NEW ENG. J. MED. 394 (1996) for a description of the potential pitfalls with the release of quality data. The data are more equivocal about the impact of transparency on consumer choice. See note 45.

n30 Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU), 42 U.S.C. § 1395ww(b)(3)(B). See also CMS, *Hospital Quality Initiatives: Reporting Hospital Quality Data for Annual Payment Update*, available at www.cms.hhs.gov/HospitalQualityInits/08_HospitalRHQDAPU.asp.

n31 The Hospital Compare website is available at www.hospitalcompare.hhs.gov.

n32 Numerous other websites also report comparative data on hospital performance on these and other measures. Among these are the Leapfrog Group, the National Committee on Quality Assurance (NCQA), and the Health Plan Employer Data and Information Set (HEDIS). States often have their own public reporting sites, such as the one operated by California's Hospital Assessment and Reporting Taskforce

(CHART) program, which publishes its data at CalHospitalCompare.org.

n33 Voluntary collection of Hospital CAHPS (HCAHPS) data for public reporting began in October 2006, and the first public reporting of HCAHPS results occurred in March 2008. *HCAHPS Fact Sheet*.

n34 CMS, *Hospital Quality Initiatives: Reporting Hospital Quality Data for Annual Payment Update*, available at www.cms.hhs.gov/HospitalQualityInits/08_HospitalRHQDAPU.asp.

Pay-for-performance became operational for a defined set of hospital quality measures in 2005, with hospitals incentivized and reimbursed based on their performance. n35 Among the demonstration projects implemented by CMS, the Premier Hospital Quality Incentive Demonstration, started in 2003, is one of the most significant. n36 Hospitals scoring in the top 10% for a given set of quality measures received a 2% bonus payment on top of the standard DRG payment for the relevant discharges. n37 Those scoring in the next highest 10% received a 1% bonus. In the third year of the program, CMS reduced payments to hospitals that did not meet a threshold score on quality measures.

n35 CMS, Medicare "Pay-for-Performance (P4P)" Initiatives, available at www.cms.hhs.gov/apps/media/press/release.asp?counter=1343 [hereinafter Medicare "Pay-for-Performance (P4P)" Initiatives]. CMS's Value-Based Purchasing (VBP) initiatives are intended to continue the transition from Medicare's fee-for-service payment systems to a system focused on quality of care. See Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) § 131(d); US DHHS, DEVELOPMENT OF A PLAN TO TRANSITION TO A MEDICARE VALUE-BASED PURCHASING PROGRAM FOR PHYSICIAN AND OTHER PROFESSIONAL SERVICES: ISSUES PAPER (Dec. 9, 2008), available at www.cms.hhs.gov/PhysicianFeeSched/downloads/PhysicianVBP-Plan-Issues-Paper.pdf.

n36 In another effort to provide standardized mechanisms to compare healthcare quality, most HMOs report quality performance data to the National Committee for Quality Assurance (NCQA) as a basis for quality "report cards." For a discussion of the limitations of health plan reports cards for consumers, see Coye, *No Toyotas in Health Care*.

n37 Medicare "Pay-for-Performance (P4P)" Initiatives.

In November 2002, CMS implemented public reporting on comparative quality measures for **nursing homes with the Nursing Home** Quality Initiative (NHQI). n38 The NHQI measures assess **nursing home** quality of care, examining specific services such as the percent of residents given vaccinations (such as pneumococcal and influenza), and the percent of residents who have pressure sores or urinary tract infections, who lose too much weight, or who have moderate to severe pain. n39 In December 2008, CMS released quality ratings on its website--based on health inspection surveys, staffing information, and quality of care measures--for every **nursing home** in the United States that participates in Medicare and Medicaid. n40 CMS plans to implement a pay-for-performance demonstration in **nursing homes** in 2009. n41

n38 CMS, *Nursing Home Quality Initiatives: Overview*, available at www.cms.hhs.gov/NursingHomeQualityInits/01_Overview.asp#TopOfPage. In fact, national reporting of **nursing home** quality information existed prior to the introduction of the NHQI in October 1998, with the **Nursing Home** Compare website. The NHC website is available at www.medicare.gov/NHCompare.

n39 CMS, *Nursing Home Quality Initiatives: Overview*, available at www.cms.hhs.gov/NursingHomeQualityInits/01_Overview.asp#TopOfPage.

n40 CMS, ROADMAP FOR IMPLEMENTING VALUE DRIVEN HEALTHCARE IN THE TRADITIONAL MEDICARE FEE-FOR-SERVICE PROGRAM 2, available at www.cms.hhs.gov/QualityInitiativesGenInfo/downloads/VBPRoadmap_OEA_1-16_508.pdf.

n41 The **Nursing Home** Value-Based Purchasing (NHVBP) Demonstration is slated to begin in summer 2009. CMS, *Nursing Home Value-Based Purchasing Demonstration*, available at www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/NHP4P_Summary.pdf. CMS also has launched quality reporting initiatives across the continuum of care, including public reporting of End-Stage Renal Disease (ESRD) measures and physician quality measures. CMS, *End-Stage Renal Disease (ESRD) Quality Initiative: Overview*, available at www.cms.hhs.gov/ESRDQualityImproveInit/downloads/ESRDOverview.pdf.

Not surprisingly, the impact of financial incentives offered by the federal government has been magnified by the adoption of pay-for-performance by health plans. HMOs were the earliest and broadest adopters of quality measures. n42 A 2006 study found that more than half of commercial HMOs use pay-for-performance in their provider contracts. n43 Health plans also have extended pay-for-performance to physicians, provoking controversy about whether publicly released measures actually assess quality of care or cost savings. In one highly publicized enforcement action, the New York State Attorney General sought changes in health plan quality measures to assure that they reflected quality of care, rather than efficiency or cost savings. n44

n42 Coye, *No Toyotas in Health Care*.

n43 M. Rosenthal et. al., *Pay for Performance in Commercial HMOs*, 355 N. ENGL. J. MED. 1895 (2006).

n44 See Agreement on Physician Ranking Programs between New York Attorney General Andrew Cuomo and CIGNA HealthCare, available at www.massmed.org/AM/Template.cfm?Section=Home&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=20295; Press Release, Office of the Att'y Gen., Attorney General Cuomo Announces Doctor Ranking Agreement with Independent Health (Dec. 12, 2007), available at www.oag.state.ny.us/media_center/2007/dec/dec12a_07.html (Independent Health Association, Inc. agrees to adopt Cuomo's Model Code for doctor ranking programs).

Taken together, advances in quality measurement and public reporting over the past two decades create powerful new incentives for boards of healthcare institutions to focus on quality--direct financial incentives, potential harm or gain to reputation, and the impact on market share and consumer choice. n45 For the first time, boards of directors have the data and tools to fulfill their fiduciary duty to oversee quality in a meaningful way, ranging from patient safety to quality improvement and patient satisfaction. These changes have significant implications for existing legal standards and government oversight of healthcare board fiduciary duties.

n45 Generally, consumers have not used quality data but relied more on word of mouth. Judith H. Hibbard & Jacquelyn J. Jewett, *Will Quality Report Cards Help Consumers?*, 16 HEALTH AFF. 218 (1997). But a more recent study by Hibbard et al. found that consumers will use quality information if the reports are salient and actionable. Judith H. Hibbard et al., *It Isn't Just about Choice: The Potential of a Public Performance Report to Affect the Public Image of Hospitals*, 62 MED. CARE RES. & REV. 358 (2005). In a major study, **company** executives reported that they examine health plan quality data when choosing employee health plans, but few use the data to influence employee choice of plan. M. Rosenthal et. al., *Employers' Use of Value-Based Purchasing Strategies*, 298 JAMA 2281 (2007). See also Charles N. Kahn et al, *Snapshot of Hospital Quality Reporting and Pay-For-Performance Under Medicare*, 25 HEALTH AFF. 148 (2006).

Board Fiduciary Duties: Standards from Statutes and Case Law

Boards of directors for nonprofit and for-profit organizations must meet two basic fiduciary duties: the duties of care and loyalty. n46 Boards of directors for nonprofit entities are held to a third duty: the duty of obedience to mission. n47 These duties are set forth both in case law and state statutes governing nonprofit corporations. n48

n46 For an in-depth discussion of board duties, see James Fishman, *Improving Charitable Accountability*, 62 MD. L. REV. 218, 229-30 (2003) [hereinafter Fishman, *Improving Charitable Accountability*]. See also Thomas Greaney & Kathleen Boozang, *Mission, Margin, and Trust in the Nonprofit Health Care Enterprise*, 5 YALE J. HEALTH POL'Y L. & ETHICS 1 (2005) [hereinafter Greaney & Boozang, *Mission, Margin, and Trust in the Nonprofit Health Care Enterprise*].

n47 See Daniel L. Kurtz, *Board Liability: Guide for Nonprofit Directors* 85 (1988). However, the 1987 Revised Nonprofit Corporation Act and the most recent edition do not provide advice or standards on the duty of obedience, nor is the duty of obedience generally recognized in the case law. See ABA, MODEL NONPROFIT CORPORATION ACT, THIRD EDITION (Aug. 2008), § 8.30(b), available at www.abanet.org/rppt/meetings_cle/2008/jointfall/Joint08/ExemptOrgCharitablePlanOrganGroup/BlackLetter.pdf [hereinafter MODEL NONPROFIT CORPORATION ACT, THIRD EDITION]. See also Greaney & Boozang, *Mission, Margin, and Trust in the Nonprofit Health Care Enterprise*, at 43-44; Rob Atkinson, *Obedience as the Foundation of Fiduciary Duty*, 34 J. CORP. L. 43 (2008); Melanie DiPietro, *Duty of Obedience: A Medieval Explanation for Modern Nonprofit Governance Accountability*, 46 DUQ. L. REV. 99 (2007).

n48 In addition, nonprofit corporations are governed by the mandates set forth by the Internal Revenue Service (IRS) regarding their tax exemption. See I.R.C. § 501 (c)-(d) (2004). The IRS rules focus primarily on mission, or in the context of healthcare, the requirements of the community benefit standard, and the duty of loyalty. In 2007, the IRS set forth standards that cover board governance.

The duty of care requires directors to carry out their obligations in good faith with the degree of care, attention, and skill that a person in a like position would reasonably believe appropriate under the circumstances. n49 Judicial decisions interpret this duty to require board members to make an informed decision and to act in a manner that is not reckless. n50 Notably, courts have not held that board members have a duty to investigate to uncover a problem; board members may rely on others to provide them with notice or information about a problem. n51 The duty of care is shaped by the business judgment rule, which as a practical matter affords board members broad protection. n52 Specifically, the business judgment rule establishes that board members cannot be held liable for a decision they make, even if the decision later proves wrong and harmful to the corporation, if the directors acted in good faith and with the required degree of care. n53

n49 MODEL NONPROFIT CORPORATION ACT, THIRD EDITION § 8.30(b). The newest iteration of the Model Act has been revised from the 1987 version: the Revised Model Nonprofit Corp. Act § 8.30(a)(2) called for "care of an ordinary prudent person in a like position under similar circumstances," while the Third Edition § 8.30(b) requires the "care that a person in a like position would reasonably believe appropriate under the circumstances." For a detailed discussion of the duty of loyalty, see Fishman, *Improving Charitable Accountability*, at 233-37.

n50 Thus, courts are likely to find liability only when the board's conduct rises to the level of gross negligence. See Michael W. Peregrine and James R. Schwartz, *Revisiting the Duty of Care of the Nonprofit Director*, 36 J. HEALTH L. 183, 190 (2003).

n51 *Graham v. Allis-Chalmers*, 188 A.2d 125 (Del. 1963); MODEL NONPROFIT CORPORATION ACT, THIRD EDITION § 8.30(b).

n52 *In re Caremark Int'l Inc. Deriv. Litig.*, 698 A.2d 959 (Del. Ch. 1996); *Janssen v. Best & Flanagan*, 662 N.W.2d 876, 883 (Minn. 2003) (explaining the rationale behind allowing the boards of nonprofit corporations to receive the protection of the business judgment rule). See also Ellen W. McVeigh & Eve R. Borenstein, *The Changing Accountability Climate and Resulting Demands for Improved "Fiduciary Capacity" Affecting the World of Public Charities*, 31 WM. MITCHELL L. REV. 119, 123-24 (2004) [hereinafter McVeigh & Borenstein, *The Changing Accountability Climate*].

n53 See Fishman, *Improving Charitable Accountability*, at 233 for an in-depth discussion of the business judgment rule.

The duty of loyalty obligates board members to act solely in the interests of the corporation, and to place the corporation's interest above their personal gain. n54 Board members cannot enrich themselves at the expense of the corporation. While transactions between an interested director and the corporation are not barred, state statutes and case law require that any such transaction be fair to the corporation, fully disclosed, and entered into without undue influence by the interested director. n55 The Internal Revenue Code imposes other highly detailed requirements that bar directors from excess benefit in any transaction with the corporation. n56 Directors who breach the duty of loyalty may be held personally liable and may be denied indemnification for legal fees and cost of the breach. n57

n54 See MODEL NONPROFIT CORPORATION ACT, THIRD EDITION § 8.30(a)(2). Stone *ex rel.* AmSouth Bancorporation v. Ritter, 911 A.2d 362, 370 (Del. 2006), clarified the duty of good faith, explaining that the duty is breached where a fiduciary acts with a purpose other than that of advancing the best interests of the corporation, with the intent to violate the law, or where the fiduciary fails to act in the face of a known duty to act. The duty to act in good faith is not an independent fiduciary duty, but often is considered a necessary element of the duties of loyalty and care, discussed below. *See id.* at 369-70.

n55 Fishman, *Improving Charitable Accountability*, at 234-37. In some states, certain transactions, such as a loan to directors, are prohibited. In 2004, 28 states prohibited loans to directors. Marion R. Fremont-Smith, GOVERNING NONPROFIT ORGANIZATIONS 226 (2004). *See, e.g.*, NOT-FOR-PROFIT CORP. ACT § 716 "Loans to Directors and Officers." However, a majority of states limit the personal liability of nonprofit directors, unless the actions are clearly self-interested, in bad faith, or grossly negligent. *See also* McVeigh & Borenstein, *The Changing Accountability Climate*, at 123.

n56 "Taxes on Excess Benefit Transactions," IRC 7.27.30 (2002). For a discussion of the full implications of the IRS rules for tax exempt governance, *see* Fishman, *Improving Charitable Accountability*, at 265; Thomas Greaney, *New Governance Norms and Quality of Care in Nonprofit Hospitals*, 14 ANNALS HEALTH L. 421, 426 (2005).

n57 Board members may face removal by state attorneys general and criminal liability for actions that violate federal and state laws. *See, e.g.* Butterworth v. Anclote Manor Hosp., 566 So. 2d 296 (Fla. Dist. Ct. App. 1990). However, the "bar for director liability is quite high and the range of potential defenses and protection from liability is broad. Indeed, directors can go about their jobs even in a grossly negligent manner and have no liability, with one caveat: directors must act in good faith..." Gary Brown, *Unclean Hands: As Dangerous in the Boardroom as the Operating Room?* HEALTH LAW. NEWS 19, 20 (Sept. 2008) [hereinafter Brown, *Unclean Hands*]. Some states have granted immunity and mandated corporate indemnification and interim advancement of litigation expenses for directors from suits arising from affairs of the nonprofit corporation where there is good faith. *Id.*

The third core fiduciary duty for nonprofit directors is the duty of obedience: the obligation to act in a manner that preserves the mission of the corporation. n58 The duty of obedience prohibits transactions or diversion of resources for purposes outside the scope of the corporation's mission as set forth in the articles or certificate of incorporation. n59 In recent years, this duty has come to the fore, as state attorneys general have weighed the conversion of nonprofit healthcare plans to for-profit status and the closure of institutions. n60

n58 *See* note 47.

n59 For examples of cases where the board was held accountable for diverting resources for reasons outside the corporation's mission, *see* Brown v. Mem'l Nat'l Home Found., 329 P.2d 118 (Cal. Dis. Ct. App. 1958) (corporation's attempt to dedicate funds to unauthorized purpose led to removal of trustee); Queen of Angels Hosp. v. Younger, 136 Cal. Rptr. 36 (Cal. Ct. App. 1977) (articles of incorporation called for operation of hospital, not establishment of neighborhood clinics).

n60 *See, e.g.*, Manhattan Eye, Ear & Throat Hosp. v. Spitzer, 715 N.Y.S.2d 575 (Sup. Ct. 1999) (New York State Attorney General successfully blocked sale and close of Manhattan Eye, Ear & Throat Hospital (MEETH) based on failure to honor obedience to mission, but also in part on the board's failure to fulfill its duty of care in seeking alternatives to closure and the deal terms negotiated by a conflicted agent).

While fiduciary duties establish expectations for board conduct, application of these duties and the broad sweep of the business judgment rule reflect courts' reluctance to hold nonprofit board members, most of whom serve as volunteers, to an exacting standard. n61 In fact, legal commentators have noted the shortcomings of fiduciary duty standards for both for-profit and nonprofit boards as a vehicle to hold boards accountable and provide needed oversight. n62 In the nonprofit arena, the paucity of legal precedents on board duties is compounded by the lack of transparency, the absence of third parties (such as shareholders) with an interest in overseeing the corporation's actions, and the limited resources of state attorneys general. n63 While the duty of mission could serve as an important litmus test for board duties with respect to overseeing healthcare quality, it has been applied unevenly by attorneys general and the courts, and has not served as meaningful ballast. n64 Although much of the case law delineating board duties of care and loyalty focuses on financial mismanagement and self-dealing, several landmark cases have established expectations

for the duty of care that have direct application to board oversight of quality, particularly in terms of the duties to investigate and require adequate reporting systems.

n61 U.S. GEN. ACCOUNTING OFFICE, TAX-EXEMPT ORGANIZATIONS: IMPROVEMENTS POSSIBLE IN PUBLIC, IRS, AND STATE OVERSIGHT OF CHARITIES (2002), available at www.gao.gov/new.items/d02526.pdf; Fishman, *Improving Charitable Accountability*, at 218, n. 6.

n62 Greaney & Boozang, *Mission, Margin, and Trust in the Nonprofit Health Care Enterprise*, at 7; Evelyn Brody, *Agents Without Principles: The Economic Convergence of the Nonprofit and For-Profit Organizational Forms*, 40 N.Y. L. SCH. L. REV., 457, 499-500 (1996); Thomas Boyd, *A Call to Reform the Duties of Directors Under State Not-for-Profit Corporation Statutes*, 72 IOWA L. REV. 725, 745 (1987). Just as failures of governance evidenced by cases such as Enron and Worldcom called into question the effectiveness of board standards and public accountability for for-profit **companies**, the most recent financial institution failures will no doubt spark renewed debate about the public accountability of boards of for-profit corporations, especially in light of the extraordinary price paid by taxpayers. For in-depth analysis of past corporate failures, see ABA Task Force on Corporate Responsibility, Report of the American Bar Association Task Force on Corporate Responsibility (2003), available at www.abanet.org/buslaw/corporateresponsibility/final_report.pdf. See also Eric Dash & Julie Creswell, *Citigroup Pays for a Rush to Risk*, N.Y. TIMES, Nov. 23, 2008, at A1 (discussing the poor oversight and lack of risk controls at the bank and its staggering losses).

n63 Legal scholars have described the limited accountability of directors and the weaknesses in a regulatory framework dependent on state attorneys general with scarce resources to oversee a vast set of institutions. See Greaney & Boozang, *Mission, Margin, and Trust in the Nonprofit Health Care Enterprise*, at 19, 44-46.

n64 Lamenting the weakness of the doctrine as it has been applied to date, Greaney and Boozang advocate "mission primacy" as one means to invigorate and inform board oversight. *Id.* at 82-84.

One of the first notable cases to address board fiduciary duties to prevent corporate misconduct, *Graham v. Allis-Chalmers*, set forth dicta broadly **protecting** board members from liability for corporate or employee wrongdoing absent explicit knowledge of the wrongdoing or facts that should have put board members on notice of the conduct. n65 In the 1963 case, stockholders brought an action against the directors for breach of the duty of care in failing to prevent violation of federal antitrust laws. Specifically, the complaint asserted that the board members had actual knowledge of the wrongful conduct or facts that could have put them on notice, or in the alternative, were liable for failure to take action to learn of and prevent antitrust violations. The court soundly rejected the notion that the board should have put a system in place to bring misconduct to its attention, stating in what would become oft-repeated dicta, "there is no duty upon directors to install and operate a corporate system of espionage to ferret out wrongdoing which they have no reason to suspect exists." n66 The court recognized, however, that board members could be held accountable for ignoring signs of wrongdoing through willful conduct or inattention to obvious signs of misconduct.

n65 *Graham v. Allis-Chalmers*, 188 A.2d 125 (Del. 1963).

n66 *Id.* at 130.

Eleven years later, the 1974 case of *Stern v. Lucy Webb Hayes National Training School* set a somewhat higher standard for conduct of nonprofit boards. n67 A class action brought by patients of Sibley Memorial Hospital, the suit asserted that board members had breached their fiduciary duties of care and loyalty in the management of Sibley's funds. Specifically, the plaintiffs maintained that the board was negligent in managing hospital funds; the Finance Committee did not meet between 1960 and 1972, during which time the funds were in accounts that earned little or no interest at five financial institutions. Five of the hospital trustees held positions of responsibility at the five financial institutions, leading to the claim of breach of loyalty.

n67 *Stern v. Lucy Webb Hayes National Training School*, 381 F. Supp. 1003 (D. D.C. 1974). It is useful to note that *Stern* is unique in that the patients were given standing. In most jurisdictions, only the Attorney General has standing to pursue board misconduct.

Stating that corporate directors are liable for their negligent mismanagement of corporate funds, the court went on to note that while trustees often are held to a negligence standard, a director "must often have committed gross negligence." n68 The court made clear that a director who fails to acquire the information necessary to carry out his or her supervisory role has breached the duty of care. The court also noted that a board member "whose failure to supervise permits negligent mismanagement by others to go unchecked has committed an independent wrong against the corporation." n69

n68 *Id.* at 1013.

n69 *Id.* at 1014.

In re Caremark International Inc. Derivative Litigation addressed the duties of a board of directors to oversee legal compliance--or as the court framed the issue, "corporate performance." n70 The suit was brought by shareholders of the for-profit corporation. They charged that the board's failure to oversee compliance with federal anti-kickback laws resulted in significant financial losses to the corporation. Holding that the board members had not breached their duty of care, the court pointed to the fact that the board had taken numerous steps to oversee and promote compliance, including adoption of a policy to curtail certain payments to physicians, appointment of the chief financial officer to serve as compliance officer, and issuance of compliance guidance for employees.

n70 *In re Caremark Int'l Inc. Derivative Litig.*, 698 A.2d 959, 961 (Del. Ch. 1996).

The *Caremark* court noted the difficulty of holding board members of a nonprofit accountable for breach of duty in the absence of a conflict of interest or self-dealing, but went on to recognize two grounds for such accountability: (1) a board decision that is ill-advised or negligent, and (2) "an unconsidered failure of the board to act in circumstances in which due attention would, arguably, have prevented the loss." n71 Expressly narrowing the broad sweep of the dicta in *Graham v. Allis-Chalmers*, the court stated that while boards have no affirmative duty to conduct investigations to identify wrongdoing, they can and should be held responsible for assuring that an effective information gathering and reporting system exists as a predicate for the board to fulfill its duty of care. n72

n71 *Id.* at 967.

n72 *Id.* at 970. However, the court qualified this statement in the context of personal liability, asserting "that failure to do so under some circumstances may, in theory at least, render a director liable...."

In 2001, shareholders successfully pursued board personal liability for failure to act in the face of persistent board inattention to violations of federal quality standards. n73 In *In re Abbott Laboratories Derivative Shareholders Litigation*, the Food and Drug Administration (FDA) had issued post-inspection and warning letters beginning in 1993 that informed the corporation of its failure to comply with quality standards designed to protect consumers from undue risk. The corporation's safety failures were reported in the *Wall Street Journal* in 1995, and again in the press in 1999, after Abbott violated its obligations under an earlier voluntary compliance agreement with the FDA. In ruling for the plaintiffs, the court pointed to the "sustained and systematic failure of the board to exercise oversight" over a period of more than six years. n74 Given the egregious nature of the board failure, the case does not establish a high bar for board conduct; however, the ruling set significant precedent by holding the board members personally liable for breach of the duty of care in the absence of a conflict of interest or self-dealing. The *Abbott* court stated that the board's failure was

tantamount to a lack of good faith, suggesting that in even in the face of the board's long-term, serious failure, the court framed its decision in terms of willful conduct and lack of good faith, rather than relying solely on a finding of negligence. n75 Subsequent cases followed suit, making it clear that directors who commit gross negligence by failing to take action will be presumed to have violated their obligation to act in good faith, and will fall outside the protection of the business judgment rule. n76

n73 *In re Abbott Labs. Derivative Shareholders Litig.*, 325 F.3d 795 (7th Cir. 2003).

n74 *Id.* at 809.

n75 *Id.* at 809.

n76 In a decision handed down the same year as *Abbott*, two outside directors were held personally liable for approving a transaction despite having no personal interest in the transaction. *In re Emerging Commc'ns, Inc. S'holder Litig.*, C.A. No. 16415 (Del. Ch. May 3, 2004). See also *In re Walt Disney Co. Derivative Litig.*, 825 A.2d 275, 289 (Del. Ch. 2003) (finding the board's failure to inquire about conditions and terms of executive compensation or to review any written agreements constituted lack of good faith to advance the best interest of the **company**); *Stone ex rel. AmSouth Bancorporation v. Ritter*, 911 A.2d 362 (Del. 2006). While board members have protection from the business judgment rule if they decide to take no action after an informed process, the protection does not extend to board inaction in the face of notice of a problem. For further discussion of the distinction between a decision not to act and inaction, see Brown, *Unclean Hands*.

Despite *Caremark's* recognition of the board's duty to assure that an effective reporting system exists, the case law consistently reinforces the basic demarcation between the duties of the board and executive management; the board oversees the actions of executives, but is not itself responsible for managing day-to-day operations or conducting investigations without notice of the need to do so. The obligation to manage operations and senior staff in every realm, including quality measurement and improvement, is a management function. For example, the board is not responsible for developing a system of quality measurement and reporting, but must assure that an effective system exists and review the data it generates to evaluate the institution's performance.

Bringing Quality Within the Purview of Hospital and Board Duties

As case law evolved to recognize minimum standards for board fiduciary duties, legal doctrines developed to establish hospital liability for quality, bringing the quality of care within the ambit of hospital board responsibilities. Until 1965, hospital boards of directors essentially had no obligations to oversee healthcare quality, except for the duty to use reasonable care in selecting physicians. The hospital was regarded as a venue in which physicians provided treatment, rather than as a direct provider of healthcare services. The 1965 decision in *Darling v. Charleston Community Memorial Hospital* upended that assumption as a matter of prevailing law. n77 The plaintiff in *Darling* was an 18-year-old who broke his leg playing football. Due to negligent treatment provided by the physician on call in the emergency room on the day of admission, and thereafter by the physician and nurses, the plaintiff developed gangrene, resulting in the amputation of his leg. Rejecting the hospital's assertion that it had no obligation beyond using reasonable care in selecting its physicians, the court stated in what is now well-settled law, "Present day hospitals, as their manner of operation plainly demonstrates, do far more than furnish facilities for treatment." n78

n77 *Darling v. Charleston Cmty. Mem'l Hosp.*, 211 N.E.2d 253 (Ill. 1965).

n78 *Id.* at 257, 332. While *Darling* involved failure to use reasonable care in credentialing, later cases have broadened the duties of the hospital board. See *Oehler v. Humana Inc.*, 775 P.2d 1271, 1272 (Nev. 1989); *Fridena v. Evans*, 622 P.2d 463, 466 (Ariz. 1980) (discussing emerging trend imputing inherent responsibility to monitor overall quality of care to hospitals).

While *Darling* set a precedent that quickly changed legal expectations and potential liability for hospitals, courts continued to grapple with whether hospitals should bear potential liability for the actions of physicians who practice as independent contractors with medical staff privileges rather than as employees. Since 1976, the courts have chipped away at the protection accorded hospitals by the notion that hospitals are not responsible for the actions of non-employed physicians to whom they grant clinical privileges.ⁿ⁷⁹ In 1981, in *Johnson v. Misericordia Community Hospital*, the court held the hospital liable for negligence in granting privileges to an orthopedic surgeon whose privileges had been revoked or limited at other hospitals.ⁿ⁸⁰ While the case rested on negligent credentialing, the court cited to *Darling* and the hospital's broader duties to evaluate the care it provides.

ⁿ⁷⁹ See, e.g., *Tuscon Med. Ctr., Inc. v. Misevch*, 545 P.2d 958 (Ariz. 1976); *Purcell v. Zimbelman*, 500 P.2d 335 (Ariz. Ct. App. 1972); *Kitto v. Gilbert*, 570 P.2d 544, 550 (Colo. Ct. App. 1977); *Mitchell County Hosp. Auth. v. Joiner*, 189 S.E.2d 412 (Ga. 1972); *Johnson v. St. Bernard Hosp.*, 399 N.E.2d 198 (Ill. App. Ct. 1979); *Ferguson v. Gonyaw*, 236 N.W.2d 543 (Mich. Ct. App. 1976); *Bost v. Riley*, 262 S.E.2d 391 (N.C. Ct. App. 1980); *Corleto v. Shore Mem'l Hosp.*, 350 A.2d 534 (N.J. Super. Ct. Law Div. 1975) (all holding that a hospital has a direct and independent responsibility to take reasonable steps to (1) ensure that its medical staff is qualified for the privileges granted and/or (2) to evaluate the care provided).

ⁿ⁸⁰ *Johnson v. Misericordia Cmty. Hosp.*, 301 N.W.2d 156 (Wis. 1981).

Following *Misericordia*, a long line of cases upheld hospital liability under the theory of corporate negligence, recognizing that the hospital owes an independent duty of care directly to the patient.ⁿ⁸¹ In essence, courts have acknowledged the reality that hospitals have many avenues to control the quality of care, including treatment protocols, quality initiatives, and oversight of nursing and other services, as well as the fact that patients do not distinguish between employed and independent medical staff physicians in their expectations for hospital quality of care or oversight.

ⁿ⁸¹ *Oehler*, 775 P.2d at 1272 (hospital and governing board may be liable for failure to supervise treatment by nonemployed physicians under corporate negligence theory of liability); *Insinga v. Labella*, 543 So. 2d 209, 214 (Fl. 1989) (recognizing the corporate negligence doctrine as the independent duty the hospital owes to patients, and finding that because the hospital is in "a superior position to supervise and monitor physician performance," it is "the only entity that can realistically provide quality control."); *Elam v. Coll. Park Hosp.*, 183 Cal. Rptr. 156 (1982) (hospital held liable under the doctrine of corporate negligence where independent contractors negligently performed pediatric surgery at the hospital); *Pedroza v. Bryant*, 677 P.2d 166 (Wash. 1984) (expressly adopting corporate negligence theory); *Zambino v. Hosp. of the Univ. of Pa.*, No. 06-3561 (E.D. Pa. 2006) (discussing application of corporate negligence to hospital trustees); *Carter v. Hucks-Folliss*, 505 S.E.2d 177 (N.C. 1998) (negligent credentialing).

State Oversight and Enforcement

Nonprofit healthcare organizations are regulated by two independent sources of state authority: state attorneys general and public health departments. Within state governments, the primary authority to oversee nonprofit corporations is vested in state attorneys general, who have broad authority in relation to nonprofit organizations, including management of assets, fulfillment of mission, and closure.ⁿ⁸² Through licensure and regulation, state health departments directly oversee the quality of healthcare delivered in a wide array of settings, and by extension have authority to set standards and to sanction boards of directors for failure to oversee quality.

ⁿ⁸² Fishman, *Improving Charitable Accountability*, at 265.

Oversight by state attorney general offices

In the wake of scandals entailing financial management, failure to fulfill mission, and self-dealing in the late 1990s, state attorneys general became more proactive in overseeing nonprofit boards.ⁿ⁸³ By and large, state attorneys general

have continued to focus on mismanagement and self-dealing by nonprofit boards. Accordingly, in the healthcare arena, state attorneys general have intervened primarily in matters outside the purview of healthcare quality, such as conversion to for-profit status, closure, and merger of facilities. n84

n83 James Fishman describes a number of the most prominent cases of nonprofit scandals. *Id.* at 219. For examples of nonprofit scandals, see Bruce Lambert, *New York Regents Oust 18 Trustees from Adelphi U.*, N.Y. TIMES, Feb. 11, 1997, at A1; *Aramony v. United Way*, 28 F. Supp. 2d 147, 152-53 (S.D.N.Y. 1998); David Barstow, *A Nation Challenged: The Charities; In Congress, Harsh Words for Red Cross*, N.Y. TIMES, Nov. 7, 2001, at B1 (in 2001, the American Red Cross was accused of keeping over \$ 264 million in charitable donations it received for September 11 victims in reserve); John J. Goldman, *Charity Ex-Chief Admits to Theft*, L.A. TIMES, July 4, 2002, at A12 (in 2002, the director of Hale House, a charity that provides shelter for babies of drug-addicted mothers, stole approximately \$ 700,000 from the charity); Samuel P. King & Randall W. Roth, *BROKEN TRUST: GREED, MISMANAGEMENT, AND POLITICAL MANIPULATION AT AMERICA'S LARGEST CHARITABLE TRUST* (University of Hawaii Press, 2006). See also Kathleen Boozang, *Does an Independent Board Improve Nonprofit Corporate Governance?*, 75 TENN. L. REV. 83, 83 (2007).

n84 Thomas Greaney, *New Governance Norms and Quality of Care in Nonprofit Hospitals*, 14 ANNALS HEALTH L. 421, 423-44 nn. 8-12 (2005) [hereinafter Greaney, *New Governance Norms*] (discussing increased activism by state attorneys general). In one significant case, New York State Attorney General Andrew Cuomo launched an investigation in 2007 into physician-ranking programs by health plans, asserting that the rankings could mislead consumers by confusing quality with efficiency or cost savings. See discussion, note 44.

In the most extreme cases, state attorneys general have the authority to sanction or remove board members. In a 1999 case involving Allina Health System, the Minnesota Attorney General asserted that the structure of Allina Health System, which included entities that provided health services and health insurance, led to conflicting missions between the HMO ("to manage health costs and control premiums") and the hospitals (to "act as caregivers to patients"). n85 He petitioned for the authority to appoint the board of a new entity, effectively removing the Allina board members for conflict of interest.

n85 For a discussion of the Allina case, see Elizabeth Stawicki, *Medica Case Could Test Attorney General's Power over Nonprofits* (Aug. 16, 2005), available at http://news.minnesota.publicradio.org/features/2005/08/16_stawickie_medicahtac/ [hereinafter Stawicki, *Medica Case Could Test Attorney General's Power over Nonprofits*].

The *Allina* case, as well as other actions to sanction or remove nonprofit board members, demonstrate the significant authority state attorneys general can exercise in relation to nonprofit boards. n86 Indeed, states are much closer to healthcare institutions than the federal government; they oversee fewer institutions and are more knowledgeable about institutional leadership and the communities served. Despite the fact that state attorneys general are often in the most suitable position to oversee execution of the duties of care and loyalty, their efforts are hampered by limited resources. n87 On issues posed by healthcare quality, state attorneys general lack the expertise of state public health authorities and CMS.

n86 Greaney, *New Governance Norms*, at 424; See Stawicki, *Medica Case Could Test Attorney General's Power over Nonprofits*. In a non-healthcare setting in 1997, the New York State Board of Regents dismissed 18 of 19 trustees at Adelphi University for improper oversight of the university's president. Bruce Lambert, *New York Regents Oust 18 Trustees from Adelphi U.*, N.Y. TIMES, Feb. 11, 1997, at A1.

n87 Greaney & Boozang, *Mission, Margin, and Trust in the Nonprofit Health Care Enterprise*, 1, 4. See also Fishman, *Improving Charitable Accountability*, at 268 ("It has long been demonstrated that state attorney general offices have neither the person-power, nor sometimes the will, to monitor nonprofits effectively.").

Oversight by state public health agencies

States' public health agencies generally have authority to prescribe and enforce measures for hospital compliance

with minimum quality standards. This authority rests in their control of licensure for healthcare institutions. n88 The primary mechanism for oversight is surveys. n89 Most states rely on Joint Commission surveys to evaluate hospital quality, but some conduct their own surveys. In addition to state surveys, many states have established incident reporting systems as a mechanism to track and respond to adverse events. n90 By January 2008, twenty-six states had implemented adverse event reporting systems; twenty-three of those had established their own lists of reportable events, while the other three used the NQF's list of never events. n91

n88 Most states rely on Joint Commission licensure standards and often accept such accreditation as the basis for a license.

n89 However, recent findings demonstrate the infrequency of such surveys. In February 2009, the U.S. Government Accountability Office (GAO) criticized CMS's oversight of Medicare and Medicaid participating facilities, finding the time between surveys for facilities without statutory survey frequencies too long, which can increase the risk for quality problems. For example, as of September 30, 2007, approximately 2700 facilities (thirteen percent) had not been surveyed in six years or more. GAO REPORT TO CONGRESSIONAL REQUESTERS, MEDICARE AND MEDICAID PARTICIPATING FACILITIES: CMS NEEDS TO REEXAMINE ITS APPROACH FOR FUNDING STATE OVERSIGHT OF HEALTH CARE FACILITIES 27, GAO-09-64, Feb. 2009, *available at* www.gao.gov/new.items/d0964.pdf. CMS also found that twenty-five percent or more of some **nursing home** surveys in seven states missed serious deficiencies. *Id.* at 14.

n90 *See* DHHS OIG, ADVERSE EVENTS IN HOSPITALS: STATE REPORTING SYSTEMS, App. D and E (Dec. 2008), *available at* www.oig.hhs.gov/oei/reports/oei-06-07-00471.pdf.

n91 *See id.* at App. D for a list of the states, the year each state implemented its system, the agency receiving the reports, the reportable event list the states use, and the number of adverse events reported in each state in 2006.

Most states that collect adverse event data (twenty-three of the twenty-six) use the information to hold hospitals accountable, although state reporting has been inconsistent and varied. n92 State public health authorities conduct administrative reviews of data, and in the most serious cases can use the data to support a decision to revoke a hospital's license. n93

n92 *Id.* at 14. *See also* MODERN HEALTHCARE, *Variation Seen in Adverse-Event Reporting* (Dec. 16, 2008) ("Of the 26 states that operated event-reporting systems, 15 said hospitals don't always report their adverse events, although all 26 states do use the information they collect in similar ways to improve patient safety"), *available at* www.modernhealthcare.com/article/20081216/REG/312169976. In addition, in many states, healthcare providers must report to the state when healthcare professionals commit egregious errors. *See, e.g.*, N.Y. PUB. HEALTH LAW § 2803-e, "Reporting incidents of possible professional misconduct; N.Y. PUB. HEALTH LAW § 2805-(1-2).

n93 However, as explained by public health staff in one state, "revocation could occur only after the hospital conducted an inadequate investigation of an event that was deemed 'serious,' did not develop an appropriate corrective action plan, failed to correct state-cited deficiencies, and was in the process of losing or had already lost its accreditation status." DHHS OIG, ADVERSE EVENTS IN HOSPITALS: STATE REPORTING SYSTEMS at 15 (Dec. 2008), *available at* www.oig.hhs.gov/oei/reports/oei-06-07-00471.pdf.

As part of the public health oversight framework, states set standards for hospital and healthcare system boards. Most states set general standards for hospital boards; they do not delineate how the boards should fulfill the obligation to oversee quality, although most recognize the longstanding premise that the board has "ultimate responsibility" for quality. In many states, boards must credential medical staff and appoint the chief executive officer (CEO).

Besides these rather general standards, regulation of board oversight of healthcare quality varies state-to-state. For example, the New Jersey Department of Health and Human Services (DHSS) Code requires that "[t]he hospital shall have an established and functioning governing body responsible for establishing hospital-wide policy, adopting bylaws, *maintaining quality of care*, and providing institutional management and planning." n94 California law is unambiguous in vesting authority over quality of care in the board of directors, but it does not delineate how the board should

implement this responsibility. The law requires hospitals to ensure that the medical staff is responsible to the governing body "for the adequacy and quality of the medical care rendered to patients in the hospital." n95

n94 N.J. ADMIN. CODE. § 8:43G-5.1(b), emphasis added.

n95 CAL. CODE REGS. tit. 22 § 70703(a), "Organized Medical Staff."

New York's law is more explicit. n96 The New York Code states that the governing body is "legally responsible for the quality of patient care services, for the conduct and obligations of the hospital as an institution and for ensuring compliance with all Federal, State and local laws." n97 The bylaws adopted by the governing body must specify how it and the medical staff interact, and how the governing body holds the medical staff accountable for its obligations to the community. n98 New York law also requires that the governing body maintain "a coordinated program which integrates the review of activities of all hospital services for the purpose of enhancing the quality of patient care and identifying and preventing malpractice." n99 Like most states, New York requires the governing body to make the final decision to credential medical staff members and to appoint a medical director accountable to the governing body. n100

n96 The New York Department of Health has the "central, comprehensive responsibility for development and administration of the state's policy with respect to hospital and related services" due to the significance of providing health-related service "of the highest quality." N.Y. PUB. HEALTH LAW § 2800 (2008).

n97 N.Y. COMP. R. & REGS. tit. 10 § 405.2(a) (2008): "Governing Body," emphasis added. *See generally* N.Y. COMP. R. & REGS. tit. 10 § 82.1-5 (2008) "Governing Body."

n98 "The bylaws shall specify at least the following: "...the relationships and responsibilities of the governing body, hospital administration, and the medical staff, and the mechanism established by the governing body for holding such parties accountable." (10 NYCRR § 405.2(b)(4)(iv)). *The governing body shall "ensure the medical staff is accountable to the governing body for the quality of care provided to patients."* 10 NYCRR § 405.2(e)(10), emphasis added.

n99 N.Y. COMP. R. & REGS. tit. 10 § 405.2(b)(6).

n100 N.Y. COMP. R. & REG. tit. 10 § 405.2(e)(1)-(3).

States exercise oversight of board members in various ways, although generally there has been little discipline for poor quality of care by state attorneys general or public health agencies. Despite their disinclination to do so, states *can* impose penalties for board failures, although the most common penalty is a civil monetary penalty or fine imposed on the healthcare institution, not on the board members personally. n101 For example, in 2007, California regulators imposed a \$ 3 million fine on the nation's largest nonprofit health plan for failure to provide adequate oversight of quality assurance programs, particularly with respect to patient complaint management. n102 New Jersey adopted regulations in 2005 setting forth required periodic training for board members, including training on healthcare quality. n103 In addition, the NJ DHHS may cite a hospital for a deficiency or impose monetary penalties, including for failure to have a functioning governing body responsible for maintaining quality of care. Legislation introduced in 2008 created an "Early Warning System" which provides the NJ DHHS with additional oversight over the state's hospitals. n104 The bill lays out a system of progressive monitoring, with each subsequent step taken only if the hospital has neglected to take ameliorative action. n105

n101 State attorneys general have the authority to correct noncompliance of nonprofit corporations. *See, e.g.*, CAL. CORP. CODE § 5250 (1990) ("Proceedings to correct noncompliance" for nonprofit corporations: "Attorney General may institute, in the name of the state,

the proceeding necessary to correct the noncompliance or departure").

n102 See Barbara Ostrov, *Kaiser Fined \$ 3M for Poor Response*, SAN MATEO COUNTY TIMES, July 28, 2008). The fine was due to "haphazard investigations into patient complaints and physician performance." *Briefs*, DENVER ROCKY MOUNTAIN NEWS, July 27, 2007.

n103 N.J. ADMIN. CODE § 8:43G-5.22(b)(2), "General Hospital Governing Body Training," available at www.nj.gov/health/healthfacilities/documents/ac/njac43g_hoslicstd.pdf ("The trustee training program shall consist of at least seven hours of instruction and address each of the following subjects:... The role of the governing body in improving health care quality and the mechanisms available for doing so").

n104 Interview with Matt D'Orio, Deputy Comm'r, Senior Servs. & Health Sys., Feb. 11, 2009 [hereinafter Interview with Matt D'Orio]; S. B.1796, Assem. B. A2608 (N.J. 2008), see Press Release, State of N.J. Office of the Governor, Governor Corzine Signs Hospital Reform Legislation (Aug. 8, 2008), available at www.state.nj.us/governor/news/news/2008/approved/20080808.html.

n105 The more interventionist steps include: (1) the Commissioner of Health meets with the board of directors; (2) the agency assigns consultants to participate in hospital board meetings; and (3) NJ DHHS appoints a monitor with the authority to override board decisions. Although NJ DHHS has not yet taken the most extreme of these steps, the agency has required organizations to create "management action plans" and has threatened further action which has led to quality improvement. New Jersey has not imposed sanctions for breach of fiduciary duty on any particular board members. In one instance, NJ DHHS sought relief from the State Attorney General, but no action was taken. *Id.* A list of New Jersey enforcement actions is available at <http://nj.gov/health/healthfacilities/hospfines/summaries.shtml#bar043007>.

In New York, if individuals serve on boards with a poor record of quality of care, they can be effectively barred from serving on the board of newly created entities. Newly created entities or those undergoing significant reorganization must apply for approval to the New York State Public Health Council, and as part of this process, all proposed board members must be approved for "character and competence." n106 More specifically, to demonstrate their character and competence to serve on a board of a newly created entity, potential board members must disclose all previous boards on which they have served. The New York State Public Health Council reviews those entities, in and out of state, for quality and compliance deficiencies.

n106 See 10 N.Y. COMP. CODES R. & REGS. § 600.2(b)(2)(i)-(iii), "Requirements for Approval" ("The applicant must satisfactorily demonstrate to the council: that there is a public need for the facility or the proposed new facility; ... if a nonprofit corporation, that the members of the board of directors and the officers of the corporation are of such character, experience, competence and standing as to give reasonable assurance of their ability to conduct the affairs of the corporation in its best interests and in the public interest and so as to provide proper care for the patients or residents to be served by the facility or the proposed facility").

Federal Oversight of Healthcare Quality

Traditionally, the federal government exercised its responsibility to oversee quality with administrative surveys and sanctions, managed by CMS as the federal payor for healthcare. More recently, prosecution by the United States Office of Inspector General (OIG) and the Department of Justice have played an increasing role in federal oversight, as prosecutors have turned to enforcement of the False Claims Act (FCA) as a primary tool in combating poor quality of care. Moreover, under the Balanced Budget Act of 2005, states have financial incentives to pursue FCA enforcement. As a result, deferred prosecution and corporate integrity agreements have proliferated as a means to demand better performance of both institutions and the boards that oversee them.

CMS standards

At the federal level, CMS has authority to set standards for hospital boards of directors as part of the Hospital Conditions of Participation (COP) in the Medicare programs. CMS standards established for boards of directors to date relate solely to the boards' traditional role in overseeing the medical staff and granting final approval of medical staff credentials. Beginning in 1998, CMS set minimum health and safety standards for hospitals and providers to attain

Medicare or Medicaid certification. In 2003, Medicare changed the COP standards to require hospitals to develop, implement, and maintain data-driven quality assessment and performance improvement programs, but did not include specific standards for boards of directors. n107 However, institutions may be cited and penalized by CMS for a broad array of violations, including the failure of governance oversight.

n107 42 C.F.R. § 482.21 (2003); 42 C.F.R. § 488.5; 42 U.S.C. § 1395bb(a), (b), and § 1395x(e). While CMS has authority to oversee hospital quality of care, it often does not actively do so, instead delegating compliance with such standards to the states. It has been argued that the federal government has been unable, "at a ground level," to ensure quality of care. John P. Marren et al., *The Hospital Board at Risk and the Need to Restructure the Relationship with the Medical Staff: Bylaws, Peer Review and Related Solutions*, 12 ANNALS HEALTH L. 179 (2003).

Joint Commission accreditation is deemed sufficient to meet the requirements for Medicare participation and reimbursement. n108 Like state statutes, the Joint Commission Leadership Standards vest ultimate responsibility for patient safety and quality in the governing body. n109 Among other requirements, the Joint Commission standards require leadership to:

1. address conflicts among the leadership that could affect safety or quality;
2. create a culture of safety and quality, encourage teamwork, and provide education about quality to hospital employees;
3. use data to improve the safety and quality of care, treatment, and services; and
4. establish structures and processes that focus on safety and quality. n110

n108 Joint Commission Resources, *Getting the Board on Board: What Your Board Needs to Know about Quality and Patient Safety* 28 (2007). See also Michelle Mello et al., *Fostering Rational Regulation of Patient Safety*, 30 J. HEALTH POL. POL'Y & L. 375, 382 (2005). See also Donald M. Berwick & Troyen A. Brennan, *New Rules: Regulation, Markets, and the Quality of American Health Care* 43 (1995) ("Just as the federal government has accepted the role of third-party administrators in Medicare financing, so too has it been willing to go along with the traditional method of overseeing hospital quality.").

n109 Joint Commission Standard LD.01.03.01. See THE JOINT COMM'N, ACCREDITATION PROGRAM: HOSPITAL LEADERSHIP (2008), available at www.jointcommission.org/NR/rdonlyres/D53206E8-D42B-416B-B887-491B6D5AA163/0/HAP_LD.pdf [hereinafter ACCREDITATION PROGRAM: HOSPITAL LEADERSHIP]. The standards also clarify that the governing body is responsible for providing the resources required to maintain safe, quality care, treatment, and services. JCAHO Medical Staff Standard 2 states that a medical staff should develop and adopt bylaws and rules and regulations as both a framework for self-governance and as a framework for "accountability to the governing body." JCAHO Medical Staff Standard 2.

n110 ACCREDITATION PROGRAM: HOSPITAL LEADERSHIP.

The Joint Commission also encourages the reporting of "sentinel events" that require immediate investigation and response. n111 It should be noted that although Joint Commission standards provide specific steps to promote the safety and quality of care within hospitals, the standards do not delineate responsibility between the three elements of leadership: the board, medical staff, and senior management.

n111 Joint Commission, *Sentinel Events*, available at www.jointcommission.org/SentinelEvents/ ("A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof."). The Joint Commission makes a point of distinguishing between "sentinel events" and "medical errors." See also Joint Commission, *Sentinel Event Policy and Procedures*, available

at www.jointcommission.org/SentinelEvents/PolicyandProcedures/se_pp.htm. The Joint Commission sets forth specific requirements for an organization or hospital reporting a sentinel event. If the hospital or organization does not follow up as required, the Commission can deny accreditation. The Joint Commission collects and aggregates data from the review of sentinel events, but makes only the statistics, not individual cases, public.

Federal enforcement on quality

As healthcare quality has gained prominence in the public eye, it also has become the focus of mounting attention and action by government enforcement agencies. n112 Armed with data that is publicly reported or mined from the government's Medicare and Medicaid databases, the United States Department of Justice, the OIG, and state attorneys general have pursued healthcare providers for poor quality of care as a violation of the FCA. In addition to Medicare and Medicaid databases, federal and state prosecutors seeking to target quality of care investigations may examine data publicly reported on hospital and **nursing homes**, state adverse events reporting systems data, and sentinel events reported to the Joint Commission. n113 Under the Recovery Audit Contractor (RAC) Program, CMS pays contractors a percentage of the overpayments contractors identify from their examination of Medicare claims submitted by healthcare facilities, physicians, and suppliers. n114 The sanctions for violations of the FCA range from exclusion from federal and state healthcare programs to stiff monetary penalties; violation of the FCA may encompass criminal as well as civil penalties. n115

n112 See Alice Gosfield & James Reinertsen, *Avoiding Quality Fraud*, TRUSTEE pp.12-15 (Sept. 2008) [hereinafter Gosfield & Reinertsen, *Avoiding Quality Fraud*]. As reported by Gosfield and Reinertsen, James Sheehan, former federal prosecutor and now New York State Medicaid Inspector General, asserted that the federal government will pursue boards of directors for poor quality under the FCA, and enumerated four questions that will direct the government's inquiry: (1) Has there been a systemic failure by management and the board to address quality issues? (2) Has the organization made false reports about quality or failed to make mandated reports? (3) Has the organization profited from ignoring poor quality or ignoring providers of poor quality? (4) Have patients been harmed by poor quality or given false information about quality? *Id.* at 3.

n113 CMS is using a variety of sources in its datamining efforts, including data from the Hospital Quality Initiative and the Physician Quality Reporting Initiative. For a fuller discussion of these sources, see Cheryl Wagonhurst et al., *The Quality of Care Cerberus: Payments, Public Reporting and Enforcement*, 20 HEALTH LAW. *3 (Dec. 2007) [hereinafter Wagonhurst et al., *The Quality of Care Cerberus*]. State attorneys general use the Medicaid database. For example, the New York State Medicaid Inspector General uses the New York State Medicaid data for audits, investigations, and enforcement. Presentation by Jim Sheehan, Medicaid Inspector General, *Data Mining in Health Care Compliance and Regulation*, Seton Hall Law (June 4, 2008). CMS recently established "zone program integrity contractors" (ZPICs) that use databases to identify high risk areas, examine billing trends and patterns to target abnormal Medicare billing, and generally pursue fraud in a more aggressive manner. Press Release, CMS, CMS Enhances Program Integrity Efforts to Fight Fraud, Waste and Abuse in Medicare, Oct. 6, 2008, available at www.cms.hhs.gov/apps/media/press/release.asp?Counter=3291&intNumPerPa.

n114 The Deficit Reduction Act § 6031 provided a compliance enforcement incentive to states, specifying that if a state's false claims legislation meets certain federally mandated standards, the state is entitled to a ten percent increase of the amount recovered in a false claims case brought under the state's false claims act.

n115 Joan H. Krause, *Healthcare Fraud and Quality of Care: A Patient-Centered Approach*, 37 J. HEALTH L. 161 (2004) [hereinafter Krause, *Healthcare Fraud and Quality of Care*]. However, some commentators have noted that the FCA may not be the optimal mechanism for enforcing healthcare quality because of its haphazard and sometimes counterproductive application. See Michael E. Clark, *Whether the False Claims Act is the Proper Legal Tool for the Government to Use for Improving the Quality of Care in Long-Term Care Facilities*, 15 HEALTH LAW. 1, 12; 16 (2002). See also Robert Salcido, *The Government's Increasing Use of the False Claims Act Against the Health Care Industry*, 14 J. LEGAL MED. 457 (Dec. 2003) for a detailed history of the use of the FCA against the healthcare industry and relevant case law.

In the compliance context, providers generally have been found liable for substandard quality of care under the FCA based on one of two theories: (1) the treatment billed for was medically unnecessary or (2) the quality of care was so poor that the services were essentially not delivered or worthless. n116 In addition, the government has pursued enforcement actions against hospitals for failure to properly oversee and credential the quality of medical staff, and for violation of regulations, such as limitations on use of physical restraints. n117

n116 *See, e.g., United States v. NHC Health Corp.*, 163 F. Supp. 2d 1051 (W.D. Mo. 2001). *See also* John T. Brennan, Jr. & Michael W. Paddock, *Limitations on the Use of the False Claims Act to Enforce Quality of Care Standards*, J. HEALTH & LIFE SCIENCES L. 37, 48 (Oct. 2008) ("Substandard care may be so extreme as to lead to factually false claims, or claims for worthless services. Use of the FCA to punish such transgressions is appropriate. These cases are not based upon theories of false certification, however.").

n117 For example, Central Montgomery Hospital in Pennsylvania was accused of improper use of restraints and knowingly billing federal healthcare programs for care provided to the inappropriately restrained patients in violation of the FCA. The hospital agreed to pay the federal government \$ 200,000 and hire an independent consultant to review the hospital's restraint use policies. Press Release, U.S. D.O.J., U.S. Attorney's Office Reaches Agreement with Hospital to Resolve Failure of Care Allegations Stemming from Improper Use of Patient Restraints (July 25, 2005), *available at* www.usdoj.gov/usao/pae/nursing/cmmc.html.

In quality enforcement actions under the FCA, the government asserts that the claim submitted for reimbursement was fraudulent. Each time a hospital or **nursing home** submits a claim, it must certify compliance with government statutes and regulations that are a precondition for payment, including the requirement that the care is medically necessary and appropriate. A false certification may be either express or implied. n118 The implied certification theory has been more controversial, and has not been accepted by courts in all jurisdictions. n119

n118 *See Mikes v. Straus*, 274 F.3d 687, 698-99 (2d Cir. 2001); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 786 (4th Cir. 1999). *See also* Krause, *Healthcare Fraud and Quality of Care*. Express false certification occurs when the statute or regulation by its terms requires certification of compliance and establishes that compliance is a prerequisite for payment. *Mikes*, 274 F.3d at 697-98. An implied false certification claim is based on the premise that submitting the claim implies compliance with statutes and regulations that the government would perceive to be preconditions to payment. *Id.* at 699. *See also* James E. Utterback, *Substituting an Iron Fist for the Invisible Hand: The False Claims Act and Nursing Home Quality of Care--A Legal and Economic Perspective*, 10 QUINNIPIAC HEALTH L.J. 113 (2007).

n119 *See Mikes*, 274 F.3d at 698; 703 (acknowledging that a worthless services claim is valid under the FCA, but limiting the use of the implied false certification theory to cases where the "underlying statute or regulation upon which the plaintiff relies expressly states" that the contractor must comply to get paid).

Government enforcement actions have resulted in substantial penalties for healthcare providers. Under the FCA, courts can impose fines from \$ 5,000 to \$ 10,000 per claim, and a penalty of three times the value of each service that was fraudulently billed. The government can recover for claims brought within six years of the date on which a violation was committed, or within three years of the date on which the government knew or should have known that a violation was committed. n120 DOJ reported FCA settlements and judgments totaling \$ 3.1 billion in 2006, over 70 percent of which was attributed to healthcare case settlements, and \$ 1.34 billion in settlements in 2008. n121

n120 31 U.S.C. § 3729(a); 3731(b)(1)-(2) (2004). *See* Krause, *Healthcare Fraud and Quality of Care*.

n121 Nat'l Consumer Prot. Technical Res. Ctr., *Health Care Cases Comprise Bulk of DOJ's Record Amount Recoveries in Fiscal 2006*, 10 HEALTH CARE FRAUD REP. 870 (Dec. 6, 2006), *available at* <http://ndcpd.misu.nodak.edu/smp/pdf/Clippings1128.pdf>; 2008 *Year-End False Claims Act Update* (Jan. 1, 2009), *available at* www.boardmember.com/Article_Details.aspx?id=2569. FCA settlements for allegations of healthcare fraud have resulted in single payments up to \$ 875 million dollars. Press Release, Dep't of Justice, TAP Pharmaceutical Products, Inc., and Seven Others Charged with Health Care Crimes; **Company** Agrees to Pay \$ 875 Million to Settle Charges (Oct. 3, 2001), *available at* www.usdoj.gov/opa/pr/2001/October/513civ.htm.

For the past decade, enforcement of substandard quality of care has been a priority for the OIG, which can pursue administrative remedies, including exclusion from the Medicare program. n122 In 2000, the OIG issued compliance guidance for **nursing homes**. Noting that quality of care is one basis for lack of compliance, the guidance enumerated nine grounds of poor quality that could lead to an enforcement action: n123

1. absence of a comprehensive assessment of each resident's functional capacity and a responsive care plan;
2. inappropriate or insufficient treatment to address residents' clinical conditions, including pressure ulcers, dehydration, malnutrition, incontinence of the bladder, and mental or psychosocial problems;
3. failure to accommodate individual resident needs and preferences;
4. failure to properly prescribe, administer, and monitor prescription drug usage;
5. inadequate staffing levels or insufficiently trained or supervised staff to provide medical, nursing, and related services;
6. failure to provide appropriate therapy services;
7. failure to provide appropriate services to assist residents with activities of daily living (e.g., feeding, dressing, bathing, etc.);
8. failure to provide an ongoing activities program to meet the individual needs of all residents; and
9. failure to report incidents of mistreatment, neglect, or abuse to the administrator of the facility and other officials as required by law.

n122 See Wagonhurst et al., *The Quality of Care Cerberus*, at *3, n. 19, citing *OIG's Morris Tells AHLA to Watch for Increases in False Claims Act Cases*, 10 BNA HEALTH CARE FRAUD REP. 524 (July 5, 2006) (Lewis Morris, Counsel to the U.S. DHHS OIG, explaining OIG's focus on using the FCA to "combat quality of care violations in hospitals and **nursing homes**"). For example, in *U.S. v. United Mem'l Hosp.*, the hospital entered into a federal plea agreement admitting overutilization of pain management surgical procedures and inadequate credentialing of a practicing physician. *Plea Agreement*, Docket No. 1-CR-238 (W.D. Mich. Jan. 8, 2003). Two years before Tenet entered into the 2005 CIA resolving liability for conduct including DRG upcoding, improper outlier payments, kickbacks to physicians, and other fraudulent activities (discussed below), it settled allegations of lack of medical necessity involving surgeries at one its hospitals. See Press Release, OIG, OIG and Tenet Healthcare Corporation Reach Divestiture Agreement to Address Exclusion of Redding Medical Center (Dec. 11, 2003), available at www.oig.hhs.gov/publications/docs/press/2003/121103release.pdf. Tenet paid \$ 54 million in federal fines and agreed to divest Redding Medical Center, which was accused of inadequate credentialing of cardiologists who conducted unnecessary invasive heart procedures.

n123 *Publication of the OIG Compliance Program for Nursing Facilities*, 65 Fed. Reg. 52, at 14,289 (Mar. 16, 2000), available at <http://oig.hhs.gov/authorities/docs/cpgnf.pdf> [hereinafter *Publication of the OIG Compliance Program for Nursing Facilities*]. In identifying potential risks for fraud and abuse, the OIG Supplemental Compliance Program for Nursing Facilities issued in 2008 listed quality of care first, again providing in-depth guidance about common areas of risk for poor quality. OIG SUPPLEMENTAL COMPLIANCE PROGRAM GUIDANCE FOR NURSING FACILITIES, 73 Fed. Reg. 190 at 56,832 (Sept. 30, 2008), available at www.oig.hhs.gov/fraud/docs/complianceguidance/nhg_fr.pdf [hereinafter OIG SUPPLEMENTAL COMPLIANCE PROGRAM GUIDANCE FOR NURSING FACILITIES].

The recent proliferation of healthcare and pharmaceutical Corporate Integrity Agreements (CIAs) and Deferred Prosecution Agreements (DPAs) reflects the federal government's escalating compliance scrutiny. n124 The agreements with hospitals, pharmaceutical **companies**, and other healthcare entities have clear implications for board leadership. n125 Specifically, CIAs and DPAs have delineated the expectations and roles of the board and identified detailed oversight remedies. n126 Recent CIAs all set forth core requirements for the entities' boards of directors, including the responsibility to oversee and certify that the corporation is in compliance with the agreement and federal law. n127

n124 Commentators have predicted that the number of quality-based enforcement actions will continue to increase. Carl Jean-Baptiste,

Dropping the "Boom" on Healthcare, MD. B.J. 32, 36 (Jan./Feb. 2009).

n125 See November 2008 CIA with Bayer Corporation, which includes "specific requirements for the board of directors and management that will enable the OIG to closely monitor **company** practices affecting Federal health care programs and beneficiaries." Press Release, U.S. D.O.J., Bayer Healthcare to Pay U.S. \$ 97.5 Million to Settle Allegations of Paying Kickbacks to Diabetic Suppliers (Nov. 25, 2008), available at www.usdoj.gov/usao/fls/PressReleases/081125-01.html. In January 2009, Eli Lilly & Co. entered into a five-year CIA with the OIG as part of a \$ 1.4 billion settlement, with similar requirements. Press Release, U.S. D.O.J., Eli Lilly & Co. Corporate Integrity Agreement (Jan. 14, 2009), available at www.usdoj.gov/civil/oclc/cases/Cases/Eli_Lilly/Corporate%20Integrity%20Agreement%20Eli%20Lilly.pdf.

n126 Healthcare organizations and other entities enter into CIAs with the OIG (or DPAs with the U.S. Attorney's Office) to settle investigations arising out of false claims and other legal violations. Some commentators assert that DPAs permit the federal government to take an intrusive role in "policing, and supervising, corporate America." See Peter Spivack & Sujit Raman, *Regulating the 'New Regulators': Current Trends in Deferred Prosecution Agreements*; 45 AM. CRIM. L. REV. 1, 3 (2008); Kathleen Boozang & Simone Handler-Hutchinson, "Monitoring" Corporate Corruption: DOJ's Use of Deferred Prosecution Agreements, AM. J. L. MED. (forthcoming 2009) [hereinafter Boozang & Handler-Hutchinson, "Monitoring" Corporate Corruption].

n127 According to the OIG website, the most comprehensive CIAs have certain elements in common, such as the requirement to implement a comprehensive employee training program and provide an implementation report and annual reports to the OIG on the status of the entity's compliance activities. U.S. H.H.S. O.I.G., *Corporate Integrity Agreements*, available at www.oig.hhs.gov/fraud/cias.asp. They also include specific requirements for board action, such as the requirement to hire a compliance officer or appoint a compliance committee, to establish a quality assurance monitoring committee as part of the board of directors, and to develop written standards and policies. For example, the Green Valley Pavilion CIA, discussed below, requires that "the Board of Directors may determine to appoint itself or a committee of its members to serve as the [Compliance] Committee." Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Green Valley Pavilion et al. 3 (May 2007), available at http://oig.hhs.gov/fraud/cia/agreements/green_valley_pavilion_05012007.pdf [hereinafter *Green Valley Pavilion CIA*]. However, CIAs are tailored to the particular circumstances of misconduct. A list of all CIAs, CCAs, and Settlement Agreements with Integrity Provisions for healthcare providers and entities is available at www.oig.hhs.gov/fraud/cia/cia_list.asp. As of February 2009, the site listed 480 entities with whom the OIG has entered into such agreements since 2000, including hospitals and **nursing homes**.

While most CIAs address financial issues, prominent settlements have focused on healthcare quality. In 2001, Vencor, one of the nation's largest operators of **nursing homes** and long-term hospital services, was accused of submitting false claims to Medicare, Medicaid, and TRICARE, the military's healthcare program, based on poor quality of care and failure to staff its facilities adequately. n128 The **company** entered a five-year CIA mandating a comprehensive quality assurance infrastructure at the corporate, regional, and facility levels. The CIA required quality committees to collect and review quality-related data to identify problems, determine the root cause of the problems, develop corrective action plans to improve care, and monitor the effectiveness of the interventions to ensure overall improvement in the quality of care and services delivered.

n128 HHS AND DOJ HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2001 (April 2002), available at <http://oig.hhs.gov/publications/docs/hcfac/HCFAC%20Annual%20Report%20FY%202001.htm>.

The September 2006 CIA with Tenet Healthcare Corporation was a watershed agreement because of the broad sweep of provisions directing board conduct to oversee quality of care. n129 The five-year CIA required the Quality, Compliance, and Ethics Committee of the board to review the effectiveness of Tenet's compliance program and adopt resolutions summarizing its review of the **company's** compliance with the CIA and federal healthcare program requirements. The Tenet officers were required to certify the Medical Center's compliance with the CIA and submit annual reports to the OIG. n130 In addition, the CIA required an independent entity to assess (1) Tenet's compliance with its written policies and procedures to achieve compliance with federal healthcare program requirements, and (2) the "effectiveness, reliability, and thoroughness of Tenet's quality management infrastructure and systems throughout Tenet." n131

n129 Press Release, Office of Inspector Gen., *OIG Executes Tenet Corporate Integrity Agreement: Unprecedented Provisions Include Board of Directors Review* (Aug. 28, 2006), available at www.oig.hhs.gov/fraud/docs/press/Tenet%20CIA%20press%20release.pdf. The full Tenet CIA is available at <http://oig.hhs.gov/fraud/cia/agreements/TenetCIAFinal.pdf> [hereinafter *Tenet CIA*]. See also D. Scott Jones, *Combining Disciplines: Making the Connection Between Compliance, Risk, and Quality Management*, 9 J. HEALTH CARE COMPLIANCE 5 (2007) (noting that 23 of the documents' 63 pages address or name quality issues to some degree). In regard to quality, the Tenet CIA required establishment of a clinical quality department, including a chief medical officer, senior officers, and clinical quality staff; clinical audits; physician credentialing; physician privileging; physician peer review; evidence-based medicine programs; standards of clinical excellence; utilization management and review; quality metrics; and other quality improvement measures.

n130 *Id.* The 2005 CIA with HealthSouth also contained provisions requiring board of director oversight, but the CIA is not as far-reaching as the Tenet CIA in outlining the requirements. *HealthSouth Corporate Integrity Agreement* (Jan. 1, 2005), available at www.oig.hhs.gov/fraud/cia/agreements/healthsouth_corporation_01012005.pdf/.

n131 *Tenet CIA*, at 60-64; Gosfield & Reinertsen, *Avoiding Quality Fraud*.

In 2007, the OIG charged that Green Valley Pavilion, operated by the Green Acres Health System, had forged and altered patient charts to maximize reimbursement from Delaware's Medicaid Program. The Health System entered into a four-year CIA requiring creation of a board Quality Assurance Compliance Committee to address allegations of neglect and poor quality of care. The CIA also mandated a board Quality Assurance Monitoring Committee to "review the adequacy of Green Acres' system of internal controls, quality assurance monitoring, and patient care." n132 Finally, the CIA required a nurse consultant/monitor to inspect Green Valley Pavilion (and five other facilities owned by Green Valley Pavilion's parent **company**) and report to Green Acres and the OIG on the facilities' compliance with applicable regulations and standards of care. n133

n132 *Green Valley Pavilion CIA*.

n133 Press Release, Del. Attorney Gen., Attorney General Joseph R. Biden, III, Joins the United States Attorney for the District of Delaware to Announce a Settlement in a Fraudulent Medicaid Billing Scheme as Part of Agreement, Green Valley Pavilion, LLC will Make Financial Payments and be Subject to Ongoing Compliance Inspections (May 10, 2007), available at <http://attorneygeneral.delaware.gov/media/releases/2007/mfsettlement.shtml>.

A more recent CIA entered into by Corona Care Convalescent Corporation obliged the organization to create a board committee to oversee the quality of care. n134 This committee is required to:

- . review the adequacy of [Corona]'s system of internal controls, quality assurance monitoring, and patient care;

- . ensure that [Corona]'s response to state, federal, internal, and external reports of quality of care issues is complete, thorough, and resolves the issue(s) identified; and

- . [make sure] that [Corona] adopts and implements policies and procedures [] designed to [provide] each individual [with] the highest practicable physical, mental, and psychosocial level of care attainable.

n135

n134 *Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Corona Care Convalescent Corporation* 4 (Mar. 31, 2008) www.oig.hhs.gov/fraud/cia/agreements/corona_care_convalescent_corporation_03212008.pdf.

n135 *Id.*

The board committee must be readily available to the compliance officer and the independent monitor. As under the Green Valley CIA, the monitor is responsible for assessing the effectiveness of the Corona Care internal quality control system and the facility's response to quality of care issues, and for reporting to Corona Care and the OIG on the facility's compliance with regulations and standards of care.

Outside the quality arena, CIAs and DPAs entered into for violation of federal and state laws demonstrate both the breadth of remedies that government may demand in relation to boards of directors and the concomitant loss of board authority over governance and operations. n136 For example, in 2005, the University of Medicine and Dentistry of New Jersey (UMDNJ) entered into a DPA for violation of the anti-kickback law, hiring practices that favored those with political connections, and other matters. n137 The DPA required appointment of a federal monitor with substantial authority to conduct ongoing investigations. The U.S. Attorney's Office for the District of New Jersey appointed a federal monitor to oversee the activities of the leadership (board, CEO, and senior medical staff), including governance procedures and structures, cost reporting and billing, and conflicts of interest. n138 When the monitor was eventually released, the board had been reconstituted from six members to a more diverse eighteen, and the CEO, general counsel, and chief compliance officer had all been replaced, with input from the monitor.

n136 For a discussion of the trend in CIAs and DPAs, as well as the breadth of remedies incorporated into the agreements, see Boozang & Handler-Hutchinson, "Monitoring" Corporate Corruption.

n137 *Deferred Prosecution Agreement*, available at www.usdoj.gov/usao/nj/press/files/pdf/UMDNJFINALDPA.pdf. The website of the federal monitor is www.umdj.edu/ethweb/federalmonitor. See also DPA between DOJ and Bristol-Myers Squibb Corporation (2005), available at www.usdoj.gov/usao/nj/press/files/pdf/deferredpros.pdf (CEO replaced and board required to provide detailed reporting to monitor for conspiring to commit securities fraud); Press Release, Bristol-Myers Squibb Announces Agreement in Principle to Resolve Federal Antitrust Investigation, available at www.bms.com/News/press_releases/pages/default.aspx.

n138 Vasilios J. Kalogredis, *N.J. University and Hospital Released from Monitorship*, 237 LEGAL INTELLIGENCER 45 (2008). UMDNJ was required to adopt the monitor's recommendations for improvement unless the U.S. Attorney's Office agreed with UMDNJ that such a recommendation should not be adopted.

Mounting federal expectations for boards

Heightened federal and state enforcement for poor quality of care has occurred amidst rising standards for board oversight of corporate compliance and financial management. Issued in 1991, the *Federal Sentencing Guidelines for Organizations* (the Sentencing Guidelines) was one of the earliest federal statements to underscore board obligations to prevent corporate misconduct. n139 Applicable to nonprofit as well as for-profit corporations, the Sentencing Guidelines expressly recognize that an effective compliance and ethics program can mitigate the sentence for a corporation. Setting forth principles that may undergird future government compliance guidance and enforcement action, the Guidelines stress that a necessary element of a compliance program is a board that is knowledgeable about the organization's compliance program and exercises reasonable oversight of the program's effectiveness.

n139 U.S. SENTENCING GUIDELINES MANUAL (1992). The 2001 guidelines, which adopt the 1991 guidelines, are available at www.ussc.gov/2001guid/CHAP8.pdf.

In 2006, the Department of Justice amplified the importance of board conduct in prosecutorial decisions about corporate culpability in a memorandum by Deputy Attorney General Paul McNulty (the McNulty Memorandum). n140 The McNulty Memorandum advised prosecutors that in deciding about charges against a corporation and penalties, they should take into account certain enumerated factors, including the pervasiveness and history of the problem, and the corporation's pre-existing compliance program. n141 Citing the *Caremark* decision, the McNulty Memorandum turned to the role of the board, advising that prosecutors can take into account:

1. governance practices to identify wrongdoing;
2. whether board members exercise independent judgment in reviewing transactions;
3. whether they receive sufficient information to do so; and
4. whether the directors have established an information and reporting system reasonably designed to provide the board with timely and accurate information to make an informed judgment about legal compliance. n142

n140 Paul McNulty, Deputy Attorney Gen., U.S. Dep't of Justice, *Principles of Federal Prosecution of Business Organizations* (Dec. 12, 2006), available at www.usdoj.gov/dag/speeches/2006/mcnulty_memo.pdf. The McNulty Memorandum superseded a memorandum by Deputy Attorney General Larry Thompson that had set forth similar guidelines about consideration of board leadership and the adequacy of a compliance program in determining penalties. Larry D. Thompson, Deputy Attorney General, U.S. Department of Justice, *Principles of Federal Prosecution of Business Organizations* (Jan. 20, 2003), available at www.usdoj.gov/dag/cftf/corporate_guidelines.htm.

n141 While recognizing that the existence of a corporate compliance program is not sufficient by itself to justify a decision not to charge the corporation with criminal conduct, the memorandum stated that an active, well-designed program--or its absence--could play a role in prosecutorial decisions. Paul McNulty, Deputy Attorney Gen., U.S. Dep't of Justice, *Principles of Federal Prosecution of Business Organizations*, at 4 (Dec. 12, 2006), available at www.usdoj.gov/dag/speeches/2006/mcnulty_memo.pdf.

n142 *Id.* at 14.

In February 1998, OIG issued its *Compliance Guidance for Hospitals*, setting forth expectations for the goals and operation of an effective compliance program and enumerating the basic elements of any such program. n143 The *Compliance Guidance for Hospitals* underscored the importance of culture and leadership for compliance, with specific guidelines for boards. At the outset, the *Compliance Guidance for Hospitals* noted, "The OIG believes that every effective compliance program must begin with a formal commitment by the hospital's governing body to include *all* of the applicable elements...." n144 Among the elements cited is the designation of a Chief Compliance Officer who reports directly to the CEO and the governing body. The document also highlights the importance of accountability, asserting that the evaluation of managers and supervisors should include their performance in promoting and adhering to compliance. Two years later, the OIG issued the *Compliance Program Guidance for Nursing Facilities*, reiterating the importance of the board's role and the need for direct reporting about compliance to the board. n145 Updated revised compliance guidance statements were issued for hospitals and **nursing homes** in 2005 and 2008, respectively. Notably, both statements emphasize that, among other benefits, implementation of a voluntary compliance program "may significantly reduce the risk of unlawful conduct and corresponding sanctions." n146

n143 *Publication of the OIG Compliance Program for Hospitals*, 63 Fed. Reg. 35 at 8,987 (Feb. 23, 1998), available at <http://oig.hhs.gov/authorities/docs/cpghosp.pdf>.

n144 *Id.* at 8,989. The seven elements cited were: (1) written standards of conduct as well as policies and procedures to promote compliance; (2) a Chief Compliance Officer charged to operate the compliance program who reports to the CEO and Board of Directors; (3) training programs for all employees; (4) a process to receive complaints; (5) a system to respond to allegations of wrongdoing and disciplinary action against employees who violate compliance policies or federal or state law; (6) audits or other methods to monitor compliance; and (7) investigation and remediation of identified systemic problems and policies addressing sanctioned individuals. These same basic elements were set forth in the Compliance Guidance for **Nursing Homes**. *Publication of the OIG Compliance Program for Nursing Facilities*, at 14,289.

n145 *Publication of the OIG Compliance Program for Nursing Facilities* at 14,289.

n146 OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 19 at 4,858 (Jan. 31, 2005), available at www.oig.hhs.gov/fraud/docs/complianceguidance/012705HospSupplementalGuidance.pdf; OIG SUPPLEMENTAL COMPLIANCE PROGRAM GUIDANCE FOR NURSING FACILITIES, at 56,832.

Adopted in 2002 in the aftermath of corporate scandals such as Enron, Worldcom, and Arthur Anderson, the Sarbanes-Oxley Act sought to create more stringent standards for board accountability for financial management. While Sarbanes-Oxley applies only to public **companies**, it carried over into the nonprofit arena, establishing expectations for best practices, although not for legally mandated change. n147 Among other actions, Sarbanes-Oxley required boards to appoint an independent audit committee, include financial expertise on the board, train board members in financial literacy, and oversee the credentials and work of the auditing firm retained by the corporation.

n147 The American Competitiveness and Corporate Accountability Act of 2002, Pub. L. No. 107-204, 116 Stat. 742 (2002). For a detailed discussion of the implications for and impact of Sarbanes-Oxley on nonprofit boards, See Robert T. Harper & Stephanie Schreiber, *Hospital Board of Directors--the Challenges of Being a Hospital Director-Fiduciary Duties, Governance Issues and Board Composition*, 13TH ANN. HEALTH LAW INST. (March 2007); G. Troyer et al., *Governance Issues for Nonprofit Healthcare Organizations and the Implications of the Sarbanes-Oxley Act*, 1 IND. HEALTH L. REV 175 (2004).

Over recent years, the IRS has steadily increased both its focus and standards for board governance of tax-exempt organizations. n148 Central to tax-exempt status is the notion that the organization must serve public and not private purposes. In 2002, the IRS issued final rules prohibiting "excess benefit transactions" for those in a position to influence corporate decisions, including explicit guidance for a process to set executive compensation that would create a rebuttable presumption of reasonableness. n149 In February 2008, noting the strong link between good governance and tax law compliance, the IRS released a detailed memorandum recommending good governance practices for tax exempt organizations. n150 The recommended practices cover significant ground, calling for, among other steps, an explicit statement of mission, a clear framework for governance, independent board members, and written policies on conflicts of interest and protection for whistleblowers. The emphasis on transparency and executive compensation was amplified by the release later in 2008 of the revised 990 tax form for nonprofits, which significantly expanded disclosure of governance practices and executive compensation. n151

n148 IRS rules for tax exemption have broad and complex application to nonprofit entities, with issues such as the requirement to provide community benefit that have particular salience for healthcare facilities. It has been argued that in recent years, the IRS "has become the primary regulator of nonprofit behavior." James Fishman, *Improving Charitable Accountability*, 62 MD. L. REV. 218, 265 (2003). See also Thomas Greaney, *New Governance Norms and Quality of Care in Nonprofit Hospitals*, 14 ANNALS HEALTH L. 421, 426 (2005) ("The IRS has long served as a de facto monitor of corporate governance in the nonprofit sector.").

n149 IRS Code § 4958.

n150 Internal Revenue Service, *Governance and Related Topics--501(c)(3) Organizations* (Feb. 4, 2008) available at http://www.irs.gov/pub/irs-tege/governance_practices.pdf. In addition, the memorandum recommended written policies for fundraising, careful review of financial audits, and written policies on document retention and destruction to prevent improper behavior in the face of a government investigation.

n151 IRS Code § 4958. Executive compensation has been a sustained area of focus for the IRS. In 2007, it released the results of a study of executive compensation by nonprofit entities, indicating significant problems with reporting of the compensation on 990 tax forms. *Report on Exempt Organizations Executive Compensation Compliance Projects Parts I and II* (March 2007), available at http://www.irs.gov/pub/irs-tege/exec_comp_final.pdf. In August 2008, the IRS finalized the new Form 990, which requires, for the first time, reporting on specific board governance practices such as board composition and transparency, in addition to seeking more information about executive compensation. The 2008 Form 990 is available at <http://www.irs.gov/pub/irs-pdf/f990.pdf>.

Drafting a roadmap for boards: the OIG-AHLA Joint Statement and the NQF guide

The most explicit federal guidance about board fiduciary duties on quality issued to date is set forth in a 2004 joint statement issued by OIG and the American Health Lawyers Association (the Joint Statement). n152 Identified as an educational resource for boards, the Joint Statement sets forth proactive best practices by boards. It does not specify grounds for enforcement in terms of poor or prohibited conduct. n153 Nonetheless, the actions recommended in the Joint Statement may inform federal and state prosecutors as they weigh enforcement decisions. The Joint Statement recognizes the heightened focus on quality and concomitant heightened expectations for boards, "[w]ith a new era of focus on quality and patient safety rapidly emerging, oversight of quality also is becoming more clearly recognized as a core fiduciary responsibility of health care organization directors." n154

n152 OIG & AHLA, CORPORATE RESPONSIBILITY AND HEALTH CARE QUALITY: A RESOURCE FOR HEALTH CARE BOARDS OF DIRECTORS (2007), *available at* www.oig.hhs.gov/fraud/docs/complianceguidance/CorporateResponsibilityFinal%209-4-07.pdf. This is the third in a series of joint statements by the two organizations. The earlier two provided guidance to boards on overseeing corporate compliance, and to general counsel on promoting compliance. The OIG & AHLA, CORPORATE RESPONSIBILITY AND CORPORATE COMPLIANCE: A RESOURCE FOR HEALTH CARE BOARDS OF DIRECTORS (2003), *available at* <http://oig.hhs.gov/fraud/docs/complianceguidance/040203CorpRespRsceGuide.pdf>; The OIG & AHLA, AN INTEGRATED APPROACH TO CORPORATE COMPLIANCE: A RESOURCE FOR HEALTH CARE ORGANIZATION BOARDS OF DIRECTORS, (2004), *available at* <http://oig.hhs.gov/fraud/docs/complianceguidance/Tab%204E%20Appendx-Final.pdf>. *See also* *Driving for Quality in Long-Term Care: A Board of Directors Dashboard, Government-Industry Roundtable*, a joint statement by the OIG and the Health Care Compliance Association Roundtable on Long-Term Care Board of Directors' Oversight of Quality of Care, laying out guidance for **nursing home** boards of directors. The advice echoed many of the recommendations in the Joint Statement for hospital boards, noting additional sources of information boards should consider, including resident complaints and family, resident, and staff satisfaction surveys.

n153 The Joint Statement lacks the weight of regulation, an opinion letter, or a formal guidance statement. Referring to the questions delineated to inform board inquiry in overseeing quality, the Joint Statement asserts that the questions raised in the document "are not intended to set forth any specific standards of care...." OIG & AHLA, CORPORATE RESPONSIBILITY AND HEALTH CARE QUALITY: A RESOURCE FOR HEALTH CARE BOARDS OF DIRECTORS at 1 (2007), *available at* www.oig.hhs.gov/fraud/docs/complianceguidance/CorporateResponsibilityFinal%209-4-07.pdf.

n154 *Id.* at 1. The Joint Statement notes that the heightened focus on quality "increasingly impacts the responsibilities of corporate directors." The Joint Statement implicitly recognizes that board oversight of healthcare quality has not been central to the board duties of care and obedience.

At the outset, the Joint Statement summarizes board fiduciary duties for quality, asserting that boards are responsible for overseeing patient safety and healthcare quality. The Joint Statement urges that as attention is increasing on quality of care, boards adjust their practices to be responsive to a changing national environment. n155 In addition, the Joint Statement stresses that quality has emerged as an enforcement priority for federal and state regulators. Accordingly, it advises boards to seek regular reports about compliance risks posed by poor quality, and about the organization's system to minimize and monitor these risks. The Joint Statement points to new financial arrangements at the intersection of quality and compliance that require oversight, including pay-for-performance, gain-sharing, and outcomes management. n156

n155 *Id.* at 4.

n156 *Id.* at 3.

The core of the Joint Statement is a series of questions designed to shape the board's duties in overseeing healthcare quality. The questions guide a board's inquiry into the design and implementation of the organization's program on patient safety and quality, and the means to fulfill the board's oversight obligation. The questions cover the following issues:

1. the goals for quality and the measures to assess those goals;
2. the means to improve patient care and quality, and accountability among key management and clinical staff for process and outcomes;
3. operational policies and practices to support and monitor quality of care;
4. the board's own competence to oversee quality, focusing on board training and expertise;
5. the information essential to the board to oversee quality, and a timetable for reports to the board;
6. coordination between the corporate compliance program and patient safety, and integration of quality concerns into corrective action plans;
7. mechanisms to foster internal reports of quality problems;
8. the allocation of resources for quality improvement and patient safety;
9. the alignment of medical staff credentialing standards and peer review with the organization's quality goals and measures; and
10. the response to adverse events both by the organization and by the board, so that the events are identified, analyzed, and addressed effectively.

In relation to this last goal, the Joint Statement notes the growing body of data that can point to patient safety concerns, including hospital quality data reported to CMS, adverse events reported to many state governments, and peer review reporting conducted in accord with the Health Care Quality Improvement Act. n157

n157 *Id.* at 11. While recognizing that these sources of data are a resource to the board, the Joint Statement cautions boards to seek legal counsel about the confidentiality protection accorded some of the information, and to proceed in a way that does not unnecessarily increase the organization's exposure to liability.

In 2004, the National Quality Forum (NQF) also released a guide for hospital boards of directors on fiduciary duties to oversee quality and patient safety. n158 *Hospital Governing Boards and Quality of Care: A Call to Responsibility* begins with the statement that "board members often express confusion and uncertainty about what exactly they need to do to fulfill their responsibilities" to oversee healthcare quality. n159 The NQF guide urges board engagement in many of the oversight actions proposed by the Joint Statement, with some additional guidance. The guide emphasizes that hospital governing boards must develop "quality literacy," including familiarity with the structures in place to support patient safety, quality improvement, and measurement. It also underscores the board's role in following up on poor performance on quality or safety measures, and the value of incentives for hospital executives to advance high performance.

n158 NAT'L QUALITY FORUM, HOSPITAL GOVERNING BOARDS AND QUALITY OF CARE: A CALL TO RESPONSIBILITY (Dec. 2004), *available at* www.qualityforum.org/pdf/reports/call_to_responsibility.pdf. The recommendations in the document were prepared with input from experts in board fiduciary duties, healthcare measurement and quality, hospital leadership, and consumer organizations.

n159 *Id.* at 1.

The Role of Health Systems on Healthcare Quality

In general, a board of director's statutory obligation to oversee quality and common law fiduciary duties of care and mission are non-delegable. Thus, parent boards of a health system of hospitals, **nursing homes**, and other entities that deliver healthcare services cannot supplant the boards of the facilities in overseeing quality. In some states, parent boards can share this responsibility with the entity board, subject to the express approval of state public health authorities. n160 While health system boards in general do not assume direct responsibility for overseeing quality of care, it is conceivable that they could be held accountable for poor quality if they exercise corporate authority to interfere with the subsidiary entities' efforts to improve quality or address quality-related compliance risks. n161

n160 For example, in New York state, hospitals can delegate or share operating authority with a parent entity if that entity has applied for and received state approval to serve in effect as a co-operator of the facility under Article 28 of the Public Health Law. In this process, proposed certificates of incorporation and bylaws for the parent entity and subsidiary facility must delineate the respective responsibilities for the entities on healthcare quality and other areas of operation.

n161 For example, if the parent entity demanded budget cuts that reduced staffing to a level that created risks to patient safety, or insisted on policies that led to poor care, state public health authorities might seek to hold the entity accountable.

Some health systems have adopted mirror boards for parent and (one or all) subsidiary entities, establishing that the parent and subsidiaries have the same members on the boards of directors. In this governance model, the parent and subsidiary entities do not share responsibility for healthcare quality. The board of the facility, observing corporate formalities of separate meetings, minutes and resolutions, oversees quality at the facility. n162 While this model of corporate governance reduces conflict between entities within the system, streamlines the number of meetings, and centralizes control, it presents serious challenges to a board in fulfilling its duties to oversee matters as complex and demanding as finance, quality, and compliance for numerous entities throughout the health system. n163

n162 In some states, such as New York, the health system board can share responsibility for healthcare quality, subject to the governance documents and state approval. See Edward Kornreich, *Corporate Governance Issues Faced by Orchard Health*, 9 HEALTH LAW J. 20, 22 (2004).

n163 However, as found in a recent study, boards of health systems are more likely than hospital boards to have a separate committee on quality, which could undertake oversight of numerous entities. J. Jiang et al., *Board Engagement in Quality: Findings of a Survey of Hospital and System Leaders*, 53 J. HEALTHCARE MGMT. 121 (2008) [hereinafter Jiang et al., *Board Engagement in Quality*].

Expertise and leadership on quality will vary from institution to institution in any health system. Although health system boards do not have direct responsibility for quality of care, they can play an important role in improving quality by providing expertise, setting benchmarks for performance, and holding the subsidiary boards accountable for high performance on quality. n164 The health system can offer training and protocols to enhance quality, and establish system-wide quality improvement initiatives and goals. Like the subsidiary boards, the health system board can contribute to a culture that values and recognizes high performance on quality.

n164 Many health systems may be doing so, given the preponderance of quality committees at the board health system level. *Id.* The health system's role in quality for subsidiary organizations should be delineated in its mission statement and corporate documents.

Board Engagement on Quality: What the Data Show

Several recent studies provide insight into the level of board involvement, specific activities boards undertake, and the attributes of board activity associated with higher-performing hospitals. n165 Overall, the data show a high level of board involvement in terms of review of quality measures and setting goals on quality, with more equivocal findings on board effectiveness as evaluated by chief executive officers.

n165 *Id.*; T. Vaughn et al., *Engagement of Leadership in Quality Improvement Initiatives: Executive Quality Improvement Survey Results*, 2 PATIENT SATISFACTION 2 (2006) [hereinafter Vaughn et al., *Engagement of Leadership in Quality Improvement Initiatives*]; E. Kroch et al., *Hospital Boards and Quality Dashboards*, 2 PATIENT SAFETY 10 (2006) [hereinafter Kroch et al., *Hospital Boards and Quality Dashboards*].

Board time devoted to quality varies widely, ranging from less than five percent to more than twenty-five percent. n166 Most hospital and health system boards use quality dashboards to review quality performance, and most dashboards include the CMS Quality Compare Measures. There is wide variation, however, in how boards and institution-based leaders use the dashboards. n167 Health system boards are more likely than hospital boards to use quality dashboards, to incorporate national benchmarks in those dashboards, and to have a committee of the board devoted to quality. n168

n166 Vaughn et al., *Engagement of Leadership in Quality Improvement Initiatives*, at 3.

n167 The study of 139 hospitals by Kroch et al. found that 87% of hospitals used a dashboard on quality; the study of 562 hospitals and health systems by Jiang et al. found a virtually identical percent, 86.7.

n168 Jiang et al., *Board Engagement in Quality*, at 129. 86% of health system boards have a committee of the board devoted to quality vs. 58% of hospital boards.

Hospitals or health systems where boards use dashboards with fewer measures and review them more frequently perform better in terms of quality of care. n169 Board use of the dashboards for two years or longer is also associated with higher hospital performance on quality. In addition, the involvement of a board quality committee in developing the content of the quality dashboard is associated with a significant difference in quality outcomes. n170 One study examined the association between the existence of a board committee devoted to quality of care and other markers of board engagement on quality, concluding that boards with a quality committee performed significantly better on all measures of engagement; the boards were more likely to:

- . use quality dashboards (91% versus 79%);
- . set strategic goals for quality (89.5% versus 68.2%);
- . set the agenda for the board discussion on quality (48.8% versus 32.6%);
- . include measures of quality and patient safety in executive performance evaluation (61% versus 45%); and
- . issue a written policy on quality communicated throughout the organization (34% versus 26%).

n171

n169 Kroch et al., *Hospital Boards and Quality Dashboards*, at 18.

n170 As stated by the study authors, "Perhaps the most important finding of this study is that hospitals in which the board quality committees are strongly involved with the development of the dashboard content had significantly higher performance...." *Id.* at 16.

n171 Jiang et al., *Board Engagement in Quality*, at 129.

Larger hospitals and those in the northeast were more likely than smaller hospitals to have board quality committees. n172

n172 *Id.* at 129.

Another study that examined different potential correlates between quality outcomes and quality leadership found that the following four factors were associated with better outcomes:

1. facilities with boards that spend more than twenty-five percent of board meeting time on quality;
2. a high level of interaction between board members and medical staff leaders in setting the hospital's quality agenda;
3. identification of the CEO or COO by hospital leaders as the person with the "greatest impact" on quality; and
4. compensation of senior executives based in part on quality improvement performance. n173

n173 Vaughn et al., *Engagement of Leadership in Quality Improvement Initiatives*, at 6.

Interestingly, the same study found a sharp difference in perception between CEOs and chief medical officers (CMO)/quality improvement (QI) executives about the most significant change that could improve quality. CEOs were more likely to cite physician engagement as the change factor. CMOs and QI executives ranked health information technology as more significant. n174 In the one study that asked CEOs about board performance on quality, less than half the CEOs rated the board's performance highly. n175

n174 *Id.* at 5.

n175 The CEOs were asked to rate board performance on a scale of 1 to 6, with less than half the boards receiving a score of 5 or 6. Jiang et al., *Board Engagement in Quality*, at 125.

Where Do Boards Go From Here?

Devised as a platform for improvement and pay-for-performance, scientific advances in quality measurement and reporting have changed both the tools and expectations for board oversight of healthcare quality. A passive role for the board in reviewing credentialing decisions has been replaced by an emerging paradigm of a board that is better informed, better able to lead, and more accountable for quality of care. Significantly, recent studies of board engagement on quality all suggest that many hospital boards are actively undertaking quality oversight. n176

n176 See Kroch et al., *Hospital Boards and Quality Dashboards*; Jiang et al., *Board Engagement in Quality*; Vaughn et al., *Engagement of Leadership in Quality Improvement Initiatives*.

As set forth in the roadmap laid out by the joint OIG-AHHA statement on board fiduciary duties, boards should undertake an array of tasks ranging from regular review of quality measures, training to understand the metrics for quality, creation of goals, and evaluation of resources and staff assigned to quality of care. In the traditional governance model, board members often were recruited primarily for their financial expertise and capacity to donate or raise funds.

In the face of far more data and rising expectations for board oversight of quality, it is critical that boards evaluate their membership to determine if they have the expertise and passion for quality to drive board engagement and leadership. As suggested by the study by Kroch et al., boards that have a quality committee perform better on all measures of engagement and leadership. n177

n177 Kroch et al., *Hospital Boards and Quality Dashboards*.

Boards should understand the measures used across all three dimensions of quality and require a strategic plan for how the institution will improve performance in each area, including accountability for improvement among administrative and medical leadership. Boards also should set priorities for patient safety and quality, in consultation with executive and medical staff leadership. Public quality measures provide key information for boards and must be part of an overall strategy for quality measurement and improvement. Boards should rely upon serious adverse or never events and near misses, as well as assessment of quality concerns by the medical and nursing leadership, to identify other areas for improvement. Priorities also should establish priorities or maintain practice areas of excellence key to the institution's reputation and brand.

Boards will need to evaluate where their institution stands on quality in a comparative sense, i.e., compared to the peer group for their institution in terms of academic or community hospital, size, and/or region. Boards should ask management for dashboards on quality that present the information in an actionable, concise form, and should be engaged in determining which measures are provided in the quality dashboard. For serious adverse events, boards should take an active role in seeking a corrective action plan and monitoring by appropriate staff to prevent further similar incidents.

Finally, boards should seek data to evaluate risks and seek needed improvement at the intersection of quality and compliance. With CMS undertaking datamining to pursue and target investigations for poor quality, boards should seek information that can be generated from financial and care delivery databases to flag quality of care deficiencies that would trigger enforcement. To undertake the task, the board should seek a coordinated approach from leadership in quality and compliance.

Recommendations for Government Oversight

Comparative quality measures and public reporting give government new information and tools to oversee quality. While most states have relied on periodic Joint Commission surveys and self-reporting of serious adverse events to drive investigation of serious quality concerns, states can now use quality measures to identify facilities that might have serious deficiencies in care. Measures of quality for medical treatment and certain measures of patient satisfaction (such as those that focus on adequate treatment for pain and acknowledgement of a patient's treatment choices) should be reviewed by government to determine if patient care is so deficient that it places patients at risk. State governments and the Joint Commission should reevaluate the timing and nature of surveys in light of available quality data, giving consideration to more targeted assessments that focus on either poorly performing institutions or areas of care delivery where the data indicate poor care. n178

n178 See Donald M. Berwick & Troyen A. Brennan, *New Rules: Regulation, Markets, and the Quality of American Health Care* 369 (1995).

At the state level, attorneys general have the most direct oversight responsibility to oversee board performance in fulfilling their fiduciary duties of care, loyalty, and mission. Unquestionably, quality is core to mission for healthcare institutions, and a state attorney general could choose to reprimand or even replace a board of directors in an institution with severe, persistent quality problems that place patients at risk. At the same time, attorneys general are not familiar with quality of care metrics or delivery, which fall under the oversight of state health departments and CMS as payors

and regulators of quality. For this reason, oversight of board performance on quality should rest with the agencies most able to carry out the responsibility.

The government's approach to evaluation of board leadership should follow a pattern similar to compliance; demonstration that the board has focused on quality to provide leadership should be exculpatory or reduce the size of any penalty, while board failure to address serious, persistent problems should be taken into account. The connection between leadership, quality, and culture is well recognized, and boards should be held accountable for serious quality problems if data available to the board suggest that the problem has persisted over time without attempts to improve.

Conclusion

Legal doctrines enunciating board fiduciary duties, as well as state statutes vesting ultimate oversight of the quality of care in the board of directors, had little impact on the board's role in improving patient safety and quality throughout the twentieth century. As reflected in the landmark report, *To Err is Human*, as well as in studies that preceded and followed it, serious medical errors leading to patient death or injury routinely occurred in healthcare facilities. The legal doctrine recognizing hospital responsibility for quality of care first handed down in *Darling v. Charleston* in 1965, and the rising tide of malpractice litigation that followed, did remarkably little to change the structure and nature of leadership on quality within healthcare institutions. Boards provided final approval for credentialing decisions, but mostly deferred to the organized medical staff as the locus of control and oversight of quality. n179

n179 John D. Blum, *Feng Shui and the Restructuring of the Hospital Corporation: A Call for Change in the Face of the Medical Error Epidemic*, 14 HEALTH-MATRIX: J. L.-MED. 5 (2004); Thomas Greaney, *New Governance Norms and Quality of Care in Nonprofit Hospitals*, 14 ANNALS HEALTH L. 421, 422 (2005); Brian M. Peters & Jonathan Z. Cohen, *Board Quality Oversight: A "Real World" Systemic Compliance Model*, 14TH ANNUAL HEALTH LAW INST. (Mar. 2008).

Until recently, systemic barriers impeded quality improvement, including the independence of the medical staff, the lack of reliable, comparative measures of quality, the lack of transparency in quality, and, most significantly, the absence of a business case for quality, with healthcare financial incentives misaligned to reward quality improvement. In many respects, public and private payors, frustrated by the lack of national and institutional progress on quality, have driven the quality agenda.

Medical staff control over quality rested in part on physicians' exclusive access to information about the quality of care. With the movement toward publicly reported measures, healthcare boards of directors are no longer dependent on the medical staff for information about performance across all three dimensions of quality: patient safety, quality improvement, and patient satisfaction. The expanding use of information systems, including the electronic medical record and bar coding that generate significant databases on quality under administrative control, add to institutional capacity to develop quality reports and increase board access to information.

Courts have not held healthcare boards to a duty to investigate to identify quality of care problems, recognizing that board members could rely on the CEO and other senior officers to bring problems to their attention, including poor quality of care. Once notified of a concern, however, boards are obligated to undertake an inquiry, inform themselves about the problem, and seek corrective action. n180 It can be assumed that boards have notice of problems revealed in publicly reported quality measures or publicly reported patient safety errors. Where quality scores fall well below performance measures for institutions comparable in size, patient mix, and region, boards should assume that the fiduciary duty to ask questions, seek an explanation, and demand solutions has been triggered.

n180 *Graham v. Allis-Chalmers*, 188 A.2d 125 (Del. 1963); *Stern v. Lucy Webb Hayes Nat'l Training School.*, 381 F. Supp. 1003 (D. D.C. 1974); *In re Caremark Int'l. Inc. Deriv. Litig.*, 698 A.2d 959 (Del. Ch. 1996).

While quality always has been core to healthcare facilities' mission, financial incentives from public and private

payors, transparency, and potentially large financial penalties tied to compliance sanctions for poor quality have changed the stakes for boards and their institutions. Although facilities previously may have given quality of care initiatives lower priority in the face of financial challenges and difficult choices about investment of limited capital, pay-for-performance will make quality integral to financial goals and revenue.

In the past, serious adverse events, when splashed across the headlines, had the potential to affect reputation on quality but were relatively rare and, absent specific warning signs, unanticipated by the board. In general, consumers continued to rely on word of mouth rather than quality data to select hospitals. n181 However, years of experiments and experience by business coalitions and national quality organizations seeking to make quality measures salient and actionable by the public may bear fruit. As suggested by one recent study, public measures combined with public reporting that provides a summary score or recommendation may influence both reputation and consumer choice of hospital. n182 Reputation may now be tied to quality measures in a tangible way, with explicit data that can prompt board inquiry and action to protect and promote the institution's reputation.

n181 Judith H. Hibbard & Jacquelyn J. Jewett, *Will Quality Report Cards Help Consumers?*, 16 HEALTH AFF. 218 (1997); Charles N. Kahn et al., *Snapshot of Hospital Quality Reporting and Pay-For-Performance Under Medicare*, 25 HEALTH AFF. 148 (2006).

n182 Judith H. Hibbard et al., *It Isn't Just about Choice: The Potential of a Public Performance Report to Affect the Public Image of Hospitals*, 62 MED. CARE RES. & REV. 358 (2005). The study by Hibbard et al., suggests that consumers will use quality information for choice if the information: (1) clearly identifies high and poor performers; (2) is concise; and (3) is widely disseminated.

Finally, heightened government enforcement of poor quality, combined with financial incentives for compliance recoveries under the Deficit Reduction Act, create another powerful incentive for boards to focus on patient safety. Federal and state enforcement has not only raised the financial costs of poor compliance, but increased expectations for board oversight, with direct implications for board duties on quality: enhanced board expertise and literacy, better reporting systems to identify problems, and increased accountability of senior management for outcomes. At the same time, OIG compliance guidance and Department of Justice Sentencing Guidelines make clear that board performance in overseeing quality can have a direct impact on the price paid by institutions--in prosecutors' decisions about violations and penalties. n183

n183 *Publication of the OIG Compliance Program for Nursing Facilities*, at 14,289 (listing grounds of poor quality that could lead to enforcement actions); Paul McNulty, Deputy Attorney Gen., U.S. Dep't of Justice. *Principles of Federal Prosecution of Business Organizations* (Dec. 12, 2006), available at www.usdoj.gov/dag/speeches/2006/mcnulty_memo.pdf.

It has long been a truism that the board of directors has the ultimate responsibility for the quality of care. The absence of reportable quality measures, immature information systems, and the independence of medical staffs meant that the truism often was devoid of content. Transparency in quality, comparative measures, and the rising stakes for healthcare quality have given boards powerful new incentives and new tools to lead on quality.

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TITLE: Articles: American Health Lawyers Association: The Year in Review 2002-2003

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TEXT:

ABSTRACT: Every year, the Practice Groups of the American Health Lawyers Association assemble a Year in Review summary of the leading developments in case law, legislation, and administrative actions affecting healthcare. This Article provides a comprehensive overview of these developments. The introduction presents a "Top Ten" list of the year's most noteworthy developments. The remainder of the Article is divided into fourteen topical areas, and offers a brief overview of issues in those areas. Overall, these various developments demonstrate society's efforts to balance accountability, efficiency, and affordability in the delivery of healthcare.

Every year, the Practice Groups of the American Health Lawyers Association (Health Lawyers) assemble a Year in Review summary of the leading developments in case law, legislation, and administrative actions affecting healthcare. This year's highlights include a rich variety of new and intriguing issues that will affect health law practitioners, providers, and others for years to come. This Article is the result of a joint effort of the Health Lawyers Practice Groups, and presents a brief analysis of these materials in each of fourteen topical areas. This Article is truly a collaborative effort, and is attributable to the hard work of the many individuals in each of the Practice Groups whose expertise in their respective areas makes this an important annual event for the association. n1

n1 The following Health Lawyers members read and summarized case-law and policy developments used in this Article and the full text of the Year in Review: John J. (Jeff) Miles; Sherry A. Fabina-Abney; Carl P. Bowman; Elizabeth (Beth) A. Christian; William M. Freedman; Margaret W. Galvin; R. Kenneth Gordon; Tina Batra Hershey; William H. Maruca; Albert W. Shay; Victoria (Tory) A. B. Willis; Richard Marks; Edward F. Shay; Melissa K. Waugh; Paul W. Ambrosius; Christina Bahr; Megan Flaskamper; Paul J. Giancola; Joanne (Jody) E. Joiner; Allyn Langford; Michael S. Lehv; Doug Neville; Kevin D. Gordon; Lisa A. Hathaway; Margit H. Nahra; Cynthia F. Reaves; Stuart I. Silverman; Eric Galen; James Franklin Owens; Gregory M. Duckett; William W. Horton; Michael L. Silhol; Cynthia F. Wisner; Katherine Benesch; Barry A. Guryan; Michael J. Jordan; Scotty Shively; Karen L. Goldsmith; James F. Miles; Christopher C. Puri; Victoria Jalo; Charlene L. McGinty; Jolee Hancock Bollinger; Bernard K. Ham; Kimberly Loden; Dineta Newman; Lester J. Perling; Eric P. Zimmerman; Douglas K. Anning; Lisa J. Gilden; Gerald M. Griffith; Linda Sauser Moroney; and Jan E. Murray. Lisa Cohen, Eileen Bantel, and Laurie Garvey of Health Lawyers' staff also contributed to the text and production of this Article. The full text of the Year in Review is online at www.healthlawyers.org/yearinreview/.

The Article begins with a "Top Ten" list of some of the year's most noteworthy developments. This obviously subjective collection has been culled from a much larger universe of cases and administrative and legislative events that occurred during the past year. It is the author's belief, however, that it fairly represents the range of significant new issues facing Health Lawyers members.

I. The Top Ten (In No Particular Order)

1. HIPAA. On August 14, 2002, the Centers for Medicare and Medicaid Services (CMS) issued its final modifications to the "Standards for Privacy of Individually Identifiable Health Information (final Privacy Rule)," under the Health Insurance Portability and Accountability Act (HIPAA).ⁿ² The provider community reacted to the modifications in the final Privacy Rule with relief, while advocates for patients expressed some consternation.ⁿ³ The rule became effective on April 14, 2003, and the provider community is still struggling with the myriad issues and expenses of compliance. The costs and details of implementing the Privacy Rule have had an enormous impact on health law, health lawyers, and, most importantly, the provision of healthcare throughout the country.

ⁿ² Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 53,181 (Aug. 14, 2002).

ⁿ³ See *'Minimum Necessary' Standard Retains Rule's Bite, Proponents of Changes Say*, HEALTH CARE DAILY REP. (BNA) NO. 7, Aug. 13, 2002, at 156.

2. Malpractice. Healthcare providers and professionals have responded aggressively to the skyrocketing cost of malpractice insurance in many states.ⁿ⁴ The Department of Health and Human Services (DHHS) released a report arguing that a litigious society, the lack of tort reform in certain states, and growing jury awards were major contributors to this spike in malpractice rates. DHHS supports tort reform, including a reasonable cap on noneconomic damages, as an essential means to bring costs down.ⁿ⁵ Advocates for injured patients debate these conclusions, blaming the spike in rates on mismanaged investments.ⁿ⁶ The Bush administration is seeking federal legislative relief, supported by associations for physicians and hospitals.ⁿ⁷ The American Medical Association (AMA) released a study in March indicating that eighteen states are in a malpractice insurance "crisis."ⁿ⁸ States in which premiums are skyrocketing are passing legislation of their own.ⁿ⁹ The malpractice crisis has galvanized the healthcare community, and has had a significant impact on the lives of providers, professionals, and their counsel over the last twelve months.

ⁿ⁴ See U.S. DEPT OF HEALTH & HUMAN SERVS., CONFRONTING THE NEW HEALTH CARE CRISIS: IMPROVING HEALTH CARE QUALITY AND LOWERING COSTS BY FIXING OUR MEDICAL LIABILITY SYSTEM (July 25, 2002) (states without "tort reform" experiencing largest increases in malpractice insurance premiums), *available at* aspe.os.dhhs.gov/daltcp/reports/litrefm.pdf.

ⁿ⁵ See *id.*

ⁿ⁶ *Study Blames Rising Malpractice Rates On Mismanagement, Not Bigger Jury Awards*, HEALTH CARE DAILY REP. (BNA) NO. 7, Oct. 11, 2002, at 198 (payouts have tracked inflation; premium rates have not tracked payouts).

ⁿ⁷ See U.S. DEPT OF HEALTH & HUMAN SERVS., *supra* note 4; Help Efficient, Accessible, Low Cost, Timely Health Care Act of 2003, H.R. 5, 108th Cong. (2003).

ⁿ⁸ See Press Release, Am. Med. Ass'n, 18 States Now in Full-Blown Medical Liability Crisis (Mar. 3, 2003), *at* www.ama-assn.org/ama/pub/article/1616-7340.html (last visited July 14, 2003).

ⁿ⁹ See Medical Care Availability and Reduction of Error (MCARE) Act, 2002 Pa. Laws 13 (codified at PA. STAT. ANN. tit. 40, §§ 1303.101-1303.910); H.R. 92, 57th Leg. Reg. Sess. (Idaho 2003); G.A. 281, 124th Gen. Assem. Reg. Sess. (Ohio 2003).

3. Specialty Hospitals. While community hospitals worry about their malpractice premiums, they are also worrying about competition from specialty hospitals owned in whole or in part by physicians. The General Accounting Office recently completed a study for members of Congress in which it concluded that specialty hospitals are growing rapidly,

and that seventy percent of specialty hospitals are owned in part by physicians. n10 Over the next twelve months, observers can expect continued debates between community hospitals and specialty hospitals regarding efficiencies, risk selection, and referrals.

n10 U.S. GEN. ACCOUNTING OFFICE, SPECIALTY HOSPITALS: INFORMATION ON NATIONAL MARKET SHARE, PHYSICIAN OWNERSHIP, AND PATIENTS SERVED, GAO-03-683R, at 3 (2003).

4. ERISA. Health plans continue to face both liability suits from injured patients and civil suits from professionals who chafe at perceived restrictions on their practice. In adjudicating these suits, the Supreme Court and circuit courts struggle to bring clarity to the complexities of the Employee Retirement Income Security Act (ERISA) preemption clause. This term, the Supreme Court made a fundamental change in the analysis used to determine whether a state law "regulates insurance" by rejecting use of the traditional test drawn from cases interpreting the McCarran-Ferguson Act. n11 These cases are unlikely to subside, and courts will continue to try to bring some rationality to the distinction between laws that regulate healthcare delivery and laws that regulate insurance.

n11 Ky. Ass'n of Health Plans v. Miller, 123 S. Ct. 1471, 1478-79 (2003) (to "regulate insurance," state law must: 1. Be specifically directed toward entities engaged in insurance; 2. Substantially affect the risk pooling arrangement between the insurer and the insured).

5. Outliers. In November of 2002, DHHS began an audit of Tenet Healthcare Corporation's outlier payments. n12 The Justice Department initiated its own probe in January of 2003. n13 In March of 2003, CMS issued proposed regulations modifying certain aspects of the methodology for determining Medicare outlier payments. n14 This almost familiar pattern of audit, investigation, and rule modification makes the outlier payment issue of extreme significance to health lawyers and their clients. The outlier issue obviously has the attention of those enforcing our nation's fraud and abuse laws, and for that reason alone, it is one of the most significant developments of the last twelve months.

n12 HHS to Audit Tenet's Outlier Payments; *Company Plans Investor Conference Call*, HEALTH CARE DAILY REP. (BNA) NO. 7, Nov. 7, 2002, at 216.

n13 DOJ Launches Probe into Tenet Outliers; Doctor Asks CMS to Freeze Some Payments, HEALTH CARE DAILY REP. (BNA) NO. 8, Jan. 6, 2003, at 3.

n14 Medicare Program; Proposed Change in Methodology for Determining Payment for Extraordinarily High-Cost Cases (Cost Outliers) Under the Acute Care Hospital Inpatient Prospective Payment System, 68 Fed. Reg. 10,420 (Mar. 5, 2003), cited in Elizabeth Weeks, *CMS Proposes New Medicare Outlier Policy; Still No Regulation of Charges*, 6 THE RAP SHEET 1, 1 (Health Lawyers 2003).

6. Sarbanes-Oxley. On July 30, 2002, the Sarbanes-Oxley Act became law. n15 The law's purpose, as expressed in the Report of the House Committee on Financial Services, is to protect investors by improving the accuracy and reliability of corporate disclosures made pursuant to the securities laws. n16 The law attempts to achieve this goal "through increased supervision of accountants that audit public **companies**, strengthened corporate responsibility, increased transparency of corporate financial statements, and protections for employee access to retirement accounts." n17 After the collapse of Enron, Congress, state legislators, and enforcement agencies began focusing on the responsibility of boards to carry out their fiduciary duties effectively. Although the scrutiny of public healthcare **companies** like HealthSouth has been intense, boards of nonprofit entities also need to focus on the effective implementation of their fiduciary responsibilities. n18

n15 Corporate and Auditing Accountability, Responsibility, and Transparency Act of 2002, Pub. L. No. 107-204, 116 Stat. 745 (July

30, 2002).

n16 H.R. REP. NO. 107-414 (2002).

n17 *Id.*

n18 See OFFICE OF THE INSPECTOR GENERAL OF THE U.S. DEPT OF HEALTH AND HUMAN SERVS. & THE AM. HEALTH LAWYERS ASS'N., CORPORATE RESPONSIBILITY AND CORPORATE COMPLIANCE: A RESOURCE FOR HEALTH CARE BOARDS OF DIRECTORS (2003).

7. Patient Safety. This year, patients, providers, plans, payors, accreditors, and legislators have focused intently on **protecting** the safety of patients. Effective January 1, 2003, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) approved for implementation a set of six National Patient Safety goals. n19 On January 24, 2003, CMS published a new rule directing hospitals to develop a quality assessment and performance improvement (QAPI) program, to help identify patient safety issues and reduce medical errors. n20 On March 12, 2003, the House of Representatives passed the Patient Safety and Quality Improvement Act in an effort to encourage the reporting and study of information related to adverse events. n21 Clearly, this issue will be on the minds of health lawyers and their clients for years to come.

n19 Joint Comm'n on Accreditation of Healthcare Organizations, 2003 National Patient Safety Goals, at www.jcaho.org/accredited+organizations/patient+safety/npsg/npsg_03.htm (last visited July 14, 2003).

n20 Medicare and Medicaid Programs; Hospital Conditions of Participation: Quality Assessment and Performance Improvement, 68 Fed. Reg. 3435, 3435 (Jan. 24, 2003).

n21 Patient Safety and Quality Improvement Act, H.R. 663, 108th Cong. (2003).

8. State Budget Shortfalls. States have struggled mightily over the last twelve months to balance their budgets. As the economy has slowed and tax revenues have decreased, states have looked to one of the largest items in their budgets-- Medicaid--to help make up the difference. The Kaiser Commission on Medicaid and the Uninsured reports that almost all states have cut back or plan to cut back on Medicaid in FY 2003. n22 Common actions taken by states include prescription drug controls, provider rate reductions, eligibility restrictions, and copayment increases. n23

n22 See KAISER COMM'N ON MEDICAID AND THE UNISURED, THE STATE FISCAL CRISIS AND MEDICAID: WILL HEALTH PLANS BE MAJOR BUDGET TARGETS? 13-17 (Jan. 2003), available at www.kff.org/content/2003/20030113/4074.pdf (last visited July 14, 2003).

n23 See *id.*

9. Physician Payment. Physicians lobbied CMS and their congressional representatives hard to adjust the conversion factor used to compute their reimbursement rates under Medicare. On February 13, 2003, Congress enacted the Consolidated Appropriations Resolution of 2003. n24 In that legislation, Congress permitted CMS to revise the physician conversion factor because of alleged errors made by CMS in 1998 and 1999. Due to this revision, the physicians covered by the change will receive an average 1.6% increase in Medicare reimbursement rates for the remainder of the year, rather than the average 4.4% decrease that would have impacted them had no legislation been passed. n25

n24 Joint Resolution Making Consolidated Appropriations for the Fiscal Year Ending September 30, 2003, Pub. L. No. 108-7, 117 Stat. 11 (Feb. 20, 2003).

n25 See Medicare Program; Physician Fee Schedule Update for Calendar Year 2003, 68 Fed Reg. 9567 (Feb. 28, 2003).

10. Joint Ventures. On April 23, 2003, the Office of Inspector General of the Department of Health and Human Services (OIG) issued guidance on unlawful joint-venture arrangements that fall afoul of the federal Anti-Kickback Statute. n26 Transactional health lawyers found the issuance of this guidance extremely important to their practices. The guidance targets certain complex transactions that use "shell" entities and subcontract with freestanding providers of related health services as violative of the Anti-Kickback Statute. n27

n26 News Release, Office of the Inspector General of the U.S. Dep't. of Health and Human Servs., Advisory Bulletin Targets Suspect Contractual Joint Ventures (Apr. 23, 2003), at oig.hhs.gov/publications/docs/press/2003/042303release.pdf (last visited July 14, 2003).

n27 *Id.*

II. Practice Group Developments

A. Antitrust

In the past year, the Federal Trade Commission (FTC) focused resources on combating anticompetitive conduct in the pharmaceutical and physician sectors. The FTC also formed a "merger litigation task force" to study the anticompetitive effects of past hospital mergers. n28 In general, the Bush administration has not allowed previous defeats in challenging hospital mergers to dampen its enthusiasm for a robust healthcare antitrust enforcement effort.

n28 Press Release, Federal Trade Commission, Federal Trade Commission Announces Formation of Merger Litigation Task Force (Aug. 28, 2002), at www.ftc.gov/opa/2002/08/mergerlitigation.htm (last visited July 14, 2003). See *An Overview of The FTC's Antitrust Enforcement Activities, Hearing Before the Senate Comm. on the Judiciary*, 107th Cong. (2002) (statement by Timothy J. Muris, Chairman, Fed. Trade Comm'n), at www.ftc.gov/os/2002/09/020919overviewtestimony.htm (last visited July 14, 2003).

In June 2002, the FTC entered into a consent decree with Biovail Corporation and Elan Corporation, two manufacturers of generic drugs used to treat hypertension. The consent order required the respondents to terminate an agreement that effectively reduced competition between them and not to enter into similar agreements in the future. n29

n29 In the Matter of Biovail Corp., and Elan Corp., PLC, F.T.C. File No. 011-0132, 4 (2002) (consent order), at www.ftc.gov/os/2002/06/biovailelanagreement.pdf (last visited July 14, 2003).

On March 7, 2003, the FTC settled allegations against Bristol-Myers Squibb with a proposed consent decree. The complaint alleged that Bristol-Myers prevented the entry of generic drugs that would compete against several of its own drugs by abusing the Food and Drug Administration's (FDA) Orange Book n30 procedure. n31 The consent decree prohibited Bristol-Myers from providing improper Orange Book listings, and from paying generic manufacturers to delay the introduction of their competitive drugs. n32 While the FTC negotiated settlements in each of these cases, it did not win on all of its efforts to promote the introduction of generic competition. n33

n30 The Orange Book, also known as *Approved Drug Products with Therapeutic Equivalence Evaluations*, identifies drug products approved on the basis of safety and effectiveness by the FDA under the federal Food, Drug, and Cosmetic Act. An electronic version is available at fda.gov/cder/ob/default.htm (last visited July 14, 2003).

n31 See *In the Matter of Bristol-Myers Squibb Co.*, F.T.C. File Nos. 0010221, 0110046, 0210181, 1 (2003) (complaint), at www.ftc.gov/os/2003/03/bristolmyerscmp.pdf (last visited July 14, 2003).

n32 *In the Matter of Bristol-Myers Squibb Co.*, F.T.C. File Nos. 0010221, 0110046, 0210181 (2003) (consent order), at www.ftc.gov/os/2003/03/bristolmyersconsent.pdf (last visited July 14, 2003).

n33 See *Schering-Plough Corp.*, Dkt. No. 9297 (FTC Jul. 2, 2002) (initial decision) (ALJ found against FTC on allegation that Schering-Plough paid Upsher-Smith to delay it from entering market with competing generic drug), at www.ftc.gov/os/2002/07/scheringinitialdecisionp1.pdf (last visited July 14, 2003).

With respect to the physician marketplace, the FTC focused on distinguishing between permissible "messenger model" arrangements and illegal price fixing efforts. n34

n34 See Jeff Miles, *Ticking Antitrust Time Bombs: A Message to Messed Up Messenger Models*, 6 HEALTH LAWYERS NEWS 4, 5 (Nov. 2002).

On July 19, 2002, the FTC entered into final consent orders with two networks of Denver physicians accused of price fixing. n35 On October 11, 2002, the FTC entered into a consent order with eight Denver-area OB-GYN groups and their consultant to settle allegations that the respondents engaged in price-fixing agreements in violation of antitrust laws. n36 In both cases, the FTC distinguished between impermissible price fixing and permissible "qualified risk-sharing" and "qualified clinically integrated" joint arrangements.

n35 *In the Matter of Physicians Integrated Servs., Inc.*, F.T.C. Dkt. No. C-4054 (2002) (decision and order), at www.ftc.gov/os/2002/07/pisddo.pdf (last visited July 14, 2003); *In the Matter of Aurora Associated Primary Care Physicians, LLC*, F.T.C. Dkt. No. C-4055 (2002) (decision and order), at www.ftc.gov/os/2002/07/aurorado.pdf (last visited July 14, 2003).

n36 *In the Matter of R.T. Welter & Associates, Inc.*, F.T.C. Dkt. No. C-4063 (2002) (decision and order), at www.ftc.gov/os/2002/10/piwcd.pdf (last visited July 14, 2003).

On May 2, 2003, the FTC entered into a proposed consent order with the Carlsbad (NM) Physicians Association, its executive director, and several of its board and contract committee members. n37 The FTC's complaint alleged that the physicians association, in collectively negotiating contracts for its members, engaged in unlawful price fixing. n38 All three of the FTC actions were targeted at groups of physicians seeking negotiating leverage with health plans.

n37 *Carlsbad Physicians Ass'n*, F.T.C. File No. 031-0002 (2003) (decision and order), at www.ftc.gov/os/2003/05/carlsbaddo.pdf (last visited July 14, 2003).

n38 See *Carlsbad Physicians Ass'n*, F.T.C. File No. 031-0002, 1-2 (2003) (complaint), at www.ftc.gov/os/2003/05/carlsbadcmp.pdf (last visited July 14, 2003).

In a similar case in Delaware, the district court entered a consent decree prohibiting the Federation of Physicians and Dentists, a physicians union, from serving as the negotiating agent for its member physicians. The FTC Antitrust Division rejected the federation's contention that it was simply acting as a messenger for orthopedic surgeons in Delaware, and instead argued that it was the hub of a conspiracy to restrain trade with Blue Cross and Blue Shield of Delaware. The decree prohibits the federation from engaging in a number of activities related to collective negotiations with payors. n39

n39 See *United States v. Fed'n of Physicians & Dentists*, 2002 WL 31961452, *3-*4 (D. Del. Nov 5, 2002) (consent decree and competitive impact statement).

B. Credentialing and Peer Review

Over the past twelve months, courts continued to define the contours of § 1983 actions. They did not look favorably upon public entities' attempts to avoid liability. The Tenth Circuit rejected a public hospital's effort to cloak its peer-review activity in absolute immunity. n40 The Ninth Circuit permitted several First and Fourteenth Amendment claims by a physician against a public hospital and the City and County of San Francisco to survive a summary-judgment motion. n41

n40 See *Moore v. Gunnison Valley Hosp.*, 310 F.3d 1315, 1320 (10th Cir. 2002) (statute expressing state legislature's intent that committees act as extension of state medical board was insufficient to clothe committees in same absolute immunity provided state medical board in federal § 1983 actions).

n41 See *Ulrich v. City of San Francisco*, 308 F.3d 968, 986 (9th Cir. 2002) (genuine issues of material fact as to whether chair of peer review committee at city hospital had been delegated final policymaking authority over decisions affecting physician's rights, or whether those decisions were ratified by officials, precluded summary judgment on physician's claim of retaliation against physician in violation of First and Fourteenth Amendment due process claim).

The Tenth Circuit refused to expand the scope of "state action" when it rejected the argument that compliance with a state's risk-management statute converts a privately owned healthcare organization into a public entity. n42

n42 See *Conner v. Salina Reg'l Health Ctr., Inc.*, 2003 WL 295545, *5-*6 (10th Cir. 2003).

Courts also explored the breadth of the peer-review privilege. The Missouri Court of Appeals reaffirmed that when state law is silent on waiver of the privilege, general principles of waiver will apply. The court found that defendants are not permitted to make information protected by the privilege an issue, using the privilege as a "sword," and then expect the privilege to serve as a "shield" to protect that same information. n43

n43 See *Mo. ex rel. St. John's Reg'l Med. Ctr. v. Dally*, 90 S.W.3d 209, 215 (Mo. Ct. App. 2002).

Healthcare professionals continued to battle with providers and plans over the protection granted to hospitals and other providers under the Health Care Quality Improvement Act (HCQIA). n44 A Tennessee appellate court rejected a physician's claim that an allegation of retaliatory discharge should overcome a hospital's presumptive immunity from damages for quality improvement activity under the HCQIA. n45 The First Circuit refused to deny a health plan HCQIA immunity for decisions in furtherance of healthcare quality when a physician argued that the actions were actually designed to punish his alleged inefficiency. n46

n44 Health Care Quality Improvement Act of 1986, 42 U.S.C. §§ 11101-11152 (2003).

n45 See *Peyton v. Johnson City Med. Ctr.*, 101 S.W.3d 76, 88 (Tenn. Ct. App. 2002).

n46 See *Singh v. Blue Cross/Blue Shield of Mass.*, 308 F.3d 25, 48 (1st Cir. 2002).

With patient safety and instances of medical errors making headlines throughout the country, the Fifth Circuit protected a hospital's right to suspend a physician if the hospital reasonably believes that the physician poses a danger to

patients. n47 A California appellate court ruled in favor of a medical staff executive committee that rejected an anesthesiologist for membership because his "habit of making excuses for [his] actions and knowledge deficit will manifest itself, to the detriment of patients' well being." n48

n47 *See* Patel v. Midland Mem'l Hosp. & Med. Ctr., 298 F.3d 333, 340 (5th Cir. 2002) (while generally due process requires presuspension notice and hearing, when safety of public is at risk, an adequate post suspension remedy satisfies due process).

n48 *See* Fine v. Childrens Hosp. L.A., 2002 WL 1980685, *5 (Cal. Ct. App. Aug. 29, 2002).

C. Fraud and Abuse

The Fraud and Abuse Practice Group addressed cases and developments in food and drug law, as well as the more traditional cases arising under state and federal fraud and abuse statutes.

States won several major cases in their efforts to make prescription drugs more affordable and accessible for citizens. In a 6-3 ruling issued May 19, 2003, the Supreme Court found that a district court had abused its discretion in preliminarily enjoining Maine's Act to Establish Fairer Pricing for Pharmaceuticals. Justice Stevens, writing for a fairly fractured majority, found that the act did not violate the Commerce Clause, and that petitioner had failed to show a likelihood of success in its argument that the Medicaid statute should preempt and invalidate the Maine statute. n49

n49 *See* Pharm. Research & Mfrs. of Am. v. Walsh, 123 S. Ct. 1855, 1870 (2003).

In September 2002, the Eleventh Circuit upheld a Florida law creating a "preferred drug formulary or list," rejecting the Pharmaceutical Research & Manufacturers of America's (PhRMA's) argument that the formulary did not satisfy all of the requirements set out in the federal Medicaid statute for a Medicaid formulary. n50

n50 *See* Pharm. Research & Mfrs. of Am. v. Meadows, 304 F.3d 1197, 1212 (11th Cir. 2002).

Reversing two lower courts, the Michigan Supreme Court sustained the validity of a state law that limits the liability of drug manufacturers and distributors for drugs that have been approved for safety and efficacy by the FDA. n51

n51 *See* Taylor v. Smithkline Beecham Corp., 658 N.W.2d 127, 137 (Mich. 2003).

While states came out on top, the federal government lost some significant cases in the FDA regulatory area. The FDA suffered a setback in its effort to promulgate regulations requiring manufacturers to "Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients" (Pediatric Rule). The United States District Court for the District of Columbia found that the FDA lacked authority under the Federal Food Drug and Cosmetic Act to promulgate the Pediatric Rule, which would have required manufacturers to study their products on pediatric populations, even if the products were not specifically marketed for children's use. n52

n52 *See* Ass'n of Am. Physicians & Surgeons, Inc. v. United States Food & Drug Admin., 226 F. Supp. 2d 204, 222 (D.D.C. 2002).

The Ninth Circuit affirmed a district court's order enjoining the federal government from revoking a physician's Drug Enforcement Agency registration based on the physician's recommendation to use marijuana for medical

purposes, which is permissible under California state law. n53

n53 *See Conant v. Walters*, 309 F.3d 629, 632 (9th Cir. 2002).

One of the most notable criminal cases decided this year was the Indiana Supreme Court's ruling that the state's Medicaid fraud statute was too vague to satisfy due-process concerns. The court found that the statute essentially transformed almost any violation of the Indiana Code by a Medicaid provider into Medicaid fraud. n54

n54 *See Healthscript, Inc. v. Indiana*, 770 N.E.2d 810, 816 (Ind. 2002).

With respect to federal fraud and abuse cases, courts split on whether a plaintiff could use an alleged violation of the Anti-Kickback Statute or the Stark Law as the "false claim" in a case brought under the False Claims Act (FCA). n55 The Southern District of New York was not persuaded that an allegation of a kickback scheme could form the basis for an FCA claim, reasoning that Congress did not intend to provide a private right of action for an anti-kickback violation. n56 A District of Columbia court, however, found that an allegation of a violation of the Anti-Kickback Statute or Stark Law was sufficient to state a claim under the FCA on an "implied certification" theory. n57 On a related issue, a district court in Illinois rejected a physician's argument that a contractual provision encouraging violations of the Anti-Kickback Statute and Stark Law constituted a "false claim" for purposes of the FCA if the physician never made referrals in violation of those laws. n58

n55 31 U.S.C. § 3729 (2003).

n56 *See United States ex rel. Barmak v. Sutter Corp.*, 2002 WL 987109, *6 (S.D.N.Y. May 14, 2002).

n57 *See United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., Inc.*, 238 F. Supp. 2d 258, 265-66 (D.D.C. 2002).

n58 *See United States ex rel. Perales v. St. Margaret's Hosp.*, 243 F. Supp. 2d 843, 867-68 (C.D. Ill. 2003).

Courts also began to interpret the Phase I regulations interpreting the Stark II Law. A District of Columbia district court clarified the regulations' reach by determining that lithotripsy is not a "designated health service" within the meaning of Stark II. n59

n59 *See Am. Lithotripsy Soc'y v. Thompson*, 215 F. Supp. 2d 23, 37 (D.D.C. 2002).

D. Healthcare Liability and Litigation

The most significant liability-related developments in the last twelve months involved legislative and common law responses to the "medical malpractice crisis." Important cases relating to the Emergency Medical Treatment and Active Labor Act (EMTALA) were also decided. n60

n60 Emergency Medical Treatment Active Labor Act, 42 U.S.C. § 1395dd (2003).

President Bush has made federal medical malpractice reform a key component of his healthcare legislative agenda. n61 Several states in which healthcare professionals are enduring huge increases in the cost of malpractice insurance are

seeking to enact state legislative relief. n62 On March 13, 2003, the House of Representatives passed the Help Efficient, Accessible, Low Cost, Timely Health Care Act of 2003 (HELP Act) by a vote of 229-196. n63 This legislation defines a healthcare liability claim broadly and contains many federal tort reforms, including a cap on noneconomic damages of \$ 250,000. n64 The HELP Act legislation is on the Senate legislative calendar, but has not yet been considered by the full Senate.

n61 *See President Bush Renews Push for Medical Liability Reform, Two States Eye Malpractice Reform Measures*, 7 HEALTH LAWYERS NEWS 15, 15 (Feb. 2003).

n62 *See id.* (discussing developments in Ohio and West Virginia); Med. Care Availability and Reduction of Error (MCARE) Act, 2002 Pa. Laws 13 (codified at PA. STAT. ANN. tit. 40, §§ 1303.101-1303.910); Med. Liab. Reform Act, H.R. 92, 57th Leg. Reg. Sess. (Idaho 2003); G.A. 281, 124th Gen. Assem. Reg. Sess. (Ohio 2003).

n63 *See* Help Efficient, Accessible, Low Cost, Timely Health Care Act of 2003 (HELP Act), H. REP. NO. 108-32 (2003).

n64 *Id.* at Part I, § 4 (b).

Courts have permitted creative new theories of liability when an adverse event occurs in the course of treatment. In *Howard v. University of Medicine & Dentistry*, the New Jersey Supreme Court found that, while misrepresentation of qualifications could not constitute the substance of a malpractice or fraud action, it could provide the basis for a lack-of-informed-consent claim. n65 A Texas appellate court permitted a patient to allege a violation of the state Deceptive Trade Practices Act when an anesthesiologist violated a patient's wishes to remain conscious during a procedure. n66

n65 *Howard v. University of Medicine & Dentistry*, 800 A.2d 73, 85 (N.J. 2002).

n66 *See Russell v. Murphy*, 86 S.W.3d 745, 750-51 (Tex. Ct. App. 2002).

The First Circuit explored the distinction between a malpractice claim and an EMTALA claim. The court upheld summary judgment for a hospital on the appropriateness of its screening exam when the plaintiff's expert applied the standard of care applicable in a malpractice action rather than that applicable in an EMTALA action. n67

n67 *See Del Carmen Guad. v. Agosto*, 299 F.3d 15, 21 (1st Cir. 2002).

E. Health Information & Technology

The last twelve months have seen enormous activity in the area of health information and technology, much of it revolving around how to keep personal health information private and secure. The rule implementing HIPAA's privacy standards was modified and finalized in August of 2002, and implemented in April of 2003. At least two groups of plaintiffs filed constitutional challenges to those rules and lost. DHHS issued final security regulations and important amendments to the HIPAA Standard Transactions and Code Sets Rule.

On August 14, 2002, DHHS issued the Final Privacy Rule, formally titled the "Standards for Privacy of Individually Identifiable Health Information," under HIPAA. n68 The modifications were intended to simplify compliance efforts and address concerns regarding unintended consequences on the healthcare industry. Among other changes, the final rule shifted the focus away from consent and onto notice, simplified the authorization requirements, and expanded the ability of Covered Entities to disclose protected healthcare information for payment purposes. n69

n68 Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191.

n69 See Victoria A. B. Willis, *Unraveling HIPAA*, 6 HEALTH LAWYERS NEWS 38, 38-39 (Nov. 2002).

The Fourth Circuit upheld the constitutionality of the privacy standards, rejecting arguments that (1) Congress had unconstitutionally delegated legislative authority to the DHHS secretary; (2) the regulations were beyond the grant of congressional authority; and (3) the statute and regulations were impermissibly vague. n70 Earlier, a district court in Texas had reached the same conclusion about the rule and DHHS' authority to implement it. n71

n70 See *S.C. Med. Ass'n v. Thompson*, 327 F.3d 346, 348 (4th Cir. 2003).

n71 See *Ass'n of Am. Physicians & Surgeons, Inc. v. D.H.H.S.*, 224 F. Supp. 2d 1115, 1129 (S.D. Tex. 2002) (nonprofit organization with physician and patient members brought declaratory judgment action against DHHS, challenging Privacy Rule as beyond scope of HIPAA and as violative of the First, Fourth, and Tenth Amendments).

On February 20, 2003, DHHS issued the final Security Standards. n72 This final rule meshes the security requirements with the privacy standards, explicitly recognizing that the cost of implementation is an important consideration for those governed by its terms. The final rule eliminates some redundancy in the proposed rule. n73

n72 Health Insurance Reform: Security Standards, 68 Fed. Reg. 8334 (Feb. 20, 2003).

n73 See Press Release, Davis Wright Tremaine LLP, DWT Releases Analysis and Comments on HHS's Just- Released HIPAA Security Rules (Feb. 2003), at www.dwt.com/practc/hc_ecom/bulletins/02-03_HIPAA_SecRules.htm (last visited July 14, 2003).

On the same date, DHHS issued long-awaited amendments to the HIPAA Standard Transactions and Code Sets Rule. n74 The final amendments addressed two proposed rules published earlier by the secretary. While highly technical in nature, they were deemed essential to effective implementation of the final transaction standards.

n74 Health Insurance Reform; Modifications to Elec. Data Transaction Standards and Code Set, 68 Fed Reg. 8381 (Feb. 20, 2003).

F. HMOs and Health Plans

Health plans continued to struggle with liability issues, attempting to defend themselves through use of ERISA's pre-emption clause. They also faced major jury verdicts and growing class action litigation. Health plans followed with interest significant cases in the area of alternative dispute resolution and tax exemption.

The Supreme Court continues its struggle to define the scope of ERISA's preemption clause. On April 2, 2003, the Court upheld two Kentucky statutes requiring health insurers to admit into their networks any provider willing to meet the terms and conditions set by the insurer. n75 The Court not only declined to expand the scope of ERISA's preemption clause, it rejected the use of the traditional McCarran-Ferguson factors to reach its conclusion. n76

n75 See *Ky. Ass'n of Health Plans v. Miller*, 123 S. Ct. 1471, 1479 (2003).

n76 *See id.* at 1478-79.

On June 20, 2002, the Supreme Court ruled 5-4 that the Illinois Health Maintenance Organization Act's requirement of independent review of health plan benefit denials is not preempted under ERISA. n77 The Court believed that the external review provisions regulate insurance, fall within ERISA's savings clause, and do not conflict with ERISA's civil-enforcement mechanisms because they do not provide any new cause of action or remedy not authorized by ERISA. n78

n77 *See* Rush Prudential HMO v. Moran, 536 U.S. 355, 387 (2002).

n78 *See id.* at 379-80.

Appellate courts struggled with preemption and health plan liability issues. The Fifth Circuit found an allegation that a health maintenance organization (HMO) negligently refused to classify a physician as a network provider was preempted by ERISA. n79 The Second Circuit, in a case of first impression, held that a medical decision made in the course of prospective utilization review by a managed care organization or health insurer may not be sheltered by ERISA preemption. n80

n79 *See* Haynes v. Prudential Health Care, 313 F.3d 330, 337 (5th Cir. 2002).

n80 *See* Cicio v. Does, 321 F.3d 83, 102 (2d Cir. 2003).

Health plans also faced liability awards and class action suits by physicians. A Dallas jury awarded \$ 3 million in actual damages and \$ 10 million in punitive damages against CIGNA Health Care of Texas in the first jury award under the Texas Health Care Liability Act, enacted in 1997. n81 Moreover, a judge in Florida certified a class of approximately 600,000 doctors who provided services to patients insured by eight health plans. n82

n81 *See* Pybas v. CIGNA HealthCare, No. 01-02980-J (Tex. Dallas Cty., filed Jan 19, 2001), *cited in* John Schneider, *Cigna Hit Hard by HMO Liability Law*, NAT'L. L.J., at www.nlj.com/special/071502vow.shtml (last visited July 14, 2003).

n82 *See In re Managed Care Litig.*, 209 F.R.D. 678, 680-81 (S.D. Fla. 2002).

In April 2003, the Supreme Court held that parties could be required to arbitrate claims arising under the Racketeer Influenced and Corrupt Organizations Act n83 even when the arbitration agreement excluded the award of punitive damages. The Supreme Court reasoned that it was unclear whether the parties intended the preclusion of punitive damages to include claims for treble damages. n84

n83 18 U.S.C. §§ 1961-1968 (2003).

n84 *See* PacifiCare Health Sys., Inc. v. Book, 123 S. Ct. 1531, 1535-36 (2003).

Nonprofit HMOs followed closely Intermountain Health Care's (IHC's) effort to obtain relief from the Internal Revenue Service's (IRS's) determination that IHC Health Plans and two subsidiary health plans did not qualify for tax-exempt status. Ultimately, the Tenth Circuit denied IHC's request, reasoning that an organization seeking 501(c)(3) status must operate primarily for the benefit of the community, and that the plans at issue failed to satisfy this test. n85

n85 See *IHC Health Plans, Inc. v. Commissioner*, 325 F.3d 1188, 1199 (10th Cir 2003).

G. Hospitals and Health Systems

Several decisions involved disclosure of confidential information. A California appellate court held that a general counsel's duty of loyalty and confidentiality prevented him from disclosing sufficient evidence to support a *qui tam* action against his former employer. n86 In a significant case for healthcare entities negotiating with both the government and private plaintiffs, the Sixth Circuit required defendant HCA to provide internal, confidential coding audits to private plaintiffs after it provided the audits to the government as part of a comprehensive settlement of claims. n87 Finally, in a decision that might surprise in-house counsel, a district court in Illinois found that a general counsel's handwritten notes of an interview of a formerly employed nurse following an adverse event were not protected by privilege because the nurse cannot "control" the attorney's advice or the hospital's actions. n88

n86 See *Bury v. Cmty. Hosp.*, 2002 WL 968833, *4 (Cal. Ct. App. May 8, 2002).

n87 See *In re Columbia/HCA Healthcare Corp. Billing Practices Litig.*, 293 F.3d 289, 304 (6th Cir. 2002).

n88 See *Valenti v. Rigolin*, 2002 WL 31415770, *3 (N.D. Ill. Oct. 25, 2002).

A Texas appellate court found that boilerplate disclaimer language in a physician recruitment contract regarding allegedly erroneous details about a hospital failed to shield the hospital from potential liability for fraudulent inducement. n89

n89 See *John v. Marshall Health Servs.*, 91 S.W.3d 446, 450 (Tex. Ct. App. 2002).

The Fifth Circuit held that, under Texas law, general boilerplate indemnity language did not expressly shift the consequences of a management **company's** own negligence to the hospital contracting with the management **company**. n90

n90 See *Quorum Health Res. v. Maverick County Hosp. Dist.*, 308 F.3d 451, 461 (5th Cir. 2002).

Congress and advocates for community hospitals focused considerable attention on "specialty hospitals," a growing segment of the hospital community. Specialty hospitals focus on the performance of certain procedures and are often owned in whole or in part by the physicians who work in them. n91 General hospitals have raised concerns that specialty hospitals are siphoning off the most financially rewarding segments of a general hospital's cases. Advocates for specialty hospitals respond that their focused mission enables them to provide services more efficiently. n92

n91 U.S. GEN. ACCOUNTING OFFICE, *supra* note 10, at 3.

n92 *Id.*

H. In-House Counsel

Two trends occurring in the last twelve months of special significance for health lawyers are (1) different prevailing theories on vicarious liability working their way through the courts; and (2) the courts' struggle to balance privacy and other competing social goods.

A Texas appellate court affirmed a trial court's judgment against two anesthesiologists, organized as professional associations under Texas law, for the negligent acts of a certified nurse anesthetist who was trained, assigned, and supervised by the professional associations. The court found that this failure to supervise could support a negligence claim against the professional associations, even when neither of the anesthesiologists was directly involved in the care of a patient. n93

n93 See *Battaglia v. Alexander*, 93 S.W.3d 132, 142 (Tex. Ct. App. 2002).

The Michigan Supreme Court remanded a malpractice case for a new jury trial, finding that a hospital unit, as opposed to a particular profession, person, or specialty, was incapable of independent actions, including negligence, and was, thus, not an "employee" or "agent" of a hospital. The court found that a jury must be instructed regarding the specific agents against whom negligence is alleged and the standard of care applicable to each agent. n94

n94 See *Cox v. Bd. of Hosp. Managers*, 651 N.W.2d 356, 361-62 (Mich. 2002).

In *NME Properties v. Rudich*, a **nursing home** licensee argued that it should not be held liable in a wrongful-death action because the **nursing home** was operated by an independent contractor. n95 The court of appeals affirmed the lower court's finding to the contrary, reasoning that the **nursing home** had a nondelegable duty to deliver adequate care to its residents, whether it provided the care itself or contracted with another entity to provide it. n96

n95 *NME Properties v. Rudich*, 840 So. 2d 309 (Fla. Dist. Ct. App. 2003).

n96 *Id.* at 312-13.

The In-House Practice Group also focused on the intensity with which courts were enforcing privacy laws. The New York Court of Appeals reversed a lower court's decision to enforce a law-enforcement subpoena asking for the medical records of any male patients between the ages of thirty and forty-five treated for a particular type of injury on specific dates. The court held that the hospitals in question were permitted to protect the information under the physician-patient privilege because compliance with the subpoenas would violate state confidentiality laws. n97

n97 See *In re Grand Jury Investigation*, 779 N.E.2d 173, 174-75 (N.Y. 2002).

In another case involving governmental access to information, a federal district court in Louisiana held that HIPAA preempts the provider/patient privilege in Louisiana and that, even if the government decides not to intervene in a qui tam action, the government is entitled to receive copies of unredacted information in discovery. n98

n98 See *United States ex rel. Stewart v. La. Clinic*, 2002 WL 31819130, *9 (E.D. La. Dec. 12, 2002).

I. Labor and Employment

The Labor and Employment Practice Group reviewed important Supreme Court and circuit court case law defining

significant issues in antidiscrimination law, labor law, and alternative dispute resolution.

Recently, courts have struggled to define "employee" for purposes of determining the applicability of the Americans with Disabilities Act n99 (ADA). The Supreme Court resolved a conflict in the circuits by endorsing a common-law "control" test to determine whether four physicians, who are actively engaged in the practice of medicine and are shareholders and directors of a professional corporation, should be considered "employees" for purposes of the ADA's fifteen-employee threshold. Agreeing with the Equal Employment Opportunity Commission (EEOC), the Court found that whether a shareholder-director is an employee depends on all the incidents of the employment relationship. n100

n99 Americans with Disabilities Act, 42 U.S.C. §§ 12101-12213 (2003).

n100 See *Clackamas Gastroenterology Assoc., P.C. v. Wells*, 123 S. Ct. 1673, 1680 (2003).

In a related case, the Tenth Circuit held that the Rehabilitation Act does not incorporate the ADA's fifteen-employee threshold even though "the standards used to determine whether [the Rehabilitation Act] has been violated . . . shall be the standards applied under title I of the Americans with Disabilities Act." n101

n101 *Schrader v. Ray*, 296 F.3d 968, 971 (10th Cir. 2002).

In a case defining "sexual harassment," a panel of the Fourth Circuit found that Title VII does not prohibit all verbal or physical harassment in the workplace, but rather is directed only at discrimination "because of" sex. Thus, the panel held that the essential inquiry in a sexual-harassment suit is whether the complaining party would have suffered the same harassment had he been of a different gender. The theory is an interesting and controversial one; however, it has no precedential value because the full court sitting en banc ultimately vacated the panel's opinion. n102

n102 See *Ocheltree v. Scollon Prods., Inc.*, 308 F.3d 351, 356 (4th Cir. 2002), *vacated en banc*, 308 F.3d 351 (4th Cir. 2002).

With respect to organizing activity, the District of Columbia Circuit held that a hospital violated the National Labor Relations Act (NLRA) when it prohibited the distribution of union literature in the vestibule of the hospital. The court held that the vestibule was not a "work area" and that distribution of literature would not adversely affect patients. n103

n103 *Brockton Hosp. v. N.L.R.B.*, 294 F.3d 100, 104-05 (D.C. Cir. 2002).

In a decision significant both for law firms and their healthcare clients, the Ninth Circuit followed the recent Supreme Court decision in *Circuit City v. Adams*, n104 in finding that a law firm could refuse to hire a secretary because he would not sign an agreement to arbitrate claims arising from his employment. n105

n104 *Circuit City v. Adams*, 121 S. Ct. 1302 (2001).

n105 See *E.E.O.C. v. Luce, Forward, Hamilton, & Scripts*, 303 F.3d 994, 1008 (9th Cir. 2002).

J. Long Term Care

On May 9, 2003, the Alabama Supreme Court ruled that an arbitration agreement between an Alabama **nursing**

home and one of its residents was enforceable under Alabama law and under the Federal Arbitration Act n106 (FAA). The court ruled that the **nursing home's** agreement had sufficient impact on interstate commerce to implicate the FAA and therefore compel the enforcement of a mandatory arbitration clause for a medical malpractice claim. n107

n106 Federal Arbitration Act, 9 U.S.C. §§ 1-14 (2003).

n107 See McGuffey Health & Rehab. Ctr. v. Gibson, 2003 WL 21040590, *2 (Ala. May 9, 2003).

An Arkansas appellate court reduced a compensatory and punitive damages award against Advocat, Inc. The circuit court found a \$ 15 million compensatory award excessive and reduced it to \$ 5 million. It found a punitive award of \$ 63 million that was "far and away" the largest punitive award ever made in the state of Arkansas "shocked the court's conscience," and reduced it to \$ 21 million. n108

n108 See Advocat, Inc. v. Sauer, 2003 WL 1996087 (Ark. May 1, 2003).

California enacted a state law, commonly called the Cedillo Law, which prohibits the use of state funds to "assist, promote, or deter" union organizing by private employers receiving state funds in excess of \$ 10,000. National associations, including the United States Chamber of Commerce, argued that the NLRA n109 preempted the statute. While the district court would not grant standing to plaintiffs to challenge every section of the statute, the court did hold, on motions for summary judgment, that certain provisions of the Cedillo Law were preempted. n110

n109 National Labor Relations Act, 29 U.S.C. §§ 151-169 (2003).

n110 See United States Chamber of Commerce v. Lockyer, 225 F. Supp. 2d 1199, 1206 (C.D. Cal. 2002).

In *Beverly Health v. Thompson*, a federal district court held that the DHHS secretary had complied with the Administrative Procedure Act n111 in crafting its survey protocol and that CMS' termination of the Beverly-Springhill **nursing home** was not an abuse of discretion. n112 This case is likely to have far reaching ramifications for Medicaid and Medicare long term care providers.

n111 Administrative Procedures Act, 60 Stat. 237 (1946), *repealed* (provisions contained in Revised Title, 5 U.S.C. §§ 551-559, 701-706, 1305, 3105, 4301, 5335, 5372, 7521).

n112 223 F. Supp. 2d 73, 115 (D.D.C. 2002).

K. Physicians and Physician Organizations

Three issues have been of enormous importance to physicians over the last twelve months: (1) malpractice reform and litigation; (2) common-law developments on physician employment issues; and (3) payment issues.

On July 25, 2002, DHHS released a report calling on Congress to enact medical liability reform. n113 The president then called on Congress to pass federal healthcare liability reform based on the general principles articulated in the DHHS study. n114 On March 13, 2003, the House of Representatives took the president's encouragement to heart and passed the HELP Act by a vote of 229-196. n115

n113 U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *supra* note 4.

n114 *See President Bush Renews Push for Medical Liability Reform, supra* note 61, at 15.

n115 Help Efficient, Accessible, Low Cost, Timely Health Care Act of 2003 (HELP Act), H.R. 5, 108th Cong. (2003).

While looking for legislative relief, physicians saw courts struggling to provide compensation for those allegedly victimized by negligent medical care. In *Mejia v. Community Hospital*, n116 the California Court of Appeals held that a hospital could not avoid liability for a radiologist's malpractice because the radiologist was an independent contractor. The court agreed with plaintiffs that an ostensible agency theory was enough to avoid dismissal of the action. n117

n116 *Mejia v. Cmty. Hosp.*, 122 Cal. Rptr. 2d 233 (Ct. App. 2002).

n117 *Id.* at 235.

An Ohio appellate court articulated an even broader notion of agency in finding that a hospital may be held liable for the negligence of an independent-contractor physician even when that physician is a state employee who is immune from civil liability. n118 The crucial issue for the court was whether the patient was looking only to the physician for her care or whether she was also expecting the hospital to provide her with "competent medical care." n119

n118 *See Vanderpool v. Univ. Hosp., Inc.*, 2002 WL 31127525, *5 (Ohio Ct. App. Sept. 27, 2002).

n119 *Id.* at *3.

Physicians may be disheartened by a decision of the New York Court of Appeals in which it refused to expand an exception to New York's employment-at-will doctrine. The case involved a physician who refused to comply with the directive of her employer, the New York Times, because the request was deemed incompatible with her understanding of her professional ethical obligations to protect patient confidentiality. n120

n120 *Horn v. New York Times*, 2003 WL 443259 (N.Y. Feb. 25, 2003).

In another case involving patient confidentiality, a Georgia appellate court found that under Georgia law, a physician is permitted to inform the dentist of an human immunodeficiency virus (HIV)-positive individual about the patient's condition without the consent of the patient--even when the dentist is the patient's employer. The court found that Georgia law permits the disclosure of confidential HIV information when necessary to protect healthcare providers. n121

n121 *See Waddell v. Bhat*, 571 S.E.2d 565, 568-69 (Ga. Ct. App. 2002).

While Georgia courts protected the safety of physicians, Congress worked on their reimbursement rates. On February 13, 2003, Congress enacted the Consolidated Appropriations Resolution of 2003. n122 In that legislation, Congress permitted CMS to revise the physician conversion factor because of alleged errors made by CMS in 1998 and 1999. Due to this revision, the physicians covered by the change will receive an average 1.6% increase in Medicare reimbursement rates for the remainder of the year, rather than the average 4.4% decrease that would have occurred had no legislation been passed. n123

n122 H.J. Res. 2, 108th Cong. (2003).

n123 Medicare Program; Physician Fee Schedule Update for Calendar Year 2003, 68 Fed. Reg. 9567 (Feb. 28, 2003).

L. Regulation, Accreditation, and Payment

The proposed changes by CMS to the reimbursement policies concerning payment for cost outliers may have been the most significant development in this area over the past twelve months. Other significant developments include CMS amendments to "reopening" regulations, the final "provider-based rules," and the additional attention paid by regulatory and governmental bodies to patient safety.

On March 5, 2003, CMS issued proposed regulations modifying aspects of the methodology for determining Medicare outlier payments. The proposed rule includes three significant changes that attempt to prevent providers from manipulating charges in order to increase outlier payments. n124 CMS issued the final rule on June 9, 2003, with important modifications to the proposed rule. n125

n124 Weeks, *supra* note 14, at 1.

n125 Medicare Program; Proposed Changes to the Hosp. Inpatient Prospective Payment Sys. & Fiscal Year 2004 Rates, 68 Fed. Reg. 34,493 (Jun. 9, 2003).

CMS has ordered fiscal intermediaries to conduct audits at approximately 400 hospitals nationwide that were identified through various "screens" as having unusually high outlier payments. n126

n126 Weeks, *supra* note 14, at 1 (referencing several CMS transmittals).

On August 1, 2002, CMS published final amendments to the Medicare reopening regulation. n127 CMS responded explicitly to the District of Columbia Circuit's 2001 decision in *Monmouth Medical Center v. Thompson*, n128 with which it disagreed. In issuing the final rule, CMS prohibits an intermediary from reopening a previously settled determination or hearing decision unless it has been explicitly instructed to do so by CMS. n129

n127 Medicare Program; Changes to the Hosp. Inpatient Prospective Payment Sys. & Fiscal Year 2003 Rates, 67 Fed. Reg. 49,982 (Aug. 1, 2002).

n128 *Monmouth Med. Ctr. v. Thompson*, 257 F.3d 807 (D.C. Cir. 2001).

n129 Kenneth R. Marcus, *Centers for Medicare and Medicaid Services Amends Medicare Reopening Regulation to "Clarify" Reopening Process in Light of Monmouth but Foregoes Opportunity to Implement Further Reform*, 5 THE RAP SHEET 7, 8 (Health Lawyers 2002).

CMS' issuance of final revisions to the "provider-based" rules on August 1, 2002, constituted one of the most significant developments of the past twelve months. n130 The bar welcomed certain changes in the final rules, such as the "voluntary" attestation process replacing the mandatory "application" process, and the clarification that EMTALA applies only to those departments on the hospital's main campus that are provider-based. n131

n130 Medicare Program; Changes to the Hosp. Inpatient Prospective Payment Sys. & Fiscal Year 2003 Rates, 67 Fed. Reg. 49,982 (Aug. 1, 2002).

n131 Barry Alexander, *CMS Issues Final Provider-Based Rules: And Why Is This So Important Again?*, 5 THE RAP SHEET 1, 2-3 (Health Lawyers 2002).

Both JCAHO and CMS announced efforts to improve patient safety at our nation's healthcare institutions. Effective January 1, 2003, JCAHO approved for implementation a set of six National Patient Safety goals, including improving the safety of high-alert medications and eliminating wrong-site, wrong-patient, wrong-procedure surgery. On January 1, 2003, JCAHO began surveying all accredited healthcare organizations for implementation of its recommendations--or acceptable alternatives--as appropriate to the services the organization provides. "Alternatives must be at least as effective as the published recommendations in achieving the goals." n132

n132 Joint Comm'n on Accreditation of Healthcare Organizations, 2003 Patient Safety Goals, at www.jcaho.org/accredited+organizations/patient+safety/npsg/npsg_03.htm (last visited July 7, 2003).

On January 24, 2003, CMS published a new rule directing hospitals to develop a QAPI program in an effort to identify patient safety issues and reduce medical errors. The QAPI program, now part of the Medicare conditions of participation, must reflect the complexity of the particular hospital and its services. It became effective on March 25, 2003. n133

n133 Medicare and Medicaid Programs; Hosp. Conditions of Participation: Quality Assessment and Performance Improvement, 68 Fed. Reg. 3435 (Jan. 24, 2003).

M. Tax and Finance

The last twelve months saw the IRS lose a significant case on joint ventures, win a substantial victory in the revocation of tax exemption from IHC Health Plans, begin a process to clarify its approach to § 501(m) exemption applications, and request public comment on revisions to Form 990.

The Texas district court decision in *St. David's Health Care Systems v. United States* n134 was a stunning blow to the IRS, which had, thus far, successfully promulgated its whole hospital joint-venture analysis in Rev. Rul. 98-15 and the series of decisions in *Redlands Surgical Services v. Commissioner*. In *St. David's*, a federal district court rejected the IRS' effort to strip St. David's hospital system of its tax-exempt status after it entered into a limited partnership with HCA, a taxable corporation. The district court found that, while the governing board of the partnership was evenly divided, the arrangement included several other factors that indicated it would give precedence to community benefit over private interest. n135

n134 *St. David's Health Care Systems v. United States*, 2002 WL 1335230, *8 (W.D. Tex. Jun. 7, 2002).

n135 *Id.* at *8.

The Tenth Circuit gave the IRS' position far more deference in *IHC Health Plans v. Commissioner*. n136 The Practice Group leaders describe the impact of this case as "a decision that may sound the final death knell for 501(c)(3) status for any HMO other than a staff model HMO or Medicaid plan." In this case, the Tenth Circuit affirmed the Tax Court's decision both to uphold the IRS' revocation of 501(c)(3) status for IHC Health Plans and to refuse to grant exemption for two subsidiary HMOs. The court found that a plan must do more than simply accept enrollees from groups of all sizes and individuals. It must do something that "supplements and advances the work of public institutions

already supported by tax revenues." n137

n136 IHC Health Plans v. Commissioner, 325 F.3d. 1188 (10th Cir. 2003).

n137 *Id.* at 1197.

In May 2003, the IRS officially withdrew its § 501(m) audit guidelines for HMOs for a period of at least eighteen months. It has begun to work on regulations to provide guidance on various aspects of § 501(m), including a definition of "commercial-type insurance" and other clarifications of terms. n138 The IRS is seeking public comment on the content of such rules.

n138 Internal Revenue Bulletin, IRS Notice 2003-31, 2001-21 (May 27, 2003).

The IRS is also seeking public comment on further revisions to Form 990. On September 30, 2002, the IRS sought public comment as part of an effort to increase confidence in the integrity of the disclosures by tax-exempt organizations. Among other subjects, the IRS is seeking input on whether tax-exempt organizations should be required to disclose whether they have audit committees and conflict of interest policies. n139

n139 Internal Revenue Bulletin 39, IRS Announcement 2002-87, 625-26 (Sept. 30, 2002).

N. Teaching Hospitals and Academic Medical Centers

Over the last twelve months, private associations and accrediting bodies have been responding to the significant attention being paid to developments in the world of academic medicine. The AMA enacted a policy supporting the limitation of residents' working hours, the National Committee for Quality Assurance (NCQA) released draft standards for its Human Research Protection Accreditation Program, and PhRMA issued new principles for the conduct of clinical trials. In addition, the President's Council on Bioethics released its first report, calling for a moratorium on cloning.

On June 20, 2002, the AMA House of Delegates adopted recommendations on limiting working hours of resident physicians. Among those recommendations is that the resident physician duty hours should not exceed eighty per week over a two-week period, and that consecutively scheduled on-call hours should not exceed twenty-four. n140

n140 AM. MED. ASS'N, COUNCIL ON MEDICAL EDUCATION REPORT 9 (A-02): RESIDENT PHYSICIAN WORKING CONDITIONS (2002), at www.ama-assn.org/ama/pub/category/7094.html (last visited July 14, 2003).

On December 3, 2002, the NCQA released draft standards for its Human Research Accreditation Program in which the NCQA endorsed rigorous processes to protect and inform volunteers in clinical trials and other research. The new draft standards are based on standards previously developed by the NCQA for use by the Veterans Administration. n141

n141 Press Release, Nat'l Comm. on Quality Assurance, NCQA Releases Draft Standards for Human Research Protection Accreditation Program (Dec. 3, 2002), available at www.ncqa.org/communications/news/hrpapdraftstds.htm (last visited July 14, 2003).

In June of 2002, PhRMA released a set of principles for the conduct of clinical trials and the communication of results of clinical trials. PhRMA addressed such issues as compensation for clinical investigators, review by Institutional Review Boards, protection of informed consent, and timely communication of meaningful study results.

n142

n142 See Pharm. Research & Mfrs. Of Am., *PhRMA Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results* (June 20, 2002), at www.phrma.org/publications/quickfacts/20.06.2002.428.cfm. (last visited July 14, 2003).

Finally, on July 11, 2002, the President's Council on Bioethics released its first report analyzing the ethical implications of cloning. The report distinguished between the ethics of cloning to produce children and the ethics of cloning for biomedical research. The report ultimately called for a four-year moratorium on therapeutic cloning and a permanent ban on reproductive cloning. n143

n143 THE PRESIDENT'S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY: AN ETHICAL INQUIRY (July 11, 2002).

III. Conclusion

In the twelve months since Health Lawyers' 2002 Annual Meeting, legislators, regulators, and the courts have continued to issue important guidance for counsel to digest, understand, and communicate to their clients. The field of health law becomes more complex and specialized with each passing year.

For those attempting to knit these developments together into an overarching theme, many of these developments demonstrate society's efforts to balance accountability, efficiency, and affordability in the delivery of healthcare.

The Institute of Medicine's relentless focus on patient safety and quality since 1999 has now caught the attention of patients, providers, businesses, and legislators. The healthcare system is focusing like a laser beam on the quality of the healthcare delivered.

While the system attempts to look at long-term quality solutions, those injured in the existing flawed system are looking for ways to be compensated for their injuries. They are trying to hold providers accountable. This contributes to a liability system that some allege has helped to create a malpractice-insurance crisis in certain states across the nation. Patients not only try to hold physicians, hospitals, and other providers accountable; they also increasingly look to health plans to compensate them for injuries.

Healthcare professionals, providers, and plans reasonably argue that the existing system of accountability seems to do a poor job in targeting those delivering lower quality, and certainly makes the delivery of care less efficient and more expensive. The contrary views of consumer advocates on one hand and the healthcare community on the other make for an interesting debate regarding how to build an accountable, efficient, and affordable healthcare system.

Privacy issues touch on the same themes. The Bush administration struck a slightly different balance than the Clinton administration in holding healthcare organizations accountable for the privacy of their patients' information. The Bush administration may have given more weight to the arguments of providers regarding efficiency, quality, and research. The final privacy and security rules, however, will generate massive changes in the way healthcare is provided to our nation's citizens. These changes will not come easily or inexpensively, and will require continuous education and training of the nation's healthcare workforce.

The debates between accountability and efficiency, and between access and affordability, will not end this year, or next. These competing public goods will always be at the center of every debate among patients, providers, and legislators.

This effort to boil one year's worth of developments into a digestible whole may serve as a resource for you until Health Lawyers meets again in New York in 2004. Practice Group members expended great effort to make this resource

available to you, and they should be commended for their achievement.

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SUMMARY: ABSTRACT: This article discusses legal issues caused by the intersection of healthcare and bankruptcy laws in transactions involving distressed healthcare providers in or outside of bankruptcy. The issues discussed pertain to buyers, sellers, and lenders. The following issues are addressed: legal considerations relevant to ensuring that the healthcare provider survives long enough to undergo an acquisition; successor liability issues pertinent to a potential acquirer of the distressed healthcare provider; and considerations lenders must address before loaning money to a distressed healthcare provider or its acquirer.

KEYWORDS: Acquisition, Administrative Claims, Anti-Assignment Rule, Anti-Discrimination, Automatic Stay, Bankruptcy, CONs, Distressed, Fraud And Abuse, Healthcare Receivables, Licenses, Managed Care Organizations, Medicaid, Medicare, Medicare Advantage Plans, Overpayments, Part D Sponsors, Payor Agreement, Preference, Provider Agreement, Recoupment, Restructuring, Security Interest, Setoff, Successor Liability, Transfer

TITLE: ARTICLE: Distressed Healthcare: Significant Considerations for Buyers, Sellers, and Lenders Arising from the Intersection of Healthcare and Bankruptcy Laws

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TEXT:

Distressed Providers

Introduction

Healthcare reform will change the way many healthcare providers operate, regardless of how the reform ultimately takes shape. The primary goal of healthcare reform is to increase affordable access to quality healthcare for all Americans, while reducing the growth in healthcare expenditures. n1 This objective suggests that healthcare providers across the board will feel pressure to provide quality care at reduced costs. This pressure will be compounded as dwindling state budgets lead to cuts in Medicaid reimbursements. Some providers will be well equipped to respond to this pressure and operate efficiently and successfully in the new environment. Others will not be as successful; their failure will impact a wide cross-section of other parties, including patients, business partners, investors, and government entities.

n1 The White House, Health Care Reform, www.whitehouse.gov/issues/health_care/ (last visited Oct. 3, 2009).

Although the effects of healthcare reform remain to be seen, many healthcare providers are experiencing difficulties now. Entrenched in financial woes as a result of the recent recession, credit crunch, and industry uncertainty, many providers face restricted access to lending and options for financing in the capital markets. n2 Ultimately, the current environment puts financial stress on many providers, increasing the potential for restructurings and bankruptcies. n3

n2 Dow Jones, *Health-Care Financing Tightens in Credit Crunch*, AM. BANKER. (Sept. 4, 2009) [hereinafter AM. BANKER]; See, e.g., Associated Press, *Health Care Industry Could Face Continued Uncertainty over Reform, Despite Obama Speech*, Sept. 10, 2009, WASH. EXAMINER.

n3 AM. BANKER.

Notwithstanding the current environment, distressed healthcare providers can present attractive, profitable opportunities for potential buyers and lenders. Further, transactions before and during bankruptcy can provide real options to a provider in crisis. Before embarking on these opportunities, however, buyers, sellers, and lenders should be aware of complex legal issues that arise from the intersection of health-care and bankruptcy laws.

This article discusses many of these issues as they relate to health-care providers and to buyers, sellers, and lenders in the healthcare industry. The focus of the article is sale transactions and loans, but many of the related bankruptcy and healthcare considerations apply to any restructure or distressed healthcare business, even if a sale is not contemplated.

The authors analyze considerations for buyers and sellers of distressed healthcare providers. The considerations include (i) whether a distressed healthcare provider can survive long enough inside or outside of bankruptcy to remain an attractive target for a potential acquirer, and (ii) successor liability issues for potential buyers of distressed healthcare providers, regardless of whether a transaction occurs inside or outside of bankruptcy. The authors also analyze several significant potential issues facing lenders to buyers and sellers of distressed healthcare providers, including obtaining valid security interests in healthcare receivables and **protecting** against government recoupment of Medicare and Medicaid overpayments.

This article focuses only on issues arising out of the intersection of healthcare and bankruptcy laws as they pertain to healthcare providers, such as hospitals and health systems, skilled **nursing homes**, home health agencies, dialysis providers and medical groups. Healthcare reform efforts and other economic trends likely will impact a number of other healthcare sectors. Certain managed care organizations, Medicare Advantage plans and Part D sponsors, for example, may benefit while others may suffer. There is considerable tension between the Bankruptcy Code and state insurance laws regarding the treatment of distressed managed care organizations. That tension and other considerations related to managed care are beyond the scope of this article. Also beyond the scope of this article are the many bankruptcy-related issues relevant to distressed acquisitions generally.

Surviving Long Enough to Undergo Acquisition

Buyers and sellers of distressed healthcare providers have legal issues to consider before a healthcare provider is purchased or sold. These concerns arise in any restructure--they are not unique to sale transactions. They are relevant to an asset sale because they affect whether anything of value will be sold through the process. The issues are relevant to a wide variety of creditors and other interested parties even if a sale is not contemplated. Assuming the value of the business can be preserved, the following discussion analyzes issues specific to the purchase and sale of a distressed healthcare provider or its assets.

A distressed healthcare provider seeking to maintain its operations to undergo an acquisition outside of bankruptcy or reorganize inside of bankruptcy may face a number of issues, chiefly:

- . restricted cash flow stemming from the government's recovery of Medicare or Medicaid overpayments to the provider;
- . possible limitations on the provider's ability to operate under its private payor and Medicare and Medicaid provider agreements inside of bankruptcy;
- . potential Medicare or Medicaid fraud and abuse liability;
- . limited ability to obtain debtor-in-possession financing; and
- . costs associated with the appointment of a patient care ombudsman.

In developing a strategy to deal with these issues, a distressed healthcare provider should keep in mind certain practical business considerations, such as the provider's need to maintain a strong working relationship with the government.

Medicare or Medicaid overpayments

Medicare and Medicaid overpayments are common and often result from the complicated reimbursement methods employed by the proSurviving grams. n4 The government has authority outside of bankruptcy to offset, recoup, or suspend Medicare reimbursements as a result of actual or suspected overpayments. n5 In this context, offset occurs when the government reduces a present or future Medicare payment to recover a non-Medicare debt owed to the government. n6 Recoupment occurs when the government reduces a present or future Medicare payment to recover a Medicare debt. n7 Suspension occurs when the government withholds an approved Medicare payment from a provider or supplier before the government determines that an actual overpayment exists. n8

n4 See 42 U.S.C. § 1395g(a); Special Treatment of Certain Accrued Costs, Ctrs. for Medicare & Medicaid Servs. (CMS), Dep't of Health & Human Servs., 42 C.F.R. § 413.100(c). (Additionally, as discussed in "Fraud and abuse liability," beginning on page 29 of this article, the government may argue that overpayments also result from the imposition of civil monetary penalties and/or fraud and abuse liabilities.)

n5 See Definitions, CMS, Dep't of Health & Human Servs., 42 C.F.R. § 405.370.

n6 See *id.*

n7 See *id.*

n8 See *id.*

In addition to these more traditional overpayments, the government may argue that fraud and abuse and

administrative liabilities imposed on a healthcare provider may also be treated as overpayments. An Eighth Circuit case held that there is no distinction between liability for Medicare overpayments and liability for civil monetary penalties. n9 (For further discussion, see "Fraud and abuse liability," beginning on page 29.) The government may take the position that this court's holding should apply to all fraud and abuse and administrative liabilities, not just liabilities for civil monetary penalties.

n9 *Deerbrook Pavilion v. Shalala*, 235 F.3d 1100, 1104 (8th Cir. 2000).

The government's treatment of Medicare overpayments can have a devastating impact on a distressed healthcare provider's operations. n10 Not surprisingly, therefore, the government's ability to recover overpayments from these providers can be a hotly debated issue--one that requires a varying analysis depending on whether the government attempts to recover the overpayments before or after the distressed healthcare provider petitions for bankruptcy protection.

n10 *See In re Tidewater Mem'l Hosp.*, 106 B.R. 876 (Bankr. E.D. Va. 1989).

Individual state Medicaid agencies coordinate the handling of overpayments with healthcare providers in their respective states. Where Medicaid overpayments are an issue, a distressed healthcare provider needs to understand the Medicaid overpayment rules specific to the applicable state before assessing how those rules intersect with bankruptcy law. In many instances, general bankruptcy law principles (discussed below) with respect to Medicare overpayments apply similarly to Medicaid overpayments.

Pre-petition recovery

The government has fairly broad authority to recover overpayments prior to a healthcare provider's petition for bankruptcy. In addition, the government's recovery of overpayments likely will not be considered an avoidable preference under bankruptcy law when the healthcare provider ultimately enters bankruptcy.

Before a distressed healthcare provider petitions for bankruptcy protection, a Medicare intermediary or carrier may offset or recoup overpayments to the provider after the intermediary, the carrier, or the Centers for Medicare and Medicaid Services (CMS) determines that an overpayment has occurred. n11 Medicare intermediaries, carriers, and CMS have fairly broad pre-bankruptcy petition authority to suspend ongoing payments to protect the program from financial loss. As long as the suspending party has reliable evidence that an overpayment was made, then, after compliance with certain procedural requirements, it may suspend payments. n12

n11 Suspension, Offset, and Recoupment of Medicare Payments to Providers and Suppliers of Services, CMS, Dep't of Health & Human Servs., 42 C.F.R. § 405.371(a)(2).

n12 *See id.* § 405.371(a)(1).

Medicare intermediaries, carriers, and CMS also have discretion to suspend payments to healthcare providers experiencing financial difficulties. If there is reliable evidence that a healthcare provider will institute insolvency proceedings "shortly" in a state or federal court, an intermediary, carrier, or CMS may suspend payments without making a determination that an overpayment exists. n13 Thus, in the event of an impending bankruptcy, the government may make a preemptive withholding to recover past or prevent current overpayments, without regard to procedural requirements.

n13 *See* Payments to Providers: Specific Rules, *id.* § 413.64(i).

Subject to certain defenses, an "avoidable preference" is a transfer of a debtor's property to or for the benefit of a creditor, on account of an antecedent indebtedness made within ninety days (or, with respect to insiders, one year) before the start of the bankruptcy case, while the debtor was insolvent, which enabled the creditor to get a greater recovery than the creditor would receive in a Chapter 7 bankruptcy case if the debtor had not made the payment. n14 Two bankruptcy court decisions have held (albeit on different grounds) that the government's deduction of prior overpayments from current payments it owes a healthcare provider within ninety days prior to bankruptcy is *not* an avoidable preference. One court concluded that the recovery was part of a single transaction, and therefore the government was simply effectuating a recoupment, which (as discussed in further detail below) is not a "transfer of an interest of the debtor" under Bankruptcy Code Section 547(b), the Code's preference statute. n15

n14 *See* 11 U.S.C. § 547(c).

n15 *In re* Yonkers Hamilton Sanitarium, 34 B.R. 385 (S.D.N.Y. 1983). *But see* Univ. Med. Ctr. v. Sullivan, 973 F.2d 1065, 1081-82 (3d Cir. 1992) (holding that a similar recovery could not constitute recoupment in the post-petition context because the recovery was not part of a single transaction for recoupment purposes).

Without substantial analysis, the other court held that, assuming a transfer had occurred, the transfer did not constitute an avoidable preference or an avoidable fraudulent transfer because there was no evidence to suggest that the transfer (i) was made with actual intent to delay or defraud, or (ii) represented less than a reasonably equivalent value, especially in light of the administrative processes used to determine overpayments and the debtor's ability to have them reviewed by a federal court. n16 The court erroneously combined preference and fraudulent transfer analysis: A transfer without actual intent to delay or defraud cannot be an actual fraudulent transfer under Bankruptcy Code Section 548(a)(1)(A); a transfer made for reasonably equivalent value cannot be a constructive fraudulent conveyance under Bankruptcy Code Section 548(a)(1)(B). n17

n16 *In re* Visiting Nurse Ass'n of Tampa Bay, 121 B.R. 114 (Bankr. M.D. Fla. 1990).

n17 *See* 11 U.S.C. § 548(a)(1)(A)-(B).

These inquiries, however, have no bearing on whether a transfer is a preference. If a transfer had occurred, the relevant inquiries for determining whether the transfer was a preference would include, among other things, whether the transfer was on account of an antecedent debt and, if so, whether the bankruptcy preference defenses of contemporaneous consideration and ordinary course of business could be established. n18

n18 *See* 11 U.S.C. § 547(c)(1)-(2).

Post-petition recovery

After a distressed healthcare provider files for bankruptcy, the provider and its creditors are subject to bankruptcy law and its concepts of setoff and recoupment. These terms take on completely different meanings in the bankruptcy context as compared to their meanings under Medicare law. In the bankruptcy context, setoff is a legal principle that permits creditors to offset a pre-petition debt owed to the debtor against a pre-petition debt owed to the creditor, even if the debts did not arise out of the same transaction or occurrence. n19 To establish its right to setoff, however, the creditor must show that (i) the debt it owes the debtor arose pre-petition, (ii) the debt the debtor owes the creditor arose pre-petition, and (iii) the debts are mutual--owed directly between the debtor and creditor (and not between affiliates of

the parties). n20 Debts are considered mutual only when "they are due to and from the same persons in the same capacity." n21 Mutuality requires that the debtor and creditor each "own his claim in his own right severally, with [the creditor's] right to collect in his own name against the debtor in his own right and severally." n22

n19 *See id.* § 553 (permitting setoffs in certain circumstances); 5 Collier on Bankruptcy P 553.03[3][f] (Lawrence P. King, et al. 15th ed. rev. 1996) [hereinafter Collier]; *see, e.g.*, U.S. Abatement Corp. v. Mobil Exploration & Producing U.S. (*In re* U.S. Abatement Corp.), 79 F.3d 393, 398 n.16 (5th Cir. 1996).

n20 *See Collier*, P 553.03.

n21 *Westinghouse Credit Corp. v. D'Urso*, 278 F.3d 138, 149 (2d Cir. 2002) (citing *In re Westchester Structures*, 181 B.R. 730, 740 (Bankr. S.D.N.Y. 1995)).

n22 *In re Garden Ridge Corp.*, 338 B.R. 627, 633-34 (Bankr. D. Del. 2006) (quoting *Braniff Airways v. Exxon, U.S.A.*, 814 F.2d 1030, 1036 (5th Cir. 1987)).

Interestingly, the mutuality requirement may not have practical implications when dealing with the government. The Seventh Circuit held in *United States v. Maxwell* that the "federal government is considered to be a single entity that is entitled to set off one agency's debt to a party against that party's debt to another agency." n23 The government may argue that the Seventh Circuit's holding permits it to establish a right of setoff with respect to pre-petition payments CMS owes a healthcare provider against pre-petition fraud and abuse or administrative liabilities the healthcare provider owes the U.S. Department of Justice or Office of Inspector General.

n23 157 F.3d 1099, 1102-03 (7th Cir. 1998).

Recoupment, on the other hand, is an *equitable* doctrine pursuant to which the net amount due under a single agreement is determined by considering the parties' various credits and debits under that agreement. That is, recoupment is the process for calculating the sum due and owing under the single transaction or agreement (without considering unrelated debts of the parties). n24 In some ways, the rights granted under recoupment are broader than those available under setoff. Under recoupment, a creditor's pre-petition claim against a debtor may be deducted from a *post-petition* amount owed by the creditor to the debtor, so long as the countervailing claims arose out of the same transaction. n25 Because it is an equitable doctrine--and focuses on a single transaction or set of related transactions--the right of a creditor to recoup does not hinge on the timing or mutuality of the debts owed between the creditor and the debtor. The same transaction requirement, however, may cause the government to have a difficult time establishing its right to recoup payments CMS owes a healthcare provider against fraud and abuse or administrative liabilities the healthcare provider owes the U.S. Department of Justice or Office of Inspector General.

n24 *See Collier*, P 553.10.

n25 *See id.* P 553.10[1].

In its role as a bankruptcy creditor, the government will face two major obstacles under the Bankruptcy Code in its attempt to setoff or recoup overpayments against payments it owes the debtor: (i) the automatic stay provision n26 and (ii) the anti-discrimination provision. n27 Sovereign immunity is abrogated with respect to both of these provisions as to any governmental unit--whether federal or state. n28

n26 11 U.S.C. § 362.

n27 *Id.* § 525(a).

n28 *See id.* § 106(a).

With certain exceptions, Section 362(a) of the Bankruptcy Code prevents actions by a creditor, including the government, to collect a pre-petition claim against the debtor. With respect to Medicare overpayments, the government's right to recovery in light of the automatic stay generally depends on whether the recovery is characterized as a setoff or a recoupment.

If a bankruptcy court characterizes a right to recovery as a setoff, the automatic stay prevents the government from recovering an overpayment without first obtaining permission from the court (i.e., obtaining relief from the automatic stay). Additionally, the government could offset only pre-petition amounts (e.g., reimbursements) it owes the healthcare provider against pre-petition amounts (e.g., overpayments) owed by the healthcare provider. n29

n29 *See id.* § 553(a); *see also Collier*, P 553.03 [2].

If a bankruptcy court characterizes a right to recovery as a recoupment, however, the government may pursue it despite the automatic stay and, thus, without permission from the court. n30 Additionally, recoupment is a powerful tool for the government because it can recoup pre-petition amounts owed by the debtor from post-petition payments owed to the debtor.

n30 *In re Slater Health Ctr.*, 398 F.3d 98, 103 (1st Cir. 2005).

The United States Court of Appeals for the Third Circuit is the only federal circuit court that has refused to characterize the government's right to recover prior overpayments as a recoupment. In *University Medical Center v. Sullivan*, the Third Circuit held that the government's deduction of pre-petition Medicare overpayments from post-petition amounts it owed to University Medical Center was improper under the recoupment doctrine. n31 It held that, because the government annually pays providers only for medical services provided in the current "cost year," each annual payment represents a distinct and severable transaction. n32 The Third Circuit reasoned that the government was recovering overpayments it made in prior cost years and, as a result, the overpayments did not arise from the "same transaction" as the payments the government was required to make to reimburse the provider's current cost-year expenditures. n33 Thus, the Third Circuit held that the government's recovery violated the automatic stay. The Third Circuit also confirmed the district court's ruling that the government's withholding was not a valid setoff, despite the automatic stay violation, because the government offset post-petition debts it owed against pre-petition debts owed to it by University Medical Center. n34 Several lower courts have employed similar reasoning. n35

n31 *Univ. Med. Ctr. v. Sullivan*, 973 F.2d 1065, 1081 (3d Cir. 1992).

n32 *Id.* at 1081-82.

n33 *Id.*

n34 *Id.*

n35 *See, e.g., In re Healthback*, 226 B.R. 464, 477-79 (Bankr. W.D. Okla. 1998), *vacated In re Healthback* (Bankr. W.D. Okla. May 28, 1999) (order dismissing debtor's case and vacating July 31, 1998 memorandum opinion); *In re Mediacar Ambulance*, 166 B.R. 918, 922-28 (Bankr. N.D. Cal. 1994).

On the other hand, a majority of the circuit courts that have considered the issue have characterized the government's post-petition recovery of pre-petition overpayments as a permissible recoupment. The Court of Appeals for the D.C. Circuit in *United States v. Consumer Health Services of America*, for example, concluded that the government can recoup overpayments from all fiscal years against current and future amounts due to providers. n36 The court reasoned the recoveries are permissible because the Medicare law does not compartmentalize the government's liability for provider services into a year-to-year determination; rather, Medicare law expressly defines and modifies the government's liability for the provider's current cost-year services as the provider costs incurred in that year "with necessary adjustments on account of previously made overpayments or underpayments." n37 This reasoning is widely accepted, and courts in the First, Seventh, and Ninth Circuits have adopted the *Consumer Health* approach. n38

n36 *United States v. Consumer Health Servs. of Am.*, 108 F.3d 390 (D.C. Cir. 1997).

n37 *Id.* at 394-95; *see In re Holyoke Nursing Home*, 372 F.3d 1, 4 (1st Cir. 2004).

n38 *See In re Holyoke Nursing Home*, 372 F.3d at 4; *In re Doctor's Hosp. of Hyde Park*, 337 F.3d 951 (7th Cir. 2003); *In re TLC Hosps.*, 224 F.3d 1008 (9th Cir. 2000); *see also In re Dist. Mem'l Hosp. of Sw. N. Carolina*, 297 B.R. 451 (Bankr. W.D.N.C. 2002); *In re Slater Health Ctr.*, 294 B.R. 423 (Bankr. D. R.I. 2003), *rev'd*, 306 B.R. 20 (D.R.I. 2004), *aff'd*, 398 F.3d 98 (1st Cir. 2005); *In re Tri County Home Health Servs.*, 230 B.R. 106 (Bankr. W.D. Tenn. 1999); *In re AHN Homecare*, 222 B.R. 804 (Bankr. N.D. Tex. 1998).

Several additional considerations are relevant to the government's ability to recoup overpayments. First, the structure of the distressed healthcare provider's relationship with the government may complicate the government's recoupment argument. For example, when a provider has entered into separate payor agreements with the government to provide various Medicare or Medicaid services, such as one agreement to provide hospital services and a second agreement to provide home health services, the same transaction requirement may restrict the government's ability to recoup overpayments across the separate agreements. n39 In such circumstances, the government may need to establish its right to recoupment independently under each agreement. n40 Second, because recoupment is an equitable doctrine, a provider may be able to challenge the government's recoupment efforts by pointing to basic principles of equity. n41

n39 *In re Tidewater Mem'l Hosp.*, 106 B.R. at 882.

n40 *Id.*

n41 *See id.*

Section 525(a) of the Bankruptcy Code prohibits a governmental unit from denying, revoking, suspending, or refusing to renew "a license, permit, charter, franchise, or other similar grant . . . solely because" the holder or prospective holder of that grant has declared bankruptcy. n42 Although certain cases discuss whether the government's effort to recover pre-petition overpayments runs afoul of the anti-discrimination provision, n43 these cases are of questionable value, given the judicial trend toward allowing recoupment. Courts following the majority view on recoupment typically do not view the government's action as "solely" motivated by the provider's bankruptcy. n44 The anti-discrimination provision remains relevant in other contexts, however, including fraud and abuse actions. For further discussion, see "Administrative sanction actions," beginning on page 18.

n42 11 U.S.C. § 525(a).

n43 *In re King's Terrace Nursing Home & Health Related Facility*, No. 91 B 11478 (FGC), (Bankr. S.D.N.Y. Jan. 26, 1995), *aff'd*, 184 B.R. 200 (S.D.N.Y. 1995); *In re St. Mary Hosp.*, 89 B.R. 503 (Bankr. E.D. Pa. 1988); *In re Univ. Med. Ctr.*, 93 B.R. 412 (Bankr. E.D. Pa. 1988). *But see In re Metro. Hosp.*, 110 B.R. 731, 737 n.9 (Bankr. E.D. Pa. 1990); *In re Saunders*, 105 B.R. 781, 786-88 (Bankr. E.D. Pa. 1989).

n44 *See In re S. Inst. for Treatment & Evaluation*, 217 B.R. 962 (Bankr. S.D. Fla. 1998).

Practice Tip

Although a distressed healthcare provider may, in some circumstances, successfully challenge certain government actions against it--such as the recovery of Medicare or Medicaid overpayments--the positive impact of the victory could be negated if the government decides not to cooperate with the distressed healthcare provider as the provider seeks a potential buyer or undergoes reorganization.

For example, a potential buyer of a distressed healthcare provider, or the provider's plan of reorganization in bankruptcy, will in most cases contemplate the continuation of the provider's Medicare and Medicaid provider agreements, which may require government cooperation (for further discussion, see "Ability to transfer payor/provider agreements," beginning on page 33). n45 At the same time, the government may have an interest in maintaining the distressed healthcare provider's operations and, therefore, be willing to negotiate the timing of certain actions, including the recovery of prior Medicare or Medicaid overpayments. Thus, opening the lines of communication with the government regarding a distressed healthcare provider's goals may, depending on the circumstances, make reaching those goals easier.

A distressed healthcare provider should keep in mind the overarching practical need to communicate and maintain a good relationship with the government and its other major creditors and essential healthcare payors. These practical considerations should inform the distressed healthcare provider's strategy with respect to the many issues it may face, including:

1. the government's broad ability to suspend payments;
2. the recovery of Medicare or Medicaid overpayments by the government;
3. restrictions on the assumption and assignment of the provider's payor agreements; and
4. potential fraud and abuse liability.

n45 *See* 41 U.S.C. § 15; Change of Ownership or Leasing: Effect on Provider Agreement, CMS, Dep't of Health & Human Servs., 42 C.F.R. § 489.18.

Ability to operate under payor/provider agreements in bankruptcy

A distressed healthcare provider's ability to survive pending an acquisition likely will depend on its ability to operate under certain payor agreements during bankruptcy. In most situations, a distressed healthcare provider needs to provide care to patients even after a bankruptcy petition is filed. It is important that the government pays the healthcare provider for Medicare and Medicaid services provided to patients during bankruptcy; otherwise, it is likely that the provider will fail to remain viable pending a possible acquisition.

A debtor healthcare provider in bankruptcy may have the ability to choose whether to assume and assign, or reject its private payor agreements or its Medicare or Medicaid provider agreements. n46 The debtor healthcare entity works with a potential acquirer to assess which agreements it will assume and assign or reject. The debtor healthcare provider typically continues operating under the agreements until a potential acquirer is identified. This is common in bankruptcy, as parties to a contract generally are required to continue performing under the contract during the period after a party has filed the bankruptcy but before the contract has been assumed (or rejected). n47 Usually, the debtor may choose whether to begin the assumption and assignment process early on in the bankruptcy case or to wait until confirmation of a plan (i.e., the end of the bankruptcy case). n48 However, if a private payor or the government believes that the healthcare provider is delaying this decision inappropriately, the private payor or the government may petition the bankruptcy court to compel the debtor to decide at an earlier date. n49

n46 See 11 U.S.C. § 365(a) & (f).

n47 See *id.*; see also *In re Pittsburg-Canfield Corp.*, 283 B.R. 231, 238 (Bankr. N.D. Ohio 2002).

n48 See 11 U.S.C. § 365(d)(2).

n49 See *In re Univ. Med. Ctr.*, 973 F.2d at 1078-79; see also 11 U.S.C. § 365(d)(2); see also *In re Advanced Prof'l Home Health Care*, 94 B.R. 95, 97 (E.D. Mich. 1988).

Fraud and abuse actions during bankruptcy

Healthcare providers that receive reimbursements from a federal health program are subject to numerous fraud and abuse laws. (See the Appendix for an overview of common fraud and abuse laws and the enforcement of those laws.) Apart from the expense of defending against allegations of fraud and abuse, the sanctions and penalties authorized by the fraud and abuse laws may prove devastating to a distressed healthcare provider as it seeks to survive long enough to undergo an acquisition.

In light of various exceptions to the automatic stay, a healthcare provider usually cannot avoid defending against fraud and abuse actions by filing for bankruptcy. For example, Section 362(b)(4) of the Bankruptcy Code (discussed below) exempts governmental providers from the automatic stay to bring or continue actions during bankruptcy pursuant to their police and regulatory powers, although the execution of most monetary judgments obtained as a result of such actions are subject to the automatic stay. n50

n50 See *In re Mickman*, 144 BR 259, 261 (E.D. Pa. 1992); see also *Bd. of Governors Fed. Reserve Sys. v. MCorp Fin.*, 502 U.S. 32, 40-41 (1991).

Administrative sanction actions

The following discussion analyzes the impacts of the automatic stay and the anti-discrimination provision on the government's ability to bring administrative sanction actions against a debtor healthcare provider.

Under Bankruptcy Code Section 362(b)(28), enacted in 2005, the automatic stay does not extend to actions seeking to exclude a debtor from Medicare or other governmental programs. This highly significant change to the Bankruptcy Code prevents a distressed healthcare provider from avoiding a potential exclusion action by filing for bankruptcy.

However, Section 362(b)(28) only exempts *exclusion* proceedings from the automatic stay, and is otherwise silent regarding *termination* proceedings--an entirely different remedy under the federal statutory scheme. n51 (Termination

constitutes the refusal to renew a provider's contract for a variety of reasons, including the failure to adhere to Medicare program requirements. n52 Unlike exclusion, termination is not considered permanent because it allows the provider to reapply immediately in the event the reasons for termination have been remedied. n53) In light of this silence, commentators have suggested that termination proceedings are not exempt from the automatic stay. n54

n51 42 U.S.C. § 1395cc(b).

n52 *Id.* § 1395cc(b)(2)(A).

n53 *Id.* § 1395cc(c)(1).

n54 See Nathaniel M. Lacktman & Keith C. Owens, *Health Care Providers and the Automatic Stay: Is Medicare Termination Different than Exclusion?*, 25-9 AM. BANKR. INST. J. 32, 70-71 (2006).

Even if Section 362(b)(28) does not exempt termination proceedings from the automatic stay, the police and regulatory power exception in Section 362(b)(4) of the Bankruptcy Code may allow the government to terminate a payor agreement. The government's use of the exception to terminate or exclude a provider from the Medicare program has achieved mixed results. n55

n55 See, e.g., *In re Psychotherapy & Counseling Ctr.*, 195 B.R. 522, 529-36 (Bankr. D.C. 1996) (approving of the use of the police power exception to the automatic stay to exclude a provider from the program, although the basis for exclusion must be independent of the breach of a settlement agreement); *but see e.g. In re Rusnak*, 184 B.R. 459 (E.D. Pa. 1995) (holding that an exclusion action against a practitioner who failed to repay a government backed student loan did not fall within the police power exception to the automatic stay).

As with the automatic stay provision, courts have applied the anti-discrimination provision outside of the recoupment context to exclusion actions. n56 The court in *In re Psychotherapy & Counseling Center* held that the U.S. Department of Health and Human Services may not exclude a healthcare provider from Medicare solely because of its default in payment under an agreement settling false claims allegations. n57

n56 See 11 U.S.C. § 525(a).

n57 *In re Psychotherapy & Counseling Ctr.*, 195 B.R. 522 (Bankr. D.C. 1996).

The anti-discrimination provision likely does not bar the government from taking action to terminate a Medicare provider agreement so long as the government's action is not based solely upon the fact of bankruptcy, such as where evidence of fraudulent conduct exists or where the provider failed to comply with program requirements (including reporting obligations). n58 However, the government may not be able to satisfy this requirement in every case.

n58 See 42 U.S.C. § 1395cc(b)(2); 42 C.F.R. §§ 489.53, 489.54. See also *In re Rusnak*, 184 B.R. 459 (finding that § 525(a) is not violated where the U.S. Department of Health and Human Services excluded debtor podiatrist from Medicare program for failure to pay her Health Education Assistance Loans, not because she was a debtor under Title 11).

For example, in *Health Care Fin. Admin. v. Sun Health Care Group (In re Sun Health Care Group)*, n59 one of the debtor's **nursing homes** was:

1. terminated from Medicare participation prior to its bankruptcy filing for failing to comply with

quality of care regulations,

2. fined \$ 60,000 as a civil money penalty, and
3. assessed \$ 133,000 in Medicare overpayments.

n59 Bankr. Case Nos. 99-3657 through 99-3841, Cir. A. Nos. 50-986-GMS (D. Del. Sept. 4, 2002).

As part of a settlement, the debtor was required to pay a reduced civil money penalty and the **nursing home** was required to pass two quality surveys, which it did--one before and one after the filing for bankruptcy. However, after the bankruptcy filing, the requirement of paying the penalty and overpayments came up in an anti-discrimination context. In light of the debtor's argument that the prerequisite of repayment for reinstatement of certification violated the anti-discrimination provision, the court found that the certification was *both* a license issued by the government and an executory contract, and that the failure to pay the pre-petition debt did not permit the government to deny the license.

Similarly, in *Berkelhammer*, n60 the debtor defaulted on a pre-petition payment with the New York Medicaid agency. Nonetheless, the court found that excluding the debtor from the state Medicaid program based on a reinstatement agreement with the state violated the anti-discrimination provision.

n60 *Berkelhammer v. Novella*, 279 B.R. 660 (Bankr. S.D.N.Y. 2002).

Civil fraud and abuse actions

Under the police and regulatory power exception, the government may be able to pursue civil fraud and abuse actions against bankruptcy debtors. n61 In general, courts agree that the police and regulatory power exception is available only when the government action in question is intended to protect the health, safety, or welfare of the public, and not just to protect the government's pecuniary interest. n62

n61 *See* 11 U.S.C. § 362(b)(4).

n62 *See, e.g., In re Corporacion de Servicios Medicos Hospitalarios de Fajardo*, 805 F.2d 440, 445-47 (1st Cir. 1986).

Courts also dispute the applicability of the police and regulatory power exception to false claims actions brought by the government and/or qui tam plaintiffs. With respect to false claims actions brought by *the government*, the trend is for courts to permit the actions, at least up through the entry of a money judgment. n63 In such cases, however, the government is treated as a general unsecured creditor of the debtor. n64 With respect to false claims actions brought by *qui tam* plaintiffs, courts are split as to the applicability of the police and regulatory power exception. n65 Resolution generally depends on whether the court views the qui tam plaintiff as a governmental unit under the exception. n66

n63 *See, e.g., In re Commonwealth Cos.*, 913 F.2d 518, 524-27 (8th Cir. 1990).

n64 *Id.*

n65 *See* United States ex rel. Goldstein v. P&M Draperies, 303 B.R. 601, 603-04 (D. Md. 2004) (concluding that the exception was not applicable); United States ex rel. Jane Doe 1 v. X, 246 B.R. 817, 820-21 (E.D. Va. 2000) (concluding that the exception was applicable).

n66 *See id.*

There is little guidance on whether the automatic stay extends to civil monetary penalty actions against distressed healthcare providers that have filed for bankruptcy. In the non-healthcare context, however, courts generally have permitted civil monetary penalty actions pursuant to the police and regulatory power exception to the automatic stay. n67 Even if the government assessed a civil money penalty against a debtor, however, the resulting money judgment likely would be subject to the automatic stay. n68

n67 *See, e.g., In re Crockett*, 204 B.R. 705, 707-09 (Bankr. W.D. Tex. 1997) (permitting civil money penalties under the Fair Labor Standards Act); *In re Nelson*, 240 B.R. 802, 804-05 (Bankr. D. Me. 1999) (permitting civil money penalties under state consumer laws).

n68 *See In re Nelson*, 240 B.R. at 805 n.8; *In re Psychotherapy & Counseling Ctr.*, 195 B.R. 522, 528.

Criminal fraud and abuse actions

The criminal action exception in Section 362(b)(1) of the Bankruptcy Code generally allows for all criminal fraud and abuse actions brought by the government against a bankruptcy debtor to continue during bankruptcy. n69 A bankruptcy court may not discharge any criminal restitution orders obtained through such actions. n70

n69 *See* 11 U.S.C. § 362(b)(1).

n70 *See id.* § 523(a)(13).

Practice Tip

Although civil fraud and abuse liability judgments generally are treated as unsecured claims in bankruptcy, there is significant risk that the government will hold a buyer liable for these liabilities, even where the Medicare or Medicaid provider agreement is transferred to the acquirer through a bankruptcy proceeding. (For further discussion, see "Fraud and abuse liability," beginning on page 29.) A distressed healthcare provider should attempt to negotiate with the government to minimize civil fraud and abuse liability.

Debtor-in-possession financing

Most debtor healthcare providers operated on a thin gross margin prior to filing for bankruptcy. Such providers likely will need to obtain debtor-in-possession (DIP) financing to operate during bankruptcy long enough to sell themselves or their assets pursuant to Section 363 of the Bankruptcy Code, or pursuant to a plan of reorganization. Issues relevant to lenders of buyers and sellers of distressed healthcare providers, including DIP lenders, are discussed further below.

Patient care ombudsman

A bankruptcy court may order the trustee to appoint a patient care ombudsman to oversee a bankruptcy case involving a healthcare organization. n71 The ombudsman's duty is to "monitor the quality of patient care and to represent the interests of the patients of the health care business . . ." and, should the ombudsman find care deficient, to file written reports with the court. n72 Courts have created a two-part test to determine whether an ombudsman is necessary in a particular case: (i) whether the debtor is a healthcare business that would fall under Section 333 of the Bankruptcy Abuse Prevention and Consumer Protection Act of 2005 (BAPCPA), n73 and (ii) whether the totality of the circumstances warrants the appointment of an ombudsman. n74

n71 Although the appointment of an ombudsman seems almost mandatory under a plain reading of the applicable statute, in practice, and depending on the type of entity, an ombudsman is appointed only some of the time. See 11 U.S.C. § 333; Harold L. Kaplan & Samuel R. Maizel, *The Evolving Standards for the Appointment of a Patient Care Ombudsman: § 333 in "Operation"*, 27 AM. BANKR. INST. J. 40 (2008) [hereinafter *Kaplan & Maizel*].

n72 11 U.S.C. § 333.

n73 See *id.* § 101(27A) (defining "health care business"); *In re Med. Assocs. of Pinellas*, 360 B.R. 356 (Bankr. M.D. Fla. 2007) (Applying a four-part test based on section 101(27A) in concluding that entities primarily involved with administrative or support services, such as billing, insurance, human resources, etc., are not healthcare businesses under the Bankruptcy Code).

n74 See *In re Alternate Family Care*, 377 B.R. 754, 757-58 (Bankr. S.D. Fla. 2007) (Setting forth nine non-exclusive factors surrounding a filing that should be evaluated in a healthcare bankruptcy).

Notably, interested parties may challenge the appointment of a patient care ombudsman. For example, unsecured creditors and/or debtors may challenge an ombudsman once it becomes clear that the continued protection of patients is no longer necessary. n75 In several cases, the debtor has contended that the ombudsman would place too great a financial strain on the debtor's finances. n76 Courts have entertained this cost/benefit analysis, indicating that if the debtor is not guilty of gross mismanagement, an ombudsman may be too financially burdensome. n77

n75 See *Kaplan & Maizel*, at 62.

n76 See *In re Moshannon Valley Citizens*, Bankr. No. 06-00095, at *1-3 (Bankr. M.D. Pa. Feb. 14, 2006) ("Response of the Debtor to Order to Show Cause Why Patient Care Ombudsman Should Not Be Appointed"); *In re Banes*, 355 B.R. 532, 536 (Bankr. M.D. N.C. 2006); *In re Med. Assocs. of Pinellas*, 360 B.R. at 362.

n77 See *In re Banes*, 355 B.R. at 536; *In re Med. Assocs. of Pinellas*, 360 B.R. at 362.

The ombudsman also may present certain advantages to the debtor. For example, ombudsman reports can represent a marketing tool to the distressed provider looking for investors or buyers. The reports can, among other things, indicate a clean bill of health for the provider or, should certain issues arise, an opportunity to rectify issues and demonstrate improved operations. As the reports improve, the distressed provider can point to them as signs that the worst is over.

Buying or Selling a Distressed Healthcare Provider or its Assets

There are a number of issues to be aware of when buying or selling a distressed healthcare provider or its assets, including successor liability resulting from Medicare and Medicaid overpayments or fraud and abuse liability, the distressed healthcare provider's ability to transfer payor contracts (including Medicare and Medicaid provider agreements) to a potential buyer, and the distressed healthcare provider's ability to transfer state licenses and certificates of need to a potential buyer.

Successor liability

Successor liability is a primary concern in any acquisition, regardless of whether the target is financially distressed. The possibility of successor liability becomes even more of an issue in an acquisition of a healthcare provider because many healthcare providers receive reimbursements from a federal healthcare program. When a target healthcare provider receives any such reimbursements, the acquiring entity may be subject to significant liabilities resulting from the target's historical overpayments from Medicare or Medicaid and/or historical fraud and abuse violations.

As in all other transactions, healthcare transactions can be structured as asset purchases rather than stock purchases or mergers to insulate a buyer from a seller's liabilities. This structure allows the sale of a healthcare **company's** assets without the purchaser risking assumption of the **company's** liabilities, except for liabilities associated with Medicare and Medicaid provider agreements. However, successor liability may still attach if:

1. the purchaser expressly or impliedly assumes the seller's liabilities;
2. the transaction amounts to a de facto merger;
3. it is a mere continuation of the transferor's business by the transferee; or
4. the transaction was fraudulent. n78

n78 See Greg Radinsky, *How Health Care Attorneys Can Discern Vernon, Successor Liability and Settlement Issues*, 44 St. Louis L.J. 113, 120-21 (2000) (collecting cases).

A sale of assets of a distressed healthcare provider through Bankruptcy Code Section 363(f) may eliminate much of the successor liability risk. Bankruptcy Code Section 363(f) allows a trustee or a debtor-in-possession in bankruptcy to sell property of the bankruptcy estate "free and clear of any interest in such property" if any one of five separate criteria are satisfied. n79 Three notable criteria allowing a sale free and clear of any interest include:

1. where applicable non-bankruptcy law permits the sale free and clear of any such interest; n80
2. where the interest is in bona fide dispute; n81 and
3. where a court could compel the entity with an interest in the property to accept money satisfaction of its interest. n82

n79 See 11 U.S.C. § 363(f).

n80 See *id.* § 363(f)(1).

n81 See *id.* § 363(f)(4).

n82 See *id.* § 363(f)(5).

A Section 363(f) sale allows a debtor in bankruptcy to sell assets free and clear of any third party's interests in the assets if criteria outlined in the statute are met. The majority of courts find that a Section 363(f) sale transfers the property free and clear of any pre-bankruptcy claims against the property, regardless of whether these claims are secured by a lien on the property or are general unsecured claims against the bankruptcy estate. n83 However, purchasers pursuant to a Section 363(f) sale may not avoid certain healthcare liabilities related to Medicare and Medicaid provider agreements, where a creditor's rights against a debtor-seller are not considered interests in property within the meaning of Section 363(f).

n83 See, e.g., *In re Trans World Airlines*, 322 F.3d 283 (3d Cir. 2003) (holding that any successor liability against purchaser of debtor-airline's assets was cut off by § 363(f) sale so that airline workers' employment discrimination claims could not be asserted against the

purchaser because (1) employment discrimination claims were interests in property, and (2) damages could be reduced to a dollar amount, meaning the creditors could be forced to accept money satisfaction such that one of the five § 363(f) criteria was met); *Myers v. United States*, 297 B.R. 774 (S.D. Cal. 2003) (plaintiff's personal injury action against purchaser of debtor's assets at § 363(f) sale dismissed because sale was made free and clear of any interest); *In re Lady H Coal*, 199 B.R. 595 (S.D. W.Va. 1996) (purchaser at § 363(f) sale allowed to take free and clear of employee benefit claims); *Am. Living Sys. v. Bonapfel (In re All Am. of Ashburn)*, 56 B.R. 186 (Bankr. N.D. Ga. 1986) (any successor liability that could have attached was prevented by order approving § 363(f) sale).

Medicare or Medicaid overpayments

Medicare and Medicaid's ability to recover overpayments not only affects a distressed healthcare provider (for further discussion on such impact, see "Pre-petition recovery," beginning on page 8), but also is an important consideration for an acquirer of the distressed healthcare provider. The treatment of claims for successor liability for Medicare or Medicaid payments inside bankruptcy is inconsistent in the case law. A court's decision to allow or disallow successor liability with regard to overpayments is largely dependent on whether the court construes the overpayments to arise from a statutory entitlement program or an executory contract, and whether the government can properly apply the equitable defense of recoupment to recover against the successor.

The leading decision with respect to Medicare successor liability outside of bankruptcy is *United States v. Vernon Home Health*,ⁿ⁸⁴ where the Fifth Circuit held that a buyer who assumed an automatic transfer of the seller's Medicare provider number also was liable for overpayment claims held by the government, which were asserted thereafter. Although the buyer in *Vernon* argued that state common law providing that a buyer of assets does not assume the selling corporation's debts and liabilities should prevail,ⁿ⁸⁵ the Fifth Circuit held that the Medicare regulations preempt state law and that the regulations require the purchaser of a payor agreement to assume the seller's liability for overpayments under the payor agreement.ⁿ⁸⁶ At least one court followed the *Vernon* decision in finding that a buyer's assumption of a payor agreement gives rise to successor liability by way of the government's recoupment rights against the buyer.ⁿ⁸⁷

ⁿ⁸⁴ *United States v. Vernon Home Health*, 21 F.3d 693 (5th Cir. 1994).

ⁿ⁸⁵ *Id.* at 695.

ⁿ⁸⁶ *Id.* at 696.

ⁿ⁸⁷ *Triad at Jeffersonville I v. Leavitt*, 563 F. Supp. 2d 1, 18 (D.D.C. 2008).

The U.S. Department of Health and Human Services (HHS) likely will take the position that *Vernon* applies to bankrupt and non-bankrupt providers alike. With regard to those decisions where payor agreements are treated in bankruptcy as executory contracts, a debtor's duty to assume any overpayment obligations and to obtain the affirmative consent of HHS before assigning the payor agreements largely eliminates any material distinction with the treatment of successor claims under non-bankruptcy law. However, there are reasons to question whether HHS can hold a buyer liable for the Medicare overpayments based on the *Vernon* decision if a debtor-seller sells its payor agreement rights as a property right under Section 363(f). As previously discussed, most courts to consider the issue conclude that a Section 363(f) sale eliminates a buyer's successor liability for any unsecured claims. In *In re BDK Health Management*, a bankruptcy court held that a debtor healthcare provider could sell its Medicare provider agreement free and clear of liens pursuant to a Section 363(f) sale without curing any defaults under the agreement because of the following: the agreement was not an executory contract, the government's overpayment rights were in bona fide dispute, and the nature of the overpayments was such that the court could force the government to take payment in cash to satisfy the interest.ⁿ⁸⁸

ⁿ⁸⁸ *In re BDK Health Mgmt.*, Nos. 98-609-B1 through 98-614-B1 (Bankr. M.D. Fla. Nov. 16, 1998). However, no courts have

followed the *BDK* court's reasoning.

However, even where a Section 363(f) sale is made free and clear of interests in the property, the equitable defense of recoupment provides one method for HHS to recoup any overpayments. (For discussion of recoupment, see "Post-petition recovery," beginning on page 10.) Courts have held that the government can assert a recoupment defense against a Section 363(f) purchaser of assets because equitable defenses are not interests in property that can be sold free and clear. n89 These decisions are in accord with other decisions that have concluded more generally that recoupment rights are not claims under the Bankruptcy Code that are subject to discharge. n90

n89 *See, e.g., Folger Adam Sec. v. DeMatteis/MacGregor, JV*, 209 F.3d 252 (3d Cir. 2000) (recoupment rights are still held against purchaser of assets on a successor liability theory because recoupment rights and other equitable defenses are not interests in property under § 363(f)). One court considering this issue authorized the sale of a debtor's provider number, but also found that the § 363(f) sale did not come free and clear of the government's recoupment rights. *In re Vitalsigns Homecare*, 396 B.R. 232,241 (Bankr. D. Mass. 2008). In allowing recoupment, the court in *Vitalsigns* fashioned an equitable remedy that required the government to first seek recoupment from any payments due to the debtor's estate, then against funds held by the Chapter 7 trustee if related to Medicare payments, then against the sale proceeds from the sale of the provider number, and only after exercising recoupment rights against these parties, then against the purchaser of the debtor's provider number. *Id.*

n90 *Mercy Hosp. of Watertown v. N.Y. Dep't of Soc. Servs.*, 171 B.R. 490, 495 (N.D.N.Y. 1994) (noting that the right to recoupment gives no right to actual payment, and therefore it is not a claim that can be discharged by a bankruptcy); *Mullen v. United States*, 696 F.2d 470, 471 (6th Cir. 1983) (Air Force's right to recoup prepaid retirement benefits was not a claim dischargeable in bankruptcy). *But see In re Kings Terrace Nursing Home*, No. 91 B 11478 (FGC), (holding that the government's right to collect Medicaid overpayments was a claim that could be discharged in bankruptcy and that rights did not arise from a single transaction such that recoupment could be exercised).

Thus, a buyer may be able to avoid successor liability associated with Medicare or Medicaid overpayments where a court construes the overpayments to arise from a statutory entitlement program (rather than an executory contract) and where the government is unable to assert a successful recoupment defense in connection with the overpayments.

Fraud and abuse liability

One decision from the U.S. Court of Appeals for the Eighth Circuit, *Deerbrook Pavilion v. Shalala*, n91 held that civil monetary penalties imposed against a healthcare provider based on health and safety violations may also be collected against the buyer of the seller-entity's Medicare provider agreement. The Eighth Circuit determined that there is no distinction between liability for Medicare overpayments and liability for civil monetary penalties, citing the *Vernon* decision, and held that the buyer must pay the civil monetary penalties. n92 Because *Deerbrook* only addressed successor liability for civil monetary penalties imposed by the Health Care Financing Administration (now known as CMS), it is unclear whether *Deerbrook's* rationale would extend to fraud and abuse and other administrative liabilities beyond the civil monetary penalties analyzed by the court in that case. In particular, a buyer that did not knowingly participate in wrongdoing would have substantial arguments that the scienter requirement in many civil, criminal, and administrative and fraud and abuse laws, such as the False Claims Act, is not satisfied. Buyers in such cases could argue that the rationale in *Vernon* and *Deerbrook* (i) is tied to liabilities arising under the payor agreement and not intent-based fraud and abuse laws, and (ii) should be left to a simple return of funds to the government and civil monetary penalties that do not require a showing of scienter. These arguments, however, potentially would not extend to civil liability under the Stark law, requiring the repayment of Medicare and Medicaid claims, because Stark is a strict liability statute requiring no scienter. n93

n91 *Deerbrook Pavilion v. Shalala*, 235 F.3d 1100 (8th Cir. 2000).

n92 *Id.* at 1104.

n93 See 42 U.S.C. § 1395nn.

As with overpayments, HHS likely will take the position that a debtor healthcare provider's assets cannot be sold free and clear of fraud and abuse liability through a sale in bankruptcy because any assessed penalties arise from the payor agreement. HHS could argue that the payor agreement is an executory contract that can be assumed and assigned only after any existing defaults are cured (for further discussion on assumption and assignment of executory contracts, see "Ability to transfer payor/provider agreements," beginning on page 33). HHS would argue further that the assessed penalties are monetary defaults under the payor agreement subject to the cure provisions. Courts may construe the payor agreement as an executory contract and agree that the debtor healthcare provider must pay civil penalties for fraud and abuse before assumption is effective. With respect to a Section 363(f) sale, HHS likely will argue that the *Deerbrook* decision constitutes applicable non-bankruptcy law and prevents a debtor healthcare provider from selling its Medicare or Medicaid provider agreement free and clear of fraud and abuse liability. However, it is likely that a court will interpret Section 363(f) to allow the sale of any rights free and clear of interests, such as the unsecured civil penalty claims held by a government agency.

To overcome a free and clear sale order, HHS must establish that HHS may recoup civil penalties owed to the government against the government's obligations to the debtor-seller or purchaser. In other words, a bankruptcy court would have to find that the penalties were accrued under the same transaction as the government's obligations to the debtor-seller or purchaser under the operative payor agreement. This position stretches the boundaries of the recoupment doctrine from an equitable defense employed in the overpayment context to a means by which the government effectively (and impermissibly) would be setting off the debtor-seller's post-petition Medicare reimbursement claims against the government's pre-petition civil penalties claims. The Third Circuit's restrictive view of the same transaction requirement in *University Medical Center* works in the debtor-seller's favor on this point. A debtor-seller should rely on this view for two purposes: (i) to establish that HHS is advocating for impermissible setoff in the guise of recoupment, and (ii) to blunt the effect of any holding that the civil penalties at issue accrued under the same transaction as the government obligations. n94

n94 See *In re Univ. Med. Ctr.*, 973 F.2d at 1081.

The Bankruptcy Code does not directly address whether the sale of a Medicare or Medicaid provider agreement pursuant to a plan of reorganization protects the buyer from fraud and abuse liability to the government. Section 1141(d)(6) provides that the confirmation of a plan does not discharge a corporation debtor from any debt of a kind specified in Section 523(a)(2)(A) that the debtor owes to a domestic governmental unit. n95 Section 523(a)(2)(A) prevents a discharge for debt for money or property obtained by false pretenses, a false representation, or actual fraud. n96 Although these sections only apply directly to a debtor healthcare provider emerging from bankruptcy--and not to a purchaser of the debtor's assets pursuant to the plan of reorganization--HHS likely will argue that these non-discharge provisions apply to civil penalties for false representations or fraud, and that these provisions evidence an intent in the Bankruptcy Code to obligate a debtor-healthcare provider and any successor to the debtor to pay these penalties.

n95 11 U.S.C. § 1141(d)(6).

n96 *Id.* § 523(a)(2)(A).

Practice Tip

A potential acquirer should conduct thorough diligence of a distressed healthcare provider regardless of whether it is contemplating a purchase inside or outside of bankruptcy. When the acquirer contemplates a purchase outside of bankruptcy, it should thoroughly review the distressed healthcare

provider's:

- . contracts and arrangements with referral sources;
- . corporate compliance program materials;
- . corporate integrity agreements, consent decrees, or other agreements with state or federal enforcement authorities;
- . pending or threatened litigation (including fraud and abuse investigations or litigation);
- . private payor and Medicare and Medicaid provider agreements;
- . billing and collection practices, particularly with governmental healthcare programs;
- . licenses, certificates of need, accreditations, and other permits required to operate business; and
- . audit reports addressing regulatory and compliance issues.

The potential acquirer should negotiate fulsome representations and warranties in the purchase agreement **protecting** it from any undisclosed liabilities.

Although an acquisition inside of bankruptcy may limit many liabilities associated with private contracts and arrangements, it may not limit successor liability associated with Medicare and Medicaid provider agreements (assuming such agreements are executory contracts) where debtor healthcare providers assume and assign those agreements to an acquirer. A sale inside of bankruptcy nonetheless requires a potential acquirer to perform much of the diligence listed above. To the extent that a buyer seeks to avoid government reimbursement liabilities, any related motion or plan should make that intent clear with appropriate notice to relevant authorities, and with appropriate findings that the buyer is not liable and/or that the buyer owes the government no amounts under the relevant provider agreement. That will at least give the buyer the argument that the order approving the sale is a final determination of the parties' rights if the relief is granted. n97

n97 Absent the appellant obtaining a stay pending appeal, Section 363(m) of the Bankruptcy Code renders moot an appeal of a sale of property of a debtor's estate to a good faith purchaser. *See, e.g., Paulman v. Gateway Venture Partners III (In re Filtercorp)*, 163 F.3d 570, 576 (9th Cir. 1998) ("When a sale of assets is made to a good faith purchaser, it may not be modified or set aside unless the sale was stayed pending appeal."). Section 363(m) advances the important goal of finality in bankruptcy sales, which enhances the value obtained by a bankruptcy estate from a sale of estate property and protects the rights of third-party purchasers who rely upon sale orders. *See In re Onouli-Kona Land Co.*, 846 F.2d 1170, 1172 (9th Cir. 1988) (recognizing the importance of finality in bankruptcy dispositions).

Ability to transfer payor/provider agreements

The distressed healthcare provider's ability to transfer payor agreements differs depending on whether the transfer is made prior to or after filing a petition for bankruptcy.

Pre-petition transfers

CMS allows a healthcare provider to undergo certain changes in ownership without automatic termination of the provider's Medicare provider agreement. Under the applicable federal regulation, changes of ownership (CHOWs) include:

1. the removal, addition, or substitution of a partner in a partnership;
2. the transfer of title and property from an unincorporated sole proprietorship to another party;

3. the merger or consolidation of a provider corporation resulting in the creation of a new corporation (*but not* the transfer of stock or the merger of another corporation into the provider corporation); or

4. the lease of all or part of a provider facility. n98

n98 42 C.F.R. § 489.18(a).

Although an asset sale does not constitute a CHOW pursuant to the plain language of the applicable federal regulation, n99 CMS interprets the regulation broadly to include any transfer of the Medicare provider agreement to an entity as a result of the entity's purchase of the provider. n100 Providers who are "contemplating or negotiating a change of ownership" must notify CMS. n101 Upon a CHOW, however, a provider assigns the existing payor agreement automatically to the new owner unless the provider takes steps to terminate the existing payor agreement. n102

n99 *See id.*

n100 *See* CMS, STATE OPERATIONS MANUAL §§ 3210-10.5C [hereinafter CMS]; Rodney A. & John A. Cogan, Jr., MEDICARE, MEDICAID, AND INSOLVENCY HANDBOOK: JURISDICTION, PAYMENT, AND ENFORCEMENT (2006) [hereinafter *Johnson & Cogan*].

n101 42 C.F.R. § 489.18(b).

n102 *Id.*

Assignments of Medicaid provider agreements are subject to state law requirements, which may differ depending on the state. Buyers and sellers of a distressed healthcare provider must review relevant state laws to determine whether the contemplated transfer triggers any notice or consent requirements. In addition to reviewing the relevant laws, buyers and sellers should contact the state's Medicaid agency to confirm any determination made by review of the law. Many states have adopted the same procedures as those required by CMS with respect to transfer of a Medicare provider agreement.

Finally, the contracts between the provider and the private payors will govern a distressed healthcare provider's ability to transfer private payor contracts prior to bankruptcy.

Post-petition transfers

A debtor healthcare provider will work with a potential acquirer to determine whether to assume and assign, or to reject, its private payor agreements and its Medicare and Medicaid provider agreements. Courts will consider most private payor agreements to be executory contracts; n103 therefore, a debtor healthcare provider may choose whether to assume and assign any one of them. n104 To assume and assign a payor agreement, the healthcare provider must (i) cure monetary and non-monetary defaults on the payor agreement or provide adequate assurance that such defaults will be promptly cured, n105 and (ii) provide adequate assurance of future performance under the payor agreement. n106 Additionally, the healthcare provider may not assume and assign a payor agreement if "*applicable nonbankruptcy law excuses a party, other than the debtor, to such contract . . . from accepting performance from . . . an entity other than the debtor or the debtor in possession . . . and such party does not consent to such assumption.*" n107

n103 In the bankruptcy context, an executory contract generally is viewed as one on which performance remains due to some extent on both sides. *See Collier*, P 365.02[1].

n104 *See* 11 U.S.C. § 365(a).

n105 *See id.* § 365(b)(1)&(2).

n106 *See id.* § 365(b)(3).

n107 *See id.* § 365(c)(1) (emphasis added.)

Even where a particular payor agreement contains an anti-assignment clause, the debtor healthcare provider may assume and assign the agreement if applicable non-bankruptcy law does not excuse the payor from accepting performance by a provider other than the debtor. n108

n108 *See id.* § 365(f).

Outside of bankruptcy, most courts treat Medicare and Medicaid agreements as non-contractual statutory entitlements. n109 In bankruptcy, however, many courts come to the opposite conclusion, treating such agreements as executory contracts. n110 Assuming that a Medicare or Medicaid agreement is treated as an executory contract, the debtor healthcare provider must cure monetary and non-monetary defaults under the agreement (including the repayment of overpayments) and provide adequate assurance of its future performance before it can assume and assign the agreement.

n109 *See Johnson & Cogan*, § 13-4, §§ 14-1(c), 14-2, 14-6.

n110 *See id.*

The government may argue that applicable non-bankruptcy law prevents the debtor healthcare provider from assuming and assigning the agreement without consent from the government. The Anti-Assignment Act generally allows the government to refuse performance under a government contract that has been transferred to a third party:

No [government] contract . . . or any interest therein, shall be transferred by the party to whom such contract . . . is given to any other party, and any such transfer shall cause the annulment of the contract . . . transferred, so far as the United States is concerned. n111

n111 41 U.S.C. § 15.

However, there is a lack of case law addressing whether the Anti-Assignment Act constitutes "applicable non-bankruptcy law," thereby barring assumption and assignment of a debtor healthcare provider's Medicare and Medicaid provider agreements in the absence of government consent. n112 The court in *In re University Medical Center* recognized this lack of case law and noted the government's failure to advance an argument in favor of the Anti-Assignment Act. n113 Assuming that the Anti-Assignment Act does apply, however, the debtor healthcare provider could argue that the federal regulation allows for the automatic assignment of Medicare agreements in certain circumstances, n114 and the government's policy of applying that regulation broadly constitutes implied consent to

assignment for purposes of bankruptcy law.

n112 *But see In re W. Elecs.*, 852 F.2d 79 (3d Cir. 1988) (allowing the government to terminate a military contract with the debtor because the Anti-Assumption Act barred the debtor from assigning the contract).

n113 *See In re Univ. Med. Ctr.*, 973 F.2d at 1076 n.15 ("The Secretary, however, does not contend that the Anti-Assumption Act is a factor in this case.").

n114 42 C.F.R. 489.18.

Absent allegations against the debtor of fraud, abuse, or providing substandard services, the government is likely to consent to the assumption and assignment of a Medicare or Medicaid agreement if the debtor healthcare provider agrees to satisfy all prior overpayments and other outstanding liabilities under the agreement at issue. n115 The government may use its consent rights to leverage its positions regarding amounts necessary to cure defaults under the agreement. Further, in light of its consent rights, the government may argue that the assumption and assignment process begins *automatically* once the provider performs any post-petition services under the Medicare or Medicaid agreement and seeks post-petition reimbursements. n116 However, the Third Circuit rejected this argument in *University Medical Center*, reasoning that a court first must approve any assumption and assignment of a debtor's executory contract. n117 In this case, because neither University Medical Center nor HHS asked the court to approve University Medical Center's assumption, the court never approved the assumption; thus, no assumption occurred. n118

n115 *See* "Successor liability," beginning on page 25 of this article.

n116 *See In re Univ. Med. Ctr.*, 973 F.2d at 1076; *but see In re St. Johns Home Health Agency*, 173 B.R. 238 (Bankr. S.D. Fla. 1994) (Debtor healthcare entity moved to assume its Medicare agreement and concurrently asked the court to determine that the overpayments owed to Medicare were far less than what Medicare had recouped. The bankruptcy court refused to make the determination because the debtor healthcare entity had not exhausted its administrative remedies as required under 42 U.S.C. § 405(h).)

n117 *In re Univ. Med. Ctr.*, 973 F.2d at 1076-79.

n118 *See id.* at 1077-78.

Practice Tip

When determining whether to assume and assign or reject certain payor agreements (including Medicare and Medicaid provider agreements), the debtor healthcare provider and potential acquirer should assess the benefits of assuming the agreements against the burdens of curing any defaults the debtor has under the agreements. The debtor healthcare provider's private payor agreements may carry more favorable terms than those available on the market; the benefits of such agreements may be short lived, however, because they tend to have short terms.

Additionally, there are administrative burdens associated with a buyer obtaining its own payor agreements. For example, obtaining a Medicare or Medicaid provider agreement often takes longer than six months (the timing varies with respect to the state Medicaid agency or Medicare regional office). A buyer that carefully coordinates state licensure surveys and other prerequisites with the closing date will be eligible for Medicare or Medicaid reimbursement on or near the closing date, but may not bill the programs until the buyer receives each applicable provider number. Buyers should consider the resulting lag in cash flow in the buyer's financial projections and anticipated capital requirements.

Ability to transfer state licenses and certificates of need

As with payor agreements, the distressed healthcare provider's ability to transfer state licenses and certificates of need differs depending on whether the transfer is made before or after a petition for bankruptcy.

Pre-petition transfers

Pre-petition transfers of state licenses and certificates of need (CONs) are subject to various state statutes and regulations. Depending on the structure of a transaction, transfers of licenses and CONs can require notice or approval by the relevant state agency. Buyers and sellers of a distressed healthcare provider should conduct proper diligence in connection with any pre-petition sale of the distressed healthcare provider or its assets to determine what the relevant state agencies will require. Proper diligence is time consuming and involves a multi-step process. First, buyers and sellers should review relevant state statutes and regulations to determine whether the contemplated transfer triggers any notice or consent requirements. Additionally, buyers and sellers should contact the appropriate state agency to confirm any determination made by review of the law.

Post-petition transfers

No case law directly addresses whether a distressed healthcare provider can transfer its state licenses and CONs to an acquirer without first seeking approval from the applicable state authority. The court decision in *In re United Healthcare Systems*, however, provides some guidance on the issue.ⁿ¹¹⁹ In this case, the New Jersey Commissioner of Health and Senior Services worked closely with United--a distressed pediatric facility--in a bidding process aimed at finding an entity to purchase the pediatric facility. Once a bidder was found, the Commissioner, on an expedited basis, simultaneously granted United a CON to close the pediatric facility and the acquirer a CON to operate the facility. As part of the purchase agreement for the pediatric facility, United was required to file Chapter 11.

ⁿ¹¹⁹ *In re United Healthcare Sys.*, No. 97-1159 (NHP) (D. N.J. Mar. 26, 1997); see *In re Sun Healthcare Group, Bank.* Case Nos. 99-3657 through 99-3841 (MFW), Civ. A. Nos. 00-986-GMS, (D. Del. Sept. 4, 2002).

Upon filing Chapter 11, United sought approval of the pediatric facility sale under Section 363(f). Following several objections from unsuccessful bidders on the pediatric facility, the bankruptcy court voided the sale and ordered United to apply for reinstatement of its CON. United appealed and received a stay of the bankruptcy court's order.

On appeal, the district court reversed, determining that the bankruptcy court had substituted its judgment for that of United's board of directors. The district court instructed, among other things, that the bankruptcy court should have considered the Commissioner's role in the sale: the Commissioner ordered United to find a buyer by a certain date and the Commissioner's involvement demonstrated the public health issues at stake. The district court also noted that the bankruptcy court's role did not permit it to question the Commissioner on issues of public health and safety, which were within the Commissioner's expertise. The court explained, "[T]he bankruptcy court does not have the power to interfere with state regulations exercised under the state's police power."ⁿ¹²⁰

ⁿ¹²⁰ *In re United Healthcare Sys.*, No. 97-1159 (NHP).

Despite the court's decision in *United Healthcare*, a bankruptcy court may have authority under bankruptcy law to effectuate a transfer of a state license or CON without the consent of the appropriate state authority. The court may look to the anti-discrimination provision (discussed in further detail in "Post-petition recovery," beginning on page 10), as well as to Section 105(a) of the Bankruptcy Code, which provides the court with equitable powers to carry out the provisions of the Bankruptcy Code.ⁿ¹²¹

n121 See 11 U.S.C. § 1055(a).

Practice Tip

When a buyer purchases a distressed healthcare provider outside of bankruptcy, it should perform thorough diligence to determine whether the contemplated transaction triggers any notice or consent requirements with respect to transfers of licenses and CONs in each applicable state. Depending upon the transaction's structure, some states may require a buyer to complete a new license or CON application. It can take considerable time to perform the diligence required, provide notices, obtain consents, and apply for new licenses or CONs, especially when the seller holds various provider licenses in multiple states. A buyer and seller of a distressed healthcare provider should be aware of the time it takes to complete these tasks and should add appropriate closing conditions in the purchase agreement. Additionally, a buyer and seller should address issues related to the transfer of licenses and CONs in the representations and warranties of the purchase agreement.

Inside of bankruptcy, a distressed healthcare entity should attempt to work closely with state authorities to effectuate an efficient transfer of licenses and CONs. As exhibited in *United Healthcare*, when such interest is in the best interest of public health and safety, the state authorities may welcome the open communications.

Lenders and Financing Healthcare Receivables

Lenders to buyers and sellers of distressed healthcare providers should be aware of several issues arising from the intersection of healthcare and bankruptcy laws. First are the complications in connection with obtaining a security interest in receivables from Medicare and Medicaid. With the addition of "health care insurance receivables" under revised Article 9 of the Uniform Commercial Code (UCC), significant issues related to financing private healthcare insurance receivables appear to have been resolved. n122 However, financing Medicare and Medicaid healthcare receivables remains complicated despite revised Article 9 because the lender may not collect Medicare and Medicaid healthcare receivables directly from the government. This difficulty may affect the ability of secured lenders to establish rights to the proceeds of receivables in the event of bankruptcy.

n122 See U.C.C. § 9-109(a)(3).

Security interest in private health insurance receivables

Revised Article 9 expressly applies to private healthcare insurance receivables. n123 Before the revision, lenders had to determine whether the transfer of an interest in those receivables involved a claim under an insurance policy--which would have been excluded under the former UCC--or a regular account receivable. Revised Article 9 removes this distinction, appearing to have resolved significant uncertainty with respect to assignments of, and security interests in, private health insurance receivables.

n123 See *id.* § 9-109(d)(8).

Security interest in Medicare and Medicaid receivables

Federal law provides that, subject to a few narrow exceptions, n124 Medicare and Medicaid payments owed to a healthcare provider cannot be made to another entity (e.g., the provider's lender) under an assignment. n125 Any attempt to assign Medicare or Medicaid receivables in violation of this anti-assignment rule could lead to the termination of the provider's payor agreement. n126 Revised Article 9 does not change this analysis. n127

n124 See 42 U.S.C. § 1395g(c)(1), (c)(2) (setting forth exceptions for assignments established by an order of a court or payments to billing agents of the Medicare provider.)

n125 See 42 U.S.C. §§ 1395g(c), 1395u(b)(6); 42 C.F.R. § 424.70 *et seq.* See also 42 U.S.C. § 1396a(a)(32); 42 C.F.R. § 447.1 *et seq.*

n126 See Termination of Provider Agreement, CMS, Dep't of Health & Human Servs., 42 C.F.R. § 424.74. *Cf.* Provider Agreements and Supplier Approval, CMS, Dep't of Health & Human Servs., 42 C.F.R. pt. 489.

n127 See U.C.C. § 9-109(c)(1).

Despite this anti-assignment rule, several courts have concluded that lenders may obtain a valid and perfected security interest in a provider's Medicare and Medicaid receivables, depending on state law. n128 Lenders, however, often seek additional security when it comes to a provider's accounts receivable. Such lenders often require that the provider give some measure of control in the provider's depository accounts to the lender, frequently in the form of a blocked account agreement.

n128 See *In re* Missionary Baptist Found. of Am., 796 F.2d 752 (5th Cir. 1986); *In re* Am. Care Corp., 69 B.R. 66 (Bankr. N.D. Ill. 1986); *Snowden Inv. v. SCI-Wentzville Care Ctr.*, 896 S.W.2d 732, 733 (Mo. Ct. App. 1995); *Bank of Kansas v. Hutchinson Health Servs.*, 3 UCCRS2d 1537 (Kan. Ct. App. 1987); *In re* Angiulli, 14 UCCRS2d 1197 (N.Y. Surr. Ct. 1990).

CMS has issued guidance clarifying that providers may not give lenders control over depository accounts where Medicare or Medicaid proceeds are deposited. CMS is allowed to deposit Medicare and Medicaid payments in the provider's account with a financial institution that has a lending relationship with the provider, as long as the provider retains control over the account. This means that:

1. The account must be in the provider's name only.
2. Only the provider may issue any instructions on the account.
3. The depository bank must be bound by the provider's instructions in all instances. Where the lender is also the depository bank, the loan agreement must provide that the lender waives its right of offset. n129

n129 CMS, § 30.2.5.

CMS's guidance specifically contemplates arrangements where a provider issues standing instructions for the depository bank to sweep funds into an account that is not under the provider's sole control. Such arrangements are permissible as long as the depository bank is required to honor orders by the provider to rescind its standing sweep instructions regardless of whether such rescission violates the financing agreement between the bank and the provider. n130

n130 *Id.*

Expanded Administrative Claims Under BAPCPA

Next, lenders to buyers and sellers of distressed healthcare providers should consider the list of administrative expense priorities as expanded by BAPCPA relating to healthcare providers. BAPCPA expanded the list of administrative expense priorities that would apply to debtor healthcare providers. The expansion impacts the relative priority positions among creditors of a distressed healthcare provider. The Bankruptcy Code, as amended by BAPCPA, provides administrative expense priority to:

1. actual and necessary costs and expenses of closing a healthcare business as incurred by a trustee, federal agency or department, or agency of a state or political subdivision;
2. actual and necessary costs and expenses incurred in connection with a closure to dispose of patient records under new Section 351 of the Bankruptcy Code, and to transfer of patients under new Section 704(a)(12) of the Bankruptcy Code; and
3. fees and expenses awarded under Section 330(a)(1) of the Bankruptcy Code to a patient care ombudsman appointed under new Section 333 of the Bankruptcy Code.

Prepetition lenders to a distressed healthcare provider should be aware of these additional administrative expense priorities because the Bankruptcy Code requires a debtor healthcare provider's estate to pay these expenses before any payments can be made on unsecured claims, including deficiency claims of secured lenders. Costs associated with the appointment of a patient care ombudsman and with the closure of the healthcare provider (where applicable) could be significant. Where the value of a lender is undersecured, these administrative expenses will further deplete the debtor's estate, leaving fewer assets available to pay back any undersecured portion of the lender's loan.

Practice Tip

When a distressed healthcare entity receives reimbursement from Medicare or Medicaid, a buyer and seller of a distressed healthcare provider could face numerous actions by the government that could financially devastate the healthcare provider. Such actions include the government's ability to:

1. recover overpayments;
2. exclude or suspend the healthcare provider from receiving reimbursement from federal health programs; and
3. initiate fraud and abuse actions (including administrative actions) against the healthcare provider.

Whether a lender is providing DIP financing to a seller of a distressed healthcare provider or acquisition financing to a buyer of a distressed healthcare provider, it should take certain steps to help ensure that a buyer or seller of a distressed healthcare provider will be able to repay any financing provided by the lender.

First, a lender should take a security interest in all accounts receivables of a healthcare provider, including all Medicare and Medicaid receivables. Additionally, in the case of non-governmental receivables, a lender should require blocked account agreements giving the lender control of such accounts in the event of the provider's default. In the case of governmental receivables, such as Medicare and Medicaid receivables, a lender should require that the provider issue standing instructions to sweep proceeds of all governmental receivables into an account subject to a blocked account agreement. The loan documents should clearly state that any change in instructions without the consent of the lender constitutes an event of default under the credit agreement. This bifurcated approach with governmental and non-governmental receivables may create certain operational difficulties, but it is often the best approach to provide the lender with the maximum security permitted under the law.

Second, a lender should examine a provider's history of Medicare and Medicaid overpayments to discover any potential for excessive current payments being recovered by the government out of future revenues. A lender should review the provider's calculation of, and bases for, periodic interim payments on an ongoing basis, including comparison with prior years' experience and explanation of any discrepancies. A lender should require prompt delivery of:

1. the provider's interim and final cost reports, which are often the basis for the fiscal intermediary's determination of over or underpayment;
2. copies of any responses to such reports;
3. copies of all statements, studies, or reports submitted by the provider to the government or any nationally recognized accreditation association or commission; and
4. copies of all audits, studies, or reports prepared and delivered to the provider by the government or any such association or commission.

Third, a lender's ability to obtain the information necessary to protect its interest in Medicare and Medicaid receivables should not be left to the borrower's discretion. Thus, covenants in the loan documents should address:

1. Medicare and Medicaid overpayments and suspension of payments;
2. failure of financial tests indicating possible insolvency;
3. litigation (including qui tam, fraud and abuse, and administrative investigations);
4. complaints, claims, audits, notices, or requests for information by or on behalf of a governmental or regulatory body; or
5. suspension, termination, modification, revocation, withdrawal, decertification, or restriction of any governmental or regulatory license, agreement, or permit.

The loan documents should require the buyer or seller to deliver to the lender copies of all governmental or regulatory licenses, agreements, or permits applicable to the healthcare provider. Further, the representations and warranties in the loan documents should address (i) the sufficiency of governmental or regulatory licenses, agreements, or permits, and (ii) the existence of litigation against the healthcare provider (including qui tam, fraud and abuse, and administrative investigations). Finally, the loan documents should address potential events of default, including certain changes to governmental or regulatory licenses, agreements, or permits; investigations or audits by a governmental or regulatory body resulting in liability; and withdrawals by the healthcare provider of money from an account with respect to which the lender has entered into a sweep agreement.

Conclusion

Although distressed healthcare providers may present attractive, profitable opportunities for potential buyers and lenders, there are many difficult legal issues potential buyers, sellers, and lenders need to consider when contemplating a transaction involving a distressed healthcare provider. The complex intersection of healthcare and bankruptcy laws requires that buyers and sellers of a distressed healthcare provider remain closely involved in the reorganization of the provider so that they can monitor the short-term viability of the provider, the potential liabilities related to Medicare and Medicaid overpayments and alleged fraud and abuse violations, and the provider's ability to most efficiently transfer its payor agreements and state licenses and CONs.

The convergence of healthcare and bankruptcy laws also requires a potential lender to a distressed healthcare

provider to consider issues related to securing its loan, assessing its priority among other lenders, and ensuring that the provider remains viable during the term of its loan. Keeping these issues in mind, potential buyers and lenders can make an informed business decision regarding whether to transact with the distressed healthcare provider.

Appendix

I. Common fraud and abuse laws

All healthcare providers, distressed or not, should routinely consider their exposure to fraud and abuse laws commonly applied to healthcare providers, including the following.

The Federal Anti-Kickback Statute (AKS). n131 The AKS prohibits persons from knowingly and willfully offering or receiving remuneration in return for a referral or recommendation of federal healthcare program business. Safe harbor regulations that protect against AKS liability apply to certain financial arrangements that are viewed as less likely to lead to fraud and abuse; however, failure to satisfy the conditions of a safe harbor will not automatically lead to liability. A violation of the AKS may lead to imprisonment, exclusion from Medicare and Medicaid, criminal fines of up to \$ 25,000 per act, False Claims Act liability, and civil money penalties of up to \$ 50,000 per act plus up to three times the remuneration amount.

n131 42 U.S.C. § 1320a-7b(b).

The Stark Law (Stark). n132 Stark prohibits a physician from making referrals for designated health services to providers with which the physician (or an immediate family member) has a financial interest. Stark is a strict liability offense unless an exception applies. A violation of Stark may lead to exclusion from Medicare and Medicaid, False Claims Act liability, and civil money penalties. All Medicare and Medicaid claims made while in violation of Stark must be repaid.

n132 *Id.* § 1395nn.

The Civil False Claims Act (FCA). n133 The FCA prohibits persons from knowingly presenting or causing to be presented a false or fraudulent claim for government payment or approval. Notably, the scienter element of the FCA requires the government to demonstrate that the defendant acted with reckless disregard or deliberate ignorance of the truth or falsity of the claim in question. Potential FCA penalties include treble damages or civil money penalties of up to \$ 11,000 per claim. There also is a criminal FCA, which has a higher scienter requirement and imposes criminal penalties.

n133 31 U.S.C. §§ 3729-33.

The Civil Monetary Penalties Law (CMP). n134 The CMP allows for civil money penalties based on false or fraudulent claims, or claims for services that are not medically necessary. In addition, the CMP provides penalties for other prohibited conduct, including violations of the AKS and Stark. n135 The CMP applies to all submitted claims, regardless of whether they have been paid, and the potential penalties vary depending on the specific conduct at issue (although they generally range from \$ 10,000 to \$ 50,000 per violation). The CMP also provides for exclusion from Medicare and Medicaid.

n134 42 U.S.C. § 1320a-7a.

n135 *See id.* § 1320a-7a(a)(7); 42 U.S.C. § 1395nn(g)(3).

State Fraud and Abuse Laws. Many states have enacted laws similar to the AKS, Stark, and the FCA. The conduct reached by these provisions and the extent of the potential penalties under them vary by state. Buyers, sellers, and lenders should consider them thoroughly before contemplating a transaction involving a distressed healthcare provider.

II. Enforcement of fraud and abuse laws

Various parties may bring enforcement actions under some or all of the fraud and abuse laws, including the following.

The Office of Inspector General (OIG). The OIG may bring administrative sanction actions to exclude healthcare providers from Medicare and Medicaid, n136 and to impose civil money penalties based on violations of the CMP. n137 In determining the amount or scope of any penalty, assessment, or exclusion imposed pursuant to the CMP, the OIG must consider:

1. the nature of claims and the circumstances under which they were presented;
2. the degree of culpability, history of prior offenses, and financial condition of the person presenting the claims; and
3. such other matters as justice may require. n138

n136 *See* 42 U.S.C. § 1320a-7. Grounds for exclusion are enumerated in the statute and include crimes such as defrauding the Medicare program, and/or the revocation or suspension of a particular license. *Id.*; *see, e.g.*, *Manocchio v. Kusserow* 961 F.2d 1539 (11th Cir. 1992).

n137 *See* 42 U.S.C. § 1320a-7a.

n138 *See id.* § 1320a-7a(d).

The OIG's imposition of sanctions is governed by 42 C.F.R. parts 1001 (for exclusions) and 1003 (for civil monetary penalties), and appeals of OIG sanctions are governed by 42 C.F.R. part 1005. A health-care provider must exhaust its administrative appeals before it may seek review of OIG sanctions in federal court. n139 In addition, under the CMP, matters that were raised or could have been raised in an administrative hearing or appeal may not be raised in defense of an action brought by the U.S. Department of Justice to collect or impose a CMP penalty, assessment, or exclusion. n140

n139 *See id.* § 1320a-7a(e); 42 U.S.C. § 1320a-7(f); *see also* 42 U.S.C. § 405(g), (h).

n140 *See id.* § 1320a-7a(g).

The U.S. Department of Justice (DOJ). The DOJ may bring criminal and civil fraud and abuse actions against healthcare providers. n141 There is an effort by the DOJ to work with the OIG to facilitate the enforcement of the fraud and abuse laws as part of the Health Care Fraud and Abuse Control Program (the HCFAC). n142 The HCFAC establishes a national framework to coordinate federal, state, and local law enforcement efforts to investigate and prosecute healthcare fraud and abuse in the public and private sectors. n143

n141 See THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE DEPARTMENT OF JUSTICE HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2007 43-46 (Nov. 2008).

n142 See *id.* at 1-4; 42 U.S.C. § 1320a-7c.

n143 See *id.*

Qui Tam Plaintiffs. Private individuals may bring actions under the FCA as qui tam plaintiffs. n144 In a qui tam action, the DOJ reviews the allegations under seal and then determines whether to intervene. If the DOJ intervenes, the qui tam plaintiff is eligible to receive between 15 and 25 percent of the total recovery from the healthcare provider. n145 If the DOJ does not intervene, the qui tam plaintiff may maintain the action independently and is eligible to receive between 25 and 30 percent of the total recovery. n146

n144 31 U.S.C. § 3730(b).

n145 *Id.* § 3730(d)(1).

n146 *Id.* § 3730(d)(2).

State Attorneys General. State attorneys general may bring actions against healthcare providers under state fraud and abuse laws and Medicaid laws. As discussed, the laws governing these actions vary by state and should be considered carefully based on the circumstances of each provider.

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LENGTH: 5628 words**TITLE:** Before and After Cruzan in Illinois: A State Supreme Court Addresses the Issue of Withholding Nutrition and Hydration from an Incompetent Patient**AUTHOR:** Deborah Carroll, Joining the firm of Lord Bissell & Brook. B.S.N., 1980, University of Illinois; J.D., 1990, DePaul University College of Law.**TEXT:**

I. INTRODUCTION

The marvels of medical technology have given society hope where there was once none and have given individuals a chance for life where previously none had existed. However, in medicine's endless quest to explore the parameters of technology to improve and expand life, it has also created an extension of life, which may more appropriately be termed the threshold of death. [n1] Thousands of American citizens are successfully resuscitated from death's grasps only to survive in a vegetative state as a result of prolonged oxygen deprivation, resulting in irreversible brain damage. The fate of these American citizens will continue to be the focus of fervent legal debate in the wake of the United States Supreme Court decision in *Cruzan v. Director, Missouri Department of Health*. [n2]

In *Cruzan*, the Court recognized a patient's right to refuse treatment based on a common law right to bodily integrity and liberty interests derived from the Due Process Clause. However, since an incompetent patient cannot make such decisions, the Court concluded a state's interest in preservation of life could in some instances override a surrogate's decision to terminate treatment. Additionally, the Court concluded the federal constitution did not prohibit a state from requiring clear and convincing evidence before treatment could be terminated. Prior to the *Cruzan* decision, the majority of courts allowed surrogates to give permission for the withdrawal of treatment. [n3] The full impact of *Cruzan* on state courts remains to be seen. The Illinois Supreme Court recently provided a unique window through which to view the impact of *Cruzan* in its disposition of a pair of refusal of treatment cases. *In re Longeway*, [n4] was decided just months before *Cruzan* and *In re Greenspan* [n5] was released following issuance of the opinion in *Cruzan*. In both cases the Illinois Supreme Court upheld a surrogate's right to refuse artificial sustenance on behalf of an incompetent patient. The court in *Longeway* declined to premise their opinion on a federal constitutional analysis, absent Supreme Court delineation of a constitutional right to refuse treatment. [n6] However, the court did find a right to refuse treatment based on the common law right to bodily integrity and the doctrine of informed consent, as well as in Illinois statutes. [n7] Although the court in *Greenspan* acknowledged the *Cruzan* opinion, it did not rely on a federal liberty interest in recognizing a right to have treatment withdrawn or withhold. Instead, the *Greenspan* court continued to rest its decision on the same common law and statutory bases as in *Longeway*. [n8] In the aftermath of *Cruzan*, the *Greenspan* decision which upheld the patient's right to refuse treatment based on common law and statutory premises, rather than on constitutional grounds, suggests a continued trend toward allowing surrogate termination of treatment based on such legal premises.

Both Illinois cases utilized a substituted judgment test as the standard for determining an incompetent patient's

choice. This test may be satisfied by a finding of express intent or implied intent inferred from the patient's value system. [n9] However, the Illinois court requires such a test be satisfied by clear and convincing evidence, a seemingly unlikely possibility when the family seeks to establish the patient's intent through implied rather than express measures. Therefore, while the decisions hold that surrogates may refuse artificial nutrition and hydration for incompetents, they fail to give clear guidelines for surrogate decision-making.

However, the Illinois Supreme Court emphasized a need for a statute to govern situations where patients have not executed living wills or a durable power of attorney of health care. In response, an Illinois State's Attorney Task Force has drafted model legislation. *Cruzan* indicated states may determine what methods are appropriate for governing surrogate termination of treatment. Illinois may have an opportunity to provide national leadership by passing legislation which more definitively addresses this medical-legal dilemma.

II. BACKGROUND

Courts have utilized various legal premises to form the basis for concluding surrogates may consent, on behalf of an incompetent patient, to have medical treatment withdrawn. Termination of treatment has been allowed on the basis of the patient's constitutional right to privacy, [n10] the patient's constitutional liberty interest, [n11] the common law right to be free from nonconsensual bodily invasion, [n12] and on statutory enactments which allow a presently incompetent patient to exercise his right to refuse treatment through the execution of a living will or durable power of attorney for health care.

The constitutional basis for the right to refuse treatment was first articulated in *In re Quinlan*, [n13] when the New Jersey Supreme Court concluded a patient's right to refuse treatment was encompassed within the federal and state constitutional right to privacy. [n14] While this analysis has been adopted by some courts, it has been criticized by legal scholars as unnecessary and problematic. [n15] One of the primary problems arising from the constitutional analysis is analogizing the right to refuse treatment to abortion cases. In the abortion context, courts apply a waxing and waning approach to the right to privacy analysis. As a pregnancy comes closer to term, the woman's rights diminish and the state's interest grows. In *Quinlan*, the court concluded the state's interest weakens and individual privacy rights increase as the degree of bodily invasion increases and the prognosis decreases. [n16] However, such an analysis has been criticized as over **protecting** some patients and under **protecting** others. [n17]

Other courts addressing the right to refuse treatment have premised their analysis on the common law doctrine of informed consent, which evolved from the common law right to be free from bodily invasion. [n18] These two common law premises form the basis for a patient's right to refuse treatment and have been extended to allow surrogates to refuse treatment on behalf of incompetents. This analysis is buttressed by the findings of the Supreme Court in *Cruzan*. [n19]

Regardless of the legal premise which authorizes the surrogate to refuse treatment, any such rights are not absolute and must be balanced against countervailing state interests. The state interests include: preservation of life; protection of the interests of innocent third parties; prevention of suicide; and maintaining the ethical integrity of the medical profession. [n20] These interests are shaped by state public policy, which is reflected in common law, as well as statutory enactments such as living wills and durable powers of attorney for health care. The particular state public policy determines whether those interests override the individual's interests, as the Missouri Supreme Court concluded they did in *Cruzan*. [n21] Conversely, in *Longeway*, the Illinois Supreme Court concluded that normally none of the state interests would override a patient's refusal, through a surrogate, of artificially administered food and water since adequate safeguards existed to protect the state's interests. [n22]

Numerous courts have addressed the issue of whether life-sustaining measures may be withdrawn from incompetent patients. With the exception of the Washington and Missouri Supreme Courts, the consensus of courts has been to allow the withdrawal of life-sustaining procedures under appropriate circumstances. In *Cruzan*, the state court recognized a limited common law right to refuse treatment, but expressed serious doubts that any constitutional right to privacy applied to such circumstances. [n23] The United States Supreme Court declined to analyze *Cruzan* under the

right to privacy; instead the Court engaged in a more flexible liberty versus state interest balancing test. [n24]

Two major tests applied by courts have been characterized as the subjective test or "substituted judgment" and the objective or "best interests" test. [n25] Substituted judgment is utilized when the patient has expressed his or her intent regarding treatment, while the best interests test involves weighing the burdens and benefits of the patient's treatment. Recently, the New Jersey Supreme Court suggested the subjective test could be further divided into two standards. The "specific intent" subjective test is to be applied when a patient has clearly and specifically expressed his or her subjective intent either through verbal statements or written documentation. Alternatively, when the patient has not clearly expressed his or her intentions, the substituted judgment analysis can be used to attempt to establish as accurately as possible what decision the patient would have made if competent. [n26]

In instances where the incompetent patient never expressed his or her desire regarding life-sustaining procedures or in cases of life-long incompetents who have always lacked the capacity to decide, the courts have utilized the best interests approach. Under this approach, the surrogate decision-maker, acting as a reasonable person experiencing the patient's circumstances, chooses a course of treatment which promotes the patient's well-being. [n27] The variables considered in making a best interest analysis include "relief from suffering, preservation or restoration of functioning, and quality and extent of sustained life." [n28]

Strict application of either the subjective or objective test has been criticized as stretching an incompetent's right to choose past its breaking point. The weakness with the subjective test is that it under emphasizes the ways in which incompetent patients differ from competent ones. [n29] Conversely, the objective test obscures the ways in which incompetent patients are similar to competent patients. [n30] These weaknesses arise from the desire of courts to premise their holding on the belief that the patient is exercising his or her own right to self-determination. Framing legal decisions in such terms perhaps eliminates a need for the court to address the underlying ethical dilemma of such decisions. For if indeed, the patient is not "choosing" to refuse treatment, the question of whether such actions constitute euthanasia might become an issue.

Some commentators assert that supporting proxy termination of an incompetent patient's treatment are the beginnings of active euthanasia. [n31] A change in the obligation to provide medical treatment to seriously ill and incompetent patients is seen as creating a legal climate that is favorable to allowing intentional killing, either by omission or direct action. [n32] In particular, the removal of artificial means of providing nutrition and hydration is seen by some as particularly dangerous and the true beginnings down the slippery slope towards legalized euthanasia. According to this belief, artificial sustenance is seen as critically different from other medical treatments because of its symbolic significance of human caring and nurturing. Some believe that allowing the removal of artificial sustenance will lead to a breakdown in the societal barriers against killing. [n33] Thus, one commentator concluded: "Those few terminal patients who may desire to be 'helped to die' must rather be helped to realize that their acceptance of the natural process is an acceptable cost of securing the general protection of human life afforded by the prohibition of direct killing." [n34]

However, acceptance of the natural process has been frustrated by the unlimited bounds of medical technology, so that the natural dying process as it was once known, is a rare occurrence today. While concerns regarding a breakdown in societal prohibitions against killing are legitimate, [n35] barriers to such breakdowns can be erected without requiring individuals to endure medical treatment which serves no chance for improving the patient's condition. Active euthanasia, which involves the intentional taking of life, should and can be distinguished from passive euthanasia, wherein the individual is allowed to die. Appellate court decisions addressing the issue of withholding medical treatment and state "living will" statutes support a medical, legal, and moral consensus that a strict distinction can and should be made between the withdrawal of medical treatment and euthanasia. [n36] While one commentator noted involuntary euthanasia has become so rampant in Holland that elderly patients are afraid to be hospitalized, [n37] will the converse be true in America? Will American citizens fear being hospitalized because they too may become a Nancy Cruzan or a Dorothy Longeway or one of the countless thousands of individuals who persist in vegetative states with no hope of recovery, while their family helplessly stands by? Are endless court battles the only choice? Thus far, the

patchwork quilt of decisions has not provided a clear workable framework for addressing this problem. The Illinois Supreme Court decision in the two companion cases adds little insight into the problem.

III. THE ILLINOIS COMPANION CASES

The petitioner in *Longeway*, a seventy-six-year-old woman, suffered a stroke approximately thirteen years earlier, rendering her permanently unconscious. [n38] Mr. Greenspan, a **nursing home** resident, is also in a persistent vegetative state (PVS) as a result of a stroke. [n39] Neither patient is brain dead and both receive nutrition and hydration through feeding tubes. In *Longeway*, the patient's daughter petitioned the court to have the gastrostomy tube removed. The *Greenspan* petitioner, the public guardian, requested the same. Although neither patient had a living will nor an executed health care power of attorney, both families testified the patient's subjective intent would be to withdraw the feeding tube. [n40]

The Illinois Supreme Court in *Longeway* concluded nutrition and hydration by artificial means does constitute medical treatment and the patient has the right to refuse such treatment under the common law. [n41] Furthermore, the court found the state Probate Act implicitly authorized a guardian to exercise the right to refuse artificial sustenance on a ward's behalf. [n42]

The *Longeway* court identified four necessary conditions to be satisfied before a surrogate may refuse artificial sustenance on behalf of an incompetent. First, the patient must be terminally ill and also be diagnosed as either in a PVS or as comatose. [n43] The court relied on the state living will statutory definition of a "terminal condition": an incurable and irreversible condition which is such that death is imminent. Second, the court must balance the patient's right to discontinue artificial sustenance against any state interests. However, the court concluded normally such interests would not outweigh a patient's right to refuse sustenance. [n44] Third, the incompetent patient's wishes must be ascertained. The court utilized the substituted judgment standard, but indicated the patient's intent could be determined either directly by express intent or implicitly from the patient's personal value system. [n45] However, intent must be established by clear and convincing evidence. [n46] Fourth, the court concluded there must be a judicial determination whenever a surrogate seeks to withdraw artificial sustenance. The court requires a judicial order to prevent the possibility of greed influencing a surrogate's judgment and to protect the state policy favoring life. [n47]

The *Longeway* court required an incompetent patient be in a PVS and terminally ill before a surrogate could exercise substituted judgment on behalf of the patient. Although the *Greenspan* court purports to retain these requirements, the court takes liberties with the statutory definition of terminal illness, diluting the requirement, and arguably expanding the scope of a surrogate's authority. Under *Greenspan*, whether death is imminent must be judged as though the treatment to be refused were already absent. [n48] According to the *Greenspan* dissent, this definition of terminal illness effectively eliminates the requirement of terminal illness. [n49]

A. Substituted Judgment and the Requirement for Clear and Convincing Evidence

The Illinois Supreme Court concluded, in these companion cases, the most appropriate method to determine the patient's wishes is the use of the substituted judgment test. The court repeatedly emphasized the basis for its reasoning was to effectuate the incompetent patient's right to refuse medical treatment based on the common law right to freedom from bodily invasion and on the requirement of informed consent for medical treatment. The emphasis on the patient's right to refuse treatment has been stressed by the majority of courts addressing this issue because of the grave concern over moving onto the slippery slope towards euthanasia. [n50] Several courts have recognized that effectuating the incompetent's right to decide is the exercise of a legal fiction. [n51] However, legal fictions are sometimes necessary in addressing complex legal, ethical, and religious dilemmas that do not perfectly conform to precise legal rules.

Courts have preferred to use the substituted judgment test over the best interests approach whenever possible, as the best means of effectuating the patient's intent. [n52] However, courts have recognized substituted judgment is not equal to a competent patient exercising his or her right to bodily integrity. Nonetheless, the substituted judgment approach

seeks to effectuate what the patient would have chosen. The focus is on a subjective not an objective balancing because the latter has the potential for raising questions as to the quality of an individual's life. Because of the potential for moving towards active euthanasia based on such analysis, the courts have steered away from quality of life evaluations. However, both jurists and legal scholars have noted the inherent difficulty in applying a true subjective or objective approach. [n53]

A purely subjective approach tends to de-emphasize the fact that the patient is no longer competent and cannot actually decide. Such a focus on pure subjective intent has led to unrealistic expectations regarding the burden of proof that some courts have required. [n54] Requiring clear and convincing evidence, when the patient has not expressed clear and specific intent, may amount to an insurmountable burden that the family cannot realistically satisfy. [n55]

Courts recognize that a surrogate makes a decision based on beliefs of what the patient would have wanted and that a surrogate's decision is often based on knowledge which may be deeply and profoundly known, but is difficult to clearly articulate by clear and convincing evidence. Thus, some courts have abandoned requiring such a burden of proof. The New Jersey Supreme Court has concluded that where a patient's intentions have not been clearly established by clear and convincing evidence, the court will uphold the termination of treatment based on trustworthy evidence establishing what the patient would have wanted. [n56] Similarly, a California appellate court has rejected the requirement of clear and convincing evidence to establish a patient's intent. [n57] The Supreme Judicial Court of Massachusetts also has concluded the primary goal of substituted judgment is to determine, with as much accuracy as possible, the desires and needs of the individual involved. [n58]

Furthermore, even when courts have utilized the substituted judgment approach, there has been a recognition that the line between the substituted judgment and best interest approaches often becomes blurred. Two concurring opinions in the New Jersey decision in *Jobes* discuss the range of proof that exist in termination of life-support cases. One opinion notes that the uncertainty of the incompetent's "self-determination" inevitably leads to an intertwining of the subjective self-determination approach and an objective best interests approach, where certain objective factors may shore up decisions based on self-determination. [n59] Another opinion noted the blending of the two concepts is not surprising since "patients generally want for themselves that treatment or nontreatment that is in their best interests. Thus, in exercising their substituted judgment, family members ordinarily will make a treatment decision that is in the patient's best interest." [n60] As one commentator noted, interests are inextricably tied to preferences, goals, and desires. [n61] Thus, a blending of the subjective and objective variables may occur.

The Illinois Supreme Court did not apply the "best interests" test in the companion cases before it, because the court concluded the substituted judgment analysis was more appropriate. It did not decide the viability of such a test in Illinois, but noted a criticism of "best interests." Substituted judgment permits another to make a determination of a patient's quality of life and therefore undermines the foundation of patient self-determination. [n62] Judicial emphasis on the legal premise of the right to self-determination is understandable and appropriate in dealing with public policy issues concerning the ramifications of medical technology and the need to reach an appropriate balance between the preservation of life and the imposition of death-delaying procedures and treatment. However, commitment to such legal premises should not be blindly followed without recognition of the shortcomings when applied to incompetent patients.

While courts seek to effectuate a patient's choice, some have begun to recognize the evidentiary limitations in achieving this goal. The New Jersey Supreme Court recognized family members as the best equipped to intimately know the patient's desires, though the type of evidence they can present to support their belief the patient would have chosen to have life support withdrawn may be limited. [n63]

The Illinois Supreme Court appears to recognize the limitations the New Jersey court expressed in *Jobes*. Thus, the court in *Longeway* concluded there need not be specific express evidence of the patient's intent. The *Longeway* court rejected the requirement of a finding of specific intent to satisfy the substituted judgment. [n64] Thus, the Illinois Supreme Court openly rejects limiting the subjective approach to an evidentiary finding of express specific intent.

The court came to the conclusion that where no clear intent exists, the patient's personal value system must guide the surrogate. The court noted even when no prior specific statements were made, a court may infer the patient's intent from his or her prior mental life, including philosophical, religious and moral views, life goals, values, and attitudes towards sickness and medical procedures. [n65] While express intent may be determinative when available, it is not absolutely necessary for surrogate decision making. Therefore, the surrogate may rely on the above variables to ascertain the patient's desires. While the court recognizes that the family's knowledge may be intuitive and difficult to articulate, it nonetheless concludes such proof must be based on clear and convincing evidence to foster the state's public policy favoring life.

Clear and convincing proof is defined as proof beyond a reasonable, well-founded doubt. [n66] The *Jobes* court further defined clear and convincing evidence as that which "produces in the mind of the trier of fact a firm belief or conviction as to the truth of the allegations sought to be established, evidence so clear, direct and weighty and convincing as to enable [the factfinder] to come to a clear conviction, without hesitancy, of the truth of the precise facts in issue." [n67]

It is difficult to comprehend how a family's knowledge or intuition of a patient's prior mental life, philosophy and values, can often, if ever, satisfy a standard of evidence so clear, direct, and weighty as to enable the factfinder to come to a clear conviction without hesitancy of the true facts at issue. Indeed, it is precisely because the patient cannot speak that the facts are not clear and direct. In the face of this uncertainty, the family, who is in the best position to know the patient's desires and to be able to reflect those desires, should be given the deference necessary for them to indirectly effectuate the patient's choice. Recognizing this as an indirect determination, courts should accept the limitations of the situation and instead rely on a standard that reflects trustworthy evidence of what the patient would have intended. Such a standard does not disregard the gravity of the decision, but recognizes the limitations of the circumstances, while providing other mechanisms to safeguard the patient's rights.

B. Judicial Interventions and Other Safeguards

The majority of courts do not require judicial intervention to withdraw artificial life-support. [n68] However, the Illinois Supreme Court, concluded judicial intervention was necessary before artificial sustenance could be withdrawn. The court reasoned this was necessary to preserve strong public policy interests in preserving the sanctity of life. Whether judicial review is required for all termination of life-support cases is still an open question.

Requiring judicial intervention may be criticized for several reasons. First, the Illinois Supreme Court concluded normally none of the state's interests would override a patient's refusal of artificial sustenance. Yet, it requires court intervention to protect those very same interests. Second, such intervention removes the decision-making process from those who are in the best position to know what the incompetent patient would desire. Third, decisions regarding termination of life-support are extremely frequent occurrences in the health care setting and are more properly decided by the health care team and the incompetent's significant others. Protracted and costly court proceedings may deter families from effectively engaging in exercising the incompetent's right to refuse treatment. Last, requiring judicial review, which must be satisfied by clear and convincing evidence, creates a remedy which very few patients and their surrogates will be able to successfully procure.

Various commentators have criticized the requirement of judicial intervention as a wrongful injection of the judicial process into an essentially medical decision and a vote of no confidence in the ability of physicians and families to act in the best interest of the incompetent patient. [n69] Other courts suggest using ethics committees, an ombudsman program, or requiring additional concurring diagnosis of two other uninvolved physicians as sufficient means to protect the sanctity of life and prevent abusive decision making. [n70] This is especially true in the case of older patients in **nursing homes** who are without family.

Recognizing the limitations of judicial review, the Illinois Supreme Court openly invited the legislature to address the issue and to "streamline, tailor, or overrule" the court's articulated procedures. Because of the court's conviction that

such issues should be legislatively resolved, the opinion is narrowly written and the procedures are cautiously drafted. As such, the opinion does little to solve the pressing problem of the patient's right to refuse medical treatment and to have life-supporting mechanisms withdrawn.

IV. RESPONSE TO THE ILLINOIS DECISION

The court indicated the public policy of the State of Illinois supports a patient's right to refuse medical treatment by expressed intention or through the use of surrogate decision-makers. However, the opinion does little to enable Illinois citizens to exercise that right. In response to the *Linares* [n71] grand jury inquiry, an Illinois State's Attorney's task force was formed to study the foregoing of life-sustaining treatment and to draft model legislation.

The task force concluded that all persons have a fundamental right to make decisions relating to their own medical treatment, including the right to forego life-sustaining treatment. [n72] Most task force members concluded artificial sustenance is a form of life-sustaining medical treatment. However, some members did not consider artificial sustenance as medical treatment and would not allow its withdrawal, even from patients with decision-making capacity. [n73] The general consensus was that patients have a right to refuse medical treatment. This right is best expressed through the use of a living will or a durable power of attorney for health care. However, in the absence of either, the task force concluded a competent patient may refuse such treatment, and a surrogate may effectuate the decision for an incompetent patient.

According to the task force, the surrogate would exercise this decision through the use of a substituted judgment process. [n74] However, if evidence is insufficient to satisfy substituted judgment, then the surrogate may decide based on what is in the patient's best interests. [n75] When the health care team and the family are in disagreement, or various family members are in disagreement on the decision, a dispute resolution mechanism would be employed. The dispute would be submitted to a multi-disciplinary ethics committee for consideration. Judicial review was recommended only as a last resort after dispute mechanisms within the health care system were exhausted. [n76]

The task force also recommended various measures to educate the public about the use and benefits of living wills and durable powers of attorney for health care. Measures suggested for distributing information include: distribution with driver's licenses, license plates, and tax returns, as well as through insurance **companies** and health maintenance organization enrollment materials.

As a result of many months of interdisciplinary study, the task force drafted model legislation. The proposed legislation seeks to govern the right to refuse medical treatment in cases where the patient has neither executed a living will or durable power of attorney for health care. According to the proposed statute, in order for a patient or the surrogate to refuse life-sustaining treatment, the patient must satisfy one or more of the following qualifying conditions: the patient must have a "terminal condition," must be "permanently unconscious," or the treatment must be "disproportionately burdensome." [n77]

Additionally, the model statute creates a surrogate decision-making hierarchy which determines which of the patient's significant others have superior decision-making authority in the absence of an appointed surrogate. [n78] Furthermore, the decision-making process is to be guided by the patient's wishes, including, but not limited to, the patient's religious and moral beliefs. If reasonably diligent efforts to discern the patient's wishes are unsuccessful, the decision may be made on the basis of the patient's best interests. [n79] Challenges to the decision to terminate treatment would be governed by a non-judicial dispute mechanism. In the event a party seeks judicial review, the person challenging the advisory opinion of the dispute resolution mechanism must show by clear and convincing evidence that it is contrary to the patient's wishes or best interests. [n80]

The statute seeks to comprehensively govern who may refuse life-sustaining treatment, how surrogates may exercise the patient's right to such refusal, and what mechanisms should govern a challenge of such a decision. It also provides for criminal immunity for health care professionals and other persons who, in good faith, engage in the

decision to forego treatment. The adoption of such a statute would eliminate the endless court battles that families have thus far endured in their efforts to preserve their family member's wishes or best interests. Additionally, such a statute would provide clear guidance for all health professionals on an frequently-encountered issue.

V. CONCLUSION

The Illinois Supreme Court in *Longeway* and *Greenspan* concluded, as all other courts have, the final determination of such problems should be resolved by the legislature. In Illinois there is a Living Will Act [n81] and a Power of Attorney for Health Care Act. [n82] However, in situations where the incompetent patient has neither executed a living will nor a power of attorney for health care, there are no current legislative guidelines. The ideal, of course, would be for everyone to execute such documents. Through public education and the encouragement of probate attorneys in estate planning there may be an increase in the number of people who will execute such documents. However, there is still likely to be a large number of people who will not. In particular, young healthy adults and individuals with more limited financial resources are unlikely to do so. Because there will always be a large number of adults who will not execute such documents, legislative measures should be enacted just as probate provisions have been created to govern individuals who die intestate.

REFERENCE: [n2.] 58 U.S.L.W. 4916 (1990).

[n1.] The Illinois Supreme Court, in *In re Longeway*, noted "Hopelessly or terminally ill patients who in the past would have met with a swift end, now find that medical science can sustain them, near the threshold of death, but not yet across it." *In re Longeway*, 33 Ill. 2d 33, 39, 549 N.E.2d 292, 294 (1989). See also Cohen, *Interdisciplinary Consultation on the Care of the Critically Ill and Dying: The Role of One Hospital Ethics Committee*, 10 *CRITICAL CARE MED.* 776 (1982). Cohen comments on the future of life-sustaining care by his statement: "Unless we answer such questions now, our ICU's will become the cemeteries of the future, occupied by multitudes of artificially fed and maintained human beings who are neither alive nor dead." *Id.*

[n3.] See *Gray v. Romeo*, 694 F. Supp. 580 (D. R.I. 1988); *Rasmussen v. Fleming*, 154 Ariz. 207, 741 P.2d 674 (1987); *Barber v. Superior Court*, 147 Cal. App. 3d 1006, 195 Cal. Rptr. 484 (1983); *Foody v. Manchester Mem. Hosp.*, 40 Conn. Supp. 127, 482 A.2d 713 (1984); *Severns v. Wilmington Med. Center*, 425 A.2d 156 (Del. 1980); *John F. Kennedy Mem. Hosp. v. Blutworth*, 452 So. 2d 921 (Fla. 1984); *In re L.H.R.*, 253 Ga. 439, 321 S.E.2d 716 (1984); *In re P.V.W.*, 424 So.2d 1015 (La. 1982); *In re Gardner*, 534 A.2d 947 (Me. 1987); *Superintendent of Belchertown State School v. Saikewicz*, 373 Mass. 728, 370 N.E.2d 417, (1977); *In re Torres*, 357 N.W.2d 332 (Minn. 1984); *In re Quinlan*, 70 N.J. 10, 355 A.2d 647 (1976); *In re Jobs*, 108 N.J. 394, 529 A.2d 434 (1987); *In re Storar*, 52 N.Y.2d 363, 420 N.E.2d 64, 438 N.Y.S.2d 266 (1981); *Leach v. Akron Gen. Med. Center*, 68 Ohio Misc. 1, 426 N.E.2d 809 (1980); *In re Hamlin*, 102 Wash. 2d 810, 689 P.2d 1372 (1984).

[n4.] *Longeway*, 133 Ill. 2d 33, 549 N.E.2d 292.

[n5.] *In re Greenspan*, No. 67903-20, slip op. (Ill. Sup. Ct. filed July 9, 1990).

[n6.] *Longeway*, 133 Ill. 2d at 44, 549 N.E.2d at 297.

[n7.] *Id.*

[n8.] *Greenspan*, slip op. at 11.

[n9.] *Longeway*, 133 Ill. 2d at 48-50, 549 N.E.2d 299-300.

[n10.] The New Jersey Court in *In re Quinlan* was the first court to articulate a right to refuse treatment based on a constitutional right to privacy. *Quinlan*, 70 N.J. 10, 355 A.2d 647 (1976). See also *In re L.H.R.*, 253 Ga. 439, 321

S.E.2d 716 (1984); *Brophy v. New England Sinai Hosp.*, 398 Mass. 417, 497 N.E.2d 626 (1986).

[n11.] *Cruzan v. Director, Missouri Dept. of Health*, 58 U.S.L.W. 4916 (1990).

[n12.] See, e.g., *Rasmussen v. Fleming*, 154 Ariz. 207, 215-16, 741 P.2d 674, 682-83 (1987); *Belchertown State School v. Saikewicz*, 373 Mass. 728, 742, 370 N.E.2d 417, 426 (1977); *In re Conroy*, 98 N.J. 321, 346, 486 A.2d 1209, 1223 (1985); *In re Storar*, 52 N.Y.2d 363, 376, 420 N.E.2d 64, 70, 438 N.Y.S.2d 266, 272 (1981).

[n13.] 70 N.J. 10, 355 A.2d 647 (1976).

[n14.] *Id.* at 40, 355 A.2d at 663.

[n15.] L. TRIBE, *AMERICAN CONSTITUTIONAL LAW* 936-37 (1978).

[n16.] *Quinlan*, 70 N.J. at 41, 355 A.2d at 664.

[n17.] Capron, *Borrowed Lessons: The Role of Ethical Distinctions in Framing Law on Life-Sustaining Treatment*, ARIZ. ST. L.J. 647 (1984). Capron suggests the balancing approach would under-protect some patients because it would graduate the right of privacy by the degree of the patient's debility, while at the same time overprotecting the physical preservation of some patients' bodily functions at the expense of their other interests. *Id.* at 657-58.

[n18.] Under the common law, a patient must consent to medical treatment of any kind to maintain the person's right of personal inviolability. See *Union Pacific Ry. v. Botsford*, 141 U.S. 250, 251 (1891) (where the Court concluded "[n]o right is held more sacred, or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law."). Justice Cardozo elaborated on this right to bodily integrity in relation to medical treatment in *Schloendorff v. Society of New York Hospital*, stating: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages." *Schloendorff v. Society of New York Hosp.*, 211 N.Y. 125, 129-30, 105 N.E. 92, 93 (1914). For further discussion of the common law doctrine of informed consent, see Swartz, *The Patient Who Refuses Medical Treatment: A Dilemma for Hospitals and Physicians*, 11 AM. J. L. MED. 147, 149-50 (1985).

[n19.] *Cruzan v. Director, Missouri Dept. of Health*, 58 U.S.L.W. 4916 (1990).

[n20.] *Superintendent of Belchertown State School v. Saikewicz*, 373 Mass. 728, 741, 370 N.E.2d 417, 425 (1977).

[n21.] *Cruzan v. Harmon*, 760 S.W.2d 408, 419 (Mo. 1988) *aff'd*, *Cruzan v. Director, Missouri Dept. of Health*, 58 U.S.L.W. 4916 (1990).

[n22.] *In re Longeway*, 133 Ill. 2d 33, 48, 549 N.E.2d 292, 299 (1989).

[n23.] *Cruzan v. Harmon*, 760 S.W.2d 408, 421 (Mo. 1988), *aff'd*, *Cruzan v. Director, Missouri Dep't of Health*, 58 U.S.L.W. 4916 (1990).

[n24.] *Cruzan v. Director, Missouri Dep't of Health*, 58 U.S.L.W. 4916 (1990).

[n25.] See Rhoden, *Litigating Life and Death*, 10 HARV. L. REV. 375 (1988) for an in-depth analysis of the various standards applied in termination of life support cases.

[n26.] *In re Jobes*, 108 N.J. 394, 427, 529 A.2d 434, 451 (1987).

[n27.] PRESIDENT'S COMMISSION ON THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND

BIOMEDICAL AND BEHAVIORAL RESEARCH, DECIDING TO FOREGO LIFE-SUSTAINING TREATMENT
136 (1983).

[n28.] Rasmussen v. Fleming, 154 Ariz. 207, 222, 741 P.2d 674, 689 (1987).

[n29.] See Rhoden, *supra* note 25, at 377. Rhoden argues that the subjective test under-emphasizes the fact that the incompetent is not actually deciding.

[n30.] *Id.* Rhoden maintains that the objective test bifurcates the patient, treating him or her as an object devoid of previous values and preferences. *Id.* at 376, 406.

[n31.] See, Koop & Grant, The "Small Beginnings" of Euthanasia: Examining the Erosion in Legal Prohibitions Against Mercy-Killing, 2 J. LAW, ETHICS, & PUBLIC POLICY 585 (1986) [hereinafter Koop & Grant, Small Beginnings]; Active Voluntary Euthanasia: A Needless Pandora's Box, 3 ISSUES IN LAW & MED. 219, 230 (1987) [hereinafter Shewmon, Pandora's Box]; Weisbard & Siegler, On Killing Patients With Kindness: An Appeal For Caution, in BY NO EXTRAORDINARY MEANS 113-14 (J. Lynn ed. 1986) [hereinafter Weisbard & Siegler, Appeal for Caution].

[n32.] See Koop & Grant, Small Beginnings, *supra* note 31, at 589.

[n33.] See Weisbard & Siegler, Appeal for Caution, *supra* note 31, at 112.

[n34.] See Shewmon, Pandora's Box, *supra* note 31, at 244.

[n35.] For example, James Rachels suggests moral beliefs regarding killing both under the traditional Western or Eastern philosophies are faulty. J. RACHELS, THE END OF LIFE, EUTHANASIA AND MORALITY (1986). He suggests the prohibition against killing should not be limited to a prohibition on the intentional killing of innocent lives, as the Western tradition emphasizes. Similarly, he finds Eastern philosophy emphasis on sanctity of all life faulty. Rachels believes the emphasis should be on having a life in a biographical sense not merely being alive. *Id.* at 5. Therefore, for Rachels the rule against killing is to protect the individual's interests in life in a biographical sense, when that life ceases to exist he believes the prohibition against killing is no longer operational. *Id.* at 38. This approach, however, is an extreme minority position which supports active euthanasia. The termination of life-support systems is generally viewed as passive euthanasia and is strongly distinguished from active euthanasia.

[n36.] See Shewmon, Pandora's Box, *supra* note 31, at 230.

[n37.] See Koop & Grant, Small Beginnings, *supra* note 31, at 596.

[n38.] Longeway, 133 Ill. 2d 33, 549 N.W.2d 292 (1989).

[n39.] *In re Greenspan*, No. 67903-20, slip op. (Ill. Sup. Ct. filed July 9, 1990).

[n40.] Longeway, 133 Ill. 2d at 45, 549 N.E.2d at 297; Greenspan, slip op. at 4.

[n41.] Longeway, 133 Ill. 2d at 45, 549 N.E.2d at 298. See also *In re Peter*, 108 N.J. 365, 382, 529 A.2d 419, 428 (1987). The patient's ombudsman asserted the withdrawal of artificial feeding directly causes death while the withdrawal of other forms of life-support only indirectly causes death. The court rejected any distinction between withdrawing artificial sustenance and any other medical treatment, concluding that every competent and incompetent patient has "the right to decline any medical treatment, including artificial feeding." *Id.*

[n42.] Longeway, 133 Ill. 2d at 48, 549 N.E.2d at 299.

[n43.] *Id.*

[n44.] *Id.* at 50, 549 N.E.2d at 300.

[n45.] *Id.*

[n46.] *Id.* at 51-52, 549 N.E.2d at 300-01.

[n47.] *Id.*

[n48.] *In re Greenspan*, No. 67903-20, slip op. at 15 (Ill. Sup. Ct. filed July 9, 1990).

[n49.] *Id.* at 18 (Ward, J., dissenting).

[n50.] See, e.g., *Cruzan v. Harmon*, 760 S.W.2d 408 (Mo. 1989).

[n51.] See *In re Jobes*, 108 N.J. 394, 439, 529 A.2d 434, 457 (1987) (where the court described the substituted analysis as an "imaginative effort" which necessarily falls short of certainty about what the patient would have decided); *In re Drabick*, 200 Cal. App. 3d 185, 208, 245 Cal. Rptr. 840, 854 (1988) (where the court noted a patient's non-cognitive state prevents him from choosing anything: "Thus, to claim that his 'right to choose' survives incompetence is a legal fiction at best."). See also *TRIBE, AMERICAN CONSTITUTIONAL LAW* § 15-11, at 1368 n.25 (2d ed. 1988); *Dresser, Life, Death, and Incompetent Patients: Conceptual Infirmities and Hidden Values in the Law*, 28 *ARIZ. L. REV.* 373 (1986).

[n52.] See, e.g., *In re Conroy*, 98 N.J. 321, 486 A.2d 1209 (1985).

[n53.] See *Jobes* 108 N.J. at 436, 529 A.2d at 455 (Handler, J., concurring); *Id.* at 448, 529 A.2d at 462 (Pollack, J., concurring). See also Rhoden, *supra* note 25.

[n54.] For an in-depth discussion of the shortcomings of a pure subjective approach and problems with the burden of proof see Rhoden, *supra* note 25.

[n55.] *Id.* See also *Jobes*, 108 N.J. at 417, 529 A.2d at 477.

[n56.] *Jobes*, 108 N.J. at 417, 529 A.2d at 477.

[n57.] *In re Drabick*, 200 Cal. App. 3d 185, 209, 245 Cal. Rptr. 840, 856 (1988).

[n58.] *Brophy v. New England Sinai Hosp.*, 398 Mass. 417, 419, 497 N.E.2d 626, 635 (1986) (quoting from *Superintendent of Belchertown State School v. Saikewicz*, 373 Mass. 728, 750, 370 N.E.2d 417, 430 (1977)).

[n59.] *Jobes*, 108 N.J. at 436, 529 A.2d at 455-56 (Handler, J., concurring).

[n60.] *Id.* at 448, 529 A.2d at 462 (Pollack, J., concurring).

[n61.] Rhoden, *supra* note 25, at 400.

[n62.] *In re Longeway*, 133 Ill. 2d at 33, 49, 549 N.E.2d 292, 249 (1989).

[n63.] *Jobes*, 108 N.J. at 416, 529 A.2d at 445.

[n64.] *Longeway*, 133 Ill. 2d at 50, 549 N.E.2d at 300.

[n65.] *Id.* (quoting from *Jobes* 108 N.J. at 415, 529 A.2d at 445).

[n66.] *BLACK'S LAW DICTIONARY* 317 (4th ed. 1968).

[n67.] *Jobes*, 108 N.J. at 407, 529 A.2d at 441.

[n68.] *Rasmussen v. Fleming*, 154 Ariz. 207, 741 P.2d 674 (1986); *In re Drabick*, 200 Cal. App. 3d 185, 245 Cal. Rptr. 840 (1988); *Jobes*, 108 N.J. 394, 529 A.2d 434; *In re Quinlan*, 70 N.J. 10, 50, 355 A.2d 647, 669 (1976).

[n69.] See *Relman*, *The Saikewicz Decision: A Medical Viewpoint*, 4 AMER. J.L. & MED. 233 (1978); *Relman*, *The Saikewicz Decision: Judges as Physicians*, 298 N.E.J. MED. 508 (1978); *Dunn*, *Who "Pulls the Plug:" The Practical Effect of the Saikewicz Decision*, MEDICOLEGAL NEWS (6)4:6 (Win. 1978). See also *Annas*, *Reconciling Quinlan and Saikewicz: Decision Making for the Terminally Ill Incompetent*, 4 AMER. J.L. & MED. 367 (1978).

[n70.] See *Rasmussen*, 154 Ariz. at 207, 741 P.2d at 674; *Jobes*, 108 N.J. at 422, 529 A.2d at 448; *In re Conroy*, 98 N.J. 321, 383, 486 A.2d 1209, 1237-39 (1985); *Quinlan*, 70 N.J. at 54, 355 A.2d at 671.

[n71.] See Cook County State's Attorney's Office, *REPORT ON THE STATE'S ATORNEY'S TASK FORCE ON THE FOREGOING OF LIFE-SUSTAINING TREATMENT (Final Report)* March 6, 1990 (where the introduction discusses the presentation to a grand jury of the case of Rudy Linares, charged with removing his son from a respirator while holding hospital staff at gunpoint. The grand jury decided not to indict Linares for murder.).

[n72.] *Id.* at 41-45.

[n73.] *Id.* at 45.

[n74.] *Id.* at 66.

[n75.] *Id.* at 67.

[n76.] *Id.* at 68-70.

[n77.] Ill. S.B. 2213, 1989-90 Sess. § 3.

[n78.] Ill. S.B. 2213, 1989-90 Sess. § 6.

[n79.] *Id.*

[n80.] *Id.*

[n81.] ILL. REV. STAT. ch. 110 1/2, para. 701-1 (1987).

[n82.] *Id.* 804-10(a), (b)(1).

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LENGTH: 7042 words**SUMMARY: KEYWORDS:** Affordable Care Act, Federalism, Funding, Health Policy, Medicaid, Supreme Court, Spending Clause, Welfare

ABSTRACT: The Supreme Court's June 28, 2012 decision that the Affordable Care Act's Medicaid expansion was unconstitutionally coercive surprised many legal observers. This Comment reviews prior state challenges to federal health policy, concluding that this latest challenge to the Medicaid expansion was also a departure from the past: it was brought by a coalition of states that formed along much more partisan grounds than prior state coalitions, and it challenged a significant new funding opportunity, not a new limit on federal funding.

TITLE: State Challenges to Federal Health and Welfare Policy Prior to *NFIB v. Sebelius***AUTHOR:** Laura E. Schattschneider
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TEXT:**Introduction**

On June 28, 2012, seven Justices of the Supreme Court joined in holding that the mandatory Medicaid expansion of the Affordable Care Act exceeded Congress's Spending Clause power, finding that the threat that the federal government could withhold *all* Medicaid funding from any state not participating in the expansion was "a gun to the head" that prevented states from willingly participating in the program. n1 Only Justices Ginsburg and Sotomayor disagreed.

n1 Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566, 2604 (2012) (Roberts, C.J.) [hereinafter *NFIB*]. The case decided issues raised in three separate petitions for certiorari challenging a single decision by the U.S. Court of Appeals for the Eleventh Circuit. The Medicaid expansion issue was raised by the petition in *Florida v. Dep't of Health & Human Servs.* (No. 11-400).

The Court's decision on the Medicaid expansion came as a surprise to many observers. n2 It marked the first time the Court had struck down a federal Spending Clause program as unconstitutionally coercive. Despite the unprecedented nature of its decision, however, the Court refused to enunciate a clear test for when federal legislation becomes coercive, noting "It is enough for today that wherever that line [where 'persuasion gives way to coercion'] may be, this statute is surely beyond it." n3

n2 See, e.g., Jonathan Adler, *Lose the Battle, Win the War?*, SCOTUSBLOG (June 28, 2012, 6:10 PM), <http://www.scotusblog.com/2012/06/lose-the-battle-win-the-war/> ("For years the Court has insisted that Congress' power to impose conditions on the receipt of federal funds is limited without ever finding a limit it would enforce."); Nicole Huberfeld et al., *Plunging into Endless Difficulties: Medicaid and Coercion in the Healthcare Cases*, B.U. L. REV. (forthcoming Jan. 2013), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2128760 ("Until the 2012 Term, no Supreme Court decision since the New Deal had struck down an act of Congress as exceeding the federal spending power.").

n3 *NFIB*, at 2606.

The case that the Court resolved, which was brought by twenty-six states and state attorneys general, also was not the typical state challenge to federal health and welfare policy. Only rarely do states band together to challenge some aspect of federal health and welfare policy that affects them as a group. States generally are disinclined to mount wholesale challenges to programs that benefit them through federal funding, and there are significant political and practical difficulties involved with forming and maintaining state coalitions. Perhaps because of these difficulties, since Medicaid's enactment in 1965, the lion's share of state challenges to federal health policy have not been frontal assaults on legislation brought by state coalitions. States typically have not challenged federal programs that offer significant financial *opportunities*, such as the Medicaid expansion's enhanced federal matching funds. n4 Instead, states more typically contest specific adverse actions taken by the federal government, such as disallowances of federal Medicaid funds or disapprovals of State Plan amendments. n5

n4 Until 2016, the federal government will fully fund (by matching at 100 percent) state expenditures for beneficiaries who become eligible as a result of the Medicaid expansion. From 2016 to 2020, the federal match for this population will gradually decrease to 90 percent. See Social Security Act § 1905(y) (42 U.S.C. § 1396d(y)). The second question for the states' counsel on the day of the Medicaid expansion oral argument was Justice Kagan's query: "[W]hy is a big gift from the Federal Government a matter of coercion?" Transcript of Oral Argument at 3, *Florida v. Dep't of Health & Human Servs.* (2012), *NFIB* (No. 11-400), www.supremecourt.gov/oral_arguments/argument_transcripts/11-400.pdf.

n5 See, e.g., *La. Dep't of Health & Hosps. v. Ctr. for Medicare & Medicaid Servs.*, 346 F.3d 571 (5th Cir. 2003) (reversing federal disapproval of state Medicaid plan amendment).

Although *NFIB v. Sebelius* (*NFIB*) did not eliminate the difficulties inherent to forming state litigation coalitions, it may make it possible for states to challenge federal policy using a heretofore-discredited legal theory--that the federal government has disrupted the balance between state and federal authority by "coercing" state participation in a federal program. States may therefore increasingly seek to capitalize on this aspect of the Court's decision in future challenges to federal policy. n6

n6 Maine recently filed such a challenge, but it was summarily dismissed. See *Mayhew v. Sebelius*, No. 12-2059 (1st Cir. Sept. 13, 2012) (CM/ECF PACER) (dismissing Maine's petition for review of the federal government's failure to act on the state's request to limit Medicaid eligibility in Maine in contravention of the Affordable Care Act's maintenance-of-effort requirements). Maine's challenge stood on somewhat shaky ground procedurally as it attempted to compel a decision from the Secretary approving or disapproving Maine's proposed changes to eligibility before a regulatory deadline for that decision had elapsed.

However, in light of the Court's refusal to provide any guidance about when Spending Clause opportunities become

coercive, it is extremely difficult to predict how any such future challenges will fare. The Court's decision provides little guidance to the federal trial and appellate courts that will have to resolve these future cases. The prior cases are not much help because it is difficult to discern how the circumstances in those cases differed from those at issue in the Affordable Care Act case, if at all, and the Court had no obligation to follow or even to address them. n7 Additionally, as the dissenters pointed out, the decision may not act as a significant limit on Congress, which could avoid such challenges in the future by repealing and re-enacting Spending Clause programs, rather than amending them. n8 In the end, this part of the Court's decision may be vulnerable to the charge that it was driven not by a universally applicable legal principle, but by politics. n9 That said, the justices did not split along purely ideological lines on this part of the decision, as Justices Breyer and Kagan (two Democratic appointees) joined with the Court's more conservative members (Chief Justice Roberts and Justices Scalia, Kennedy, Alito, and Thomas) in finding the Medicaid expansion unconstitutionally coercive.

n7 Indeed, although the dissent points out that the majority's decision was "*the first time ever*" that the Court found a Spending Clause program to be unconstitutionally coercive, no prior lower court decision rejecting the coercion theory was cited by any of the *NFIB* opinions. *NFIB*, at 2630 (Ginsburg, J., dissenting) (emphasis in original).

n8 *See id.* at 2629 (Ginsburg, J., dissenting).

n9 *Id.* at 2641 ("The coercion inquiry, therefore, appears to involve political judgments that defy judicial calculation") (Ginsburg, J., dissenting).

The first section of this Comment, Significant Prior Challenges That Did Not Rely on Federalism Arguments, reviews previous state challenges to federal policy in an effort to understand the circumstances under which concerted state litigation has typically arisen in the past and to explain why *NFIB* represents a departure from the norm. The second section, Prior State Challenges That Relied on Federalism Arguments, reviews cases in which the states advanced federalism arguments similar to those that succeeded in *NFIB* and concludes that the only common thread to the prior federalism cases is that they failed, which suggests that the *NFIB* decision ushers in a new judicial approach to federalism.

Significant Prior Challenges That Did Not Rely on Federalism Arguments

Prior to the recent challenge to the Medicaid expansion, states did on rare occasion work together to challenge significant aspects of federal health and welfare policy that affected them as a group and were likely to impact them financially. This section reviews some major prior cases that were not grounded on the federalism arguments that carried the day in *NFIB*. Instead, these cases were primarily Administrative Procedure Act challenges to unfavorable agency policy; they sought to invalidate regulatory actions based on procedural failings or lack of statutory authority. Additionally, many *pre-NFIB* coalitions banded together to challenge reductions to or limits on federal funding, not programs that, like the Medicaid expansion, offer significant new federal funding (in the form of a 100 percent federal match on state expenditures).

1962 to 1976--Challenges to federal social services funding

The first major state coalitions developed around proposed Nixon-era limitations on federal social services funding. In 1962 and 1967, revisions to the Social Security Act enabled states to secure federal Title IV-A funds to provide social services to Aid to Families with Dependent Children (AFDC) recipients, including those who were potential AFDC recipients, and permitted states to contract with private nonprofit **companies** to provide these services. By 1972, as a result of these changes and the absence of any federal guidance explaining exactly what services qualified for AFDC funding, state claims for social services had increased dramatically, often covering programs previously funded entirely with state resources. The federal agency responsible for administering these programs at the time, the Department of Health, Education, and Welfare (HEW), n10 responded by issuing an informal guidance memorandum imposing new limits on state claims for Title IV-A funding for social services, and relied on the memorandum to deny

state claims for reimbursement that, in total, exceeded well over \$ 1 billion. Thirteen states that were especially impacted by the new limits formed a coalition to challenge them in a court action. They succeeded. The U.S. District Court for the District of Columbia ruled that most of the objectionable provisions of the HEW memorandum should have been issued through notice-and-comment rulemaking, but had not been, and could not therefore be relied on, to reject the states' claims. n11 Following that decision (and a change in administrations), the government settled, offering over \$ 500 million to be divided among the fifty states if they could agree on a distribution of funds within one week. Agreement was reached, and the funds were appropriated and paid out. n12

n10 This agency became the U.S. Department of Health and Human Services in 1980. *See* SSA History, Social Security Online (last visited Oct. 28, 2012), www.ssa.gov/history/orghist.html.

n11 *Florida v. Mathews*, 422 F. Supp. 1231, 1250-51 (D.D.C. 1976).

n12 *See* Act of June 12, 1978, Pub. L. No. 95-291, 92 Stat. 304, 304-06 (1978).

In 1975 to 1976, fourteen states joined forces to challenge a regulation, part of the Nixon Administration impoundment policy, that imposed penalties on states for erroneous AFDC eligibility determinations above specified thresholds. The coalition convinced the U.S. District Court for the District of Columbia that the regulation's threshold had no rational basis and therefore was arbitrary and capricious. n13

n13 *Maryland v. Mathews*, 415 F. Supp. 1206, 1214 (D.D.C. 1976). A later case in which 29 states and the District of Columbia challenged the penalty threshold subsequently set under both the AFDC and Medicaid programs was dismissed as premature. *Alabama v. Bowen*, 659 F. Supp. 297 (D.D.C. 1986).

In both these cases, the state coalitions were nonpartisan efforts to turn back federal efforts to deprive states of federal funds. Although the challenged federal actions resulted in part from rancorous partisan disputes between Congress and the President, the states' lawsuits were driven less by party politics than by practical, financial concerns. Later state challenges also objected to federal efforts to reduce or limit the scope of federal programs or funding. As with the cases that preceded them, they typically were motivated less by political considerations than by the states' concerns with the practical and fiscal impact of federal policies.

Later Challenges: 1981-2010

In 1981 to 1982, ten states challenged the Department of Health and Human Services' refusal to pay claims for federal Medicaid funds that were submitted more than one year after the underlying expenditures for services. The case hinged on which of two legislative provisions was in effect at the time the states made their claims: one provision would have barred the claims, while the other would have permitted them to file claims up to two years after the underlying expenditure for services. The states convinced the U.S. Court of Appeals for the District of Columbia Circuit that the more favorable provision was in effect at the time they made their claims. n14

n14 *Connecticut v. Schweiker*, 684 F.2d 979, 996 (D.C. Cir. 1982).

In 2008, a group of providers and provider associations, together with several state amici, successfully challenged a Centers for Medicare & Medicaid Services (CMS) "maneuver . . . deliberately designed to outfox a clear directive of Congress." n15 The agency had attempted to finalize a rule limiting reimbursement to Medicaid providers to their actual costs of providing services, despite the fact that Congress had imposed a moratorium on further rulemaking to impose that policy. The finalized rule was published in the Federal Register on the day the moratorium went into effect, after the agency rushed the publication process by calling publication of the rule an "emergency." n16 Finding that these actions contravened the "duly enacted commands of Congress," the U.S. District Court for the District of Columbia vacated and remanded the rule. n17

n15 Alameda Cnty. Med. Ctr. v. Leavitt, 559 F. Supp. 2d 1, 1-2 (D.D.C. 2008).

n16 *Id.* at 2-3.

n17 *Id.* at 5. The rule was eventually withdrawn by the Secretary of Health and Human Services. See 75 Fed. Reg. 73972, affecting 42 C.F.R. pts. 433, 447, & 457 (Nov. 30, 2010).

Also in 2008, four states were less successful in challenging a CMS policy setting forth measures states must take to prevent their Children's Health Insurance Programs from crowding out coverage in the private insurance market. The U.S. District Court for the Southern District of New York found their challenge premature. n18 More recently, in 2010, Alabama challenged a federal policy requiring states to pay the federal government a portion of any state fraud or False Claims Act recoveries, ultimately convincing the Middle District of Alabama that CMS should have issued the policy through notice-and-comment rulemaking. n19

n18 New York v. U.S. Dep't of Health & Human Servs., No. 07 Civ. 8621 (PAC) (S.D.N.Y. Dec. 15, 2008). The case was brought by a coalition of states with Democratic governors, and thus may represent a departure from the more typical nonpartisan coalition.

n19 Alabama v. Ctrs. for Medicare & Medicaid Servs., 780 F. Supp.2d 1219, 1232 (M.D. Ala., N. Div. 2011).

The coalition of states that challenged the Medicaid expansion differed from many of these prior state coalitions because it did not come together around a perceived federal threat to existing funding. Rather, it formed along almost entirely political lines to challenge a significant expansion of federal funding for states (albeit one that would eventually require some state contribution). All but one of the challengers was a state with a Republican governor or attorney general; in some instances, governors and attorneys general from the same state but different parties disagreed about whether or not to participate in the lawsuit. n20 The states' challenge to the Medicaid expansion was perhaps more of a byproduct of the divisive partisan politics surrounding the enactment of a significant federal law--in this case, the Affordable Care Act--than many previous state challenges to federal Medicaid policy.

n20 See Kevin Sack, *Florida Suit Poses a Challenge to Health Care Law*, N.Y. TIMES, May 10, 2010, at A10, available at www.nytimes.com/2010/05/11/health/policy/11lawsuit.html?pagewanted=all&_r=0; Kevin Sack, *In Partisan Battle, Clashes Over Health Lawsuits*, N.Y. TIMES, Mar. 27, 2010, at A25, available at www.nytimes.com/2010/03/28/us/politics/28govs.html.

Prior State Challenges That Relied on Federalism Arguments

Until *NFIB*, nearly all prior state challenges to federal health and welfare policy based on federalism arguments failed. Study of the cases that preceded *NFIB* underscores that the success of the coercion theory in *NFIB* may represent a new opportunity for states to raise the oft-mooted question of the extent of the federal government's power to induce states to implement federal policy through the exercise of its Spending Clause authority.

In several challenges to federal policy that preceded *NFIB*, states advanced at least one of the following federalism arguments. First, relying on a line of cases that began with *Steward Machine Co. v. Davis* n21 and continued in *South Dakota v. Dole*, n22 states have argued that the conditions placed on their receipt of federal Medicaid funds (or other Spending Clause health and welfare funds) exceeded the federal government's Spending Clause authority because they were not stated unambiguously in the statutory language, bore no relationship to the funded program, or were unduly coercive. Second, relying on *Printz v. United States* n23 and *New York v. United States*, n24 states have argued that their participation in a federal program has been commandeered directly, in contravention of the Tenth Amendment, which provides that "[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people," n25 and thereby reserves for state authority any powers not granted to the federal government by the Constitution. Third, states have argued that federal policy has improperly

invaded an area reserved to the states by the Tenth Amendment. Tenth Amendment arguments have typically failed where the court determined that the challenged program was enacted under Congress's Spending Clause authority. And prior to *NFIB*, the federal courts approached the coercion Spending Clause argument that succeeded in *NFIB* with profound suspicion, at times dismissing it almost summarily.

n21 *Steward Mach. Co. v. Davis*, 301 U.S. 548 (1937) [hereinafter *Steward Mach. Co.*].

n22 *South Dakota v. Dole*, 483 U.S. 203 (1987).

n23 *Printz v. United States*, 521 U.S. 898 (1997).

n24 *New York v. United States*, 505 U.S. 144 (1992).

n25 U.S. Const. amend. X.

Although the states did not raise the Tenth Amendment arguments directly in *NFIB*, they did argue that the Court's prior precedents **protecting** state autonomy would be threatened if the Court did not set a firm outer limit on Congress's Spending Clause authority: "If Congress were free to use its spending power to coerce States into enforcing the federal government's dictates, then the spending power would become the exception that swallows the anti-commandeering rule." n26 The *NFIB* states therefore succeeded in combining the three disparate federalism arguments that were raised in prior cases.

n26 Brief of State Petitioners on Medicaid at 21, *NFIB* (No. 11-400) [hereinafter *Brief of State Petitioners*].

Medicaid challenges: 1976-1981

In 1976, Florida challenged a federal regulation requiring that the majority of individuals on nursing facility licensing boards be persons other than nursing facility administrators. The policy directly conflicted with a state law requiring that such boards include a majority of individuals who were nursing facility administrators. Among other arguments, Florida contended that the regulation invaded the state's power to regulate **nursing home** administrators and violated the Tenth Amendment. The U.S. Court of Appeals for the Fifth Circuit quickly dispensed with this argument, noting that "[o]nce a state chooses to participate in a federally funded program, it must comply with federal standards," n27 and that "[t]he only effect of the [federal] statute and regulation is to induce, but not require, a state to license its **nursing home** administrators in a specific manner" n28 This case represents a classic example of a court rejecting a Tenth Amendment argument because the challenged federal policy was issued under Spending Clause authority.

n27 *Florida v. Mathews*, 526 F.2d 319, 326 (5th Cir. 1976).

n28 *Id.*

In 1979 to 1981, thirteen states challenged legislation that conditioned their ongoing receipt of federal Medicaid funds on their agreement to pass through annual federal cost-of-living increases to Social Security Supplemental Security Income (SSI) recipients. At the time, several states provided benefits to SSI recipients that supplemented the federal benefit, and when the federal cost-of-living increases occurred, some of these states reduced the state supplemental funding rather than increase the total payment to the beneficiary. The states argued that the legislation was "unconstitutional because there is no relationship between a state's supplementary payments, which are meant to be optional and to augment the uniform SSI benefit level set by Congress, and the Medicaid program, which provides basic medical assistance to the needy." n29 They further argued that the provision "diminishes the states' sovereign power by dictating budget choices" n30 in contravention of the Tenth Amendment, and that "the effect of violating the condition--loss of Medicaid funds--is so drastic that the states have no choice but to comply." n31

n29 *Oklahoma v. Schweiker*, 655 F.2d 401, 408 (D.C. Cir. 1981).

n30 *Id.* at 411.

n31 *Id.* at 413.

Although the third of these arguments carried the day on June 28, 2012, all three failed in 1981. Regarding the first, the U.S. Court of Appeals for the D.C. Circuit found that "SSI and Medicaid are two interrelated components of the comprehensive federal effort to aid the aged, the blind, and the disabled," n32 and thus, that there is "nothing impermissible in Congress' conditioning a state's receipt of Medicaid funds on its compliance with [a legislative] mandate regarding the use of SSI funds." n33 The court rejected the second argument because the legislation did not directly displace state policy, but only required states to "maintain their current level of assistance expenditures." n34 Finally, in rejecting the third argument, the court took note of language in *Steward Machine* warning courts that "to hold that motive or temptation is equivalent to coercion is to plunge the law in endless difficulties." n35 It "explicitly declined to enter this thicket," n36 but rejected the idea that a condition becomes increasingly coercive as the financial consequences of noncompliance increase: "We do not agree that the carrot has become a club because rewards for conforming have increased. It is not the size of the stake that controls, but the rules of the game." n37 Of all the prior state federalism challenges, this was perhaps the most analogous to the states' challenge to the Medicaid expansion in *NFIB* and was cited frequently in the *NFIB* briefs; nonetheless, none of the Court's opinions cited it. n38

n32 *Id.* at 409.

n33 *Id.* at 410.

n34 *Id.* at 412.

n35 *Id.* at 413-14 (quoting *Steward Mach. Co.*, at 589-90).

n36 *Id.* at 414.

n37 *Id.* (quoting *N.H. Dep't of Emp't Sec. v. Marshall*, 616 F.2d 240, 246 (1st Cir. 1980)).

n38 See *Brief of State Petitioners*, at 45; Brief for Respondents (Medicaid) at 33, 34, 37, *id.*; Brief of Tex. Pub. Policy Found. & 36 Tex. State Legislators, as Amici Curiae Supporting Petitioners on Medicaid at 35, *id.*; Brief for the Am. Hosp. Ass'n et al. as Amici Curiae Supporting Respondents with Respect to Medicaid at 7, 18, *id.*; Brief of Faithful Reform in Health Care & the Wisc. Health Care Working Group as Amici Curiae Supporting Respondent's Position on Medicaid at 24, *id.*; Brief of S. Majority Leader Harry Reid, H. Democratic Leader Nancy Pelosi, & Cong. Leaders & Leaders of Comms. of Relevant Jurisdiction as Amici Curiae Supporting Respondents (Medicaid) at 12, 17, *id.*

Federal immigration policy challenges in the mid-to-late 1990s

In the mid-to-late 1990s, several states challenged what they characterized as the federal government's failure to enforce federal immigration policy and prevent illegal immigration. These challenges included a claim that the federal Medicaid program's requirement that states pay for emergency services provided to undocumented immigrants unlawfully commandeered state action in an area reserved to the states by the Tenth Amendment. n39 All these claims failed on the ground that the challenged program was a Spending Clause program. The U.S. Courts of Appeal for the Second, Fifth, and Ninth Circuits, which decided these cases, uniformly observed that the Medicaid program requirement was a condition on the receipt of federal funds and that the states could choose to reject the federal funds if they did not wish to provide the emergency services. n40 One state, California, made the argument that would ultimately succeed in *NFIB*, contending that "while its choice to participate in Medicaid may have been voluntary, it now has no choice but to remain in the program to prevent a collapse of its medical system." n41 The Ninth Circuit

almost summarily disposed of this argument. Noting that it had observed previously that "no party challenging the conditioning of federal funds has ever succeeded under the coercion theory," n42 it held that "to the extent that there is any viability left in the coercion theory, it is not reflected in the facts of this record." n43

n39 *Texas v. United States*, 106 F.3d 661, 665-66 (5th Cir. 1997) [hereinafter *Texas*]; *California v. United States*, 104 F.3d 1086, 1091-93 (9th Cir. 1997) [hereinafter *California*]; *Padavan v. United States*, 82 F.3d 23, 28-29 (2d Cir. 1996) (case brought by state legislators and counties). Florida also advanced the inverse of this argument, challenging the *prohibition* on federal funding for *non-emergency* Medicaid services provided to undocumented immigrants. *Chiles v. United States*, 874 F. Supp. 1334, 1336-37, 1341-44 (S.D. Fla.1994), *aff'd*, 69 F.3d 1094, 1096-97 (11th Cir. 1995).

n40 *See Texas*, at 666; *California*, at 1092; *Padavan*, 82 F.3d at 29; *see also Chiles*, 874 F. Supp. at 1341, 69 F.3d at 1097.

n41 *California*, at 1092.

n42 *Id.* (citing *Nevada v. Skinner*, 884 F.2d 445, 448 (9th Cir. 1989)).

n43 *Id.*

Challenges in Kansas and Minnesota in 2000

In 2000, two states relied on federalism arguments in separate challenges to federal health and welfare policy. Neither succeeded. First, Kansas challenged the child support recovery provisions of the Temporary Assistance for Needy Families (TANF) program as overly coercive. These provisions required states to adopt model legislation permitting the recovery of child support income across state lines, to pass laws that would make it easier to determine a child's paternity, and to take other measures intended to optimize recovery of parental support. Kansas argued that the provisions were "too onerous and expensive, necessitate too much manpower, and encroach upon its ability to determine its own laws" and "the amount of money at stake" rendered the requirements coercive. n44 The U.S. Court of Appeals for the Tenth Circuit first found that "Kansas does not seriously argue" n45 that the challenged provisions violated the Spending Clause because they had not been enacted in furtherance of the general welfare, they were ambiguous, they bore no relationship to the federal interest in TANF, or they violated some independent constitutional bar. n46 It next rejected the theory that the sheer size of the penalty for noncompliance rendered the condition coercive, noting that "the coercion theory is unclear, suspect, and has little precedent to support its application." n47

n44 *Kansas v. United States*, 214 F.3d 1196, 1198 (10th Cir. 2000).

n45 *Id.* at 1199.

n46 *See id.* at 1198-1201.

n47 *Id.* at 1202.

In the second case, Minnesota and a group of private citizens challenged geographic disparities in managed care costs and benefits that resulted from the federal approach to reimbursing Medicare managed care plans. The state raised a commandeering argument, contending that "as a result of the funding disparities under the Medicare managed care program, it has incurred significant increased costs" for subsidizing health benefits for lower-income seniors and had to enact legislation subsidizing prescription drug costs for that population. n48 Accordingly, the state argued, the federal government "'commandeered' the State's legislative process by effectively requiring" n49 the state to appropriate funds and pass legislation. The U.S. District Court for the District of Minnesota rejected this argument, not because Medicare is a Spending Clause program (it is not) but because there was no overt federal coercion. It noted that prior cases had stated that "only *direct* federal compulsion" n50 constitutes commandeering that might violate the Tenth Amendment. In this case, however, "Congress has not required the State or its officers to do anything" and the pressure to enact legislation came from the state's "own citizens, not Congress." n51

n48 *Minnesota v. United States*, 102 F. Supp. 2d 1115, 1119 (D. Minn. 2000).

n49 *Id.* at 1121.

n50 *Id.* at 1121 (citing *New York v. United States*, 505 U.S. 144, 161 (1992) and *Printz v. United States*, 521 U.S. 898, 933 (1997)) (emphasis in original).

n51 *Id.* at 1121.

2002--West Virginia's challenges to the Medicaid statute

In 2002, West Virginia challenged newly enacted provisions of the Medicaid statute requiring states to recoup Medicaid costs from deceased beneficiaries' estates. To comply, the state had to enact legislation. West Virginia refused and was warned by the Department of Health and Human Services that continued noncompliance might result in loss of part or all of its federal Medicaid funds. In response, West Virginia enacted the required legislation but included a provision requiring the state to challenge the federal requirements in court. It did so, and its foremost argument was that the estate recovery provisions were coercive and thus violated the limits placed on Congress's Spending Clause authority. n52

n52 *West Virginia v. U.S. Dep't of Health & Human Servs.*, 289 F.3d 281, 285-86 (4th Cir. 2002) [hereinafter *West Virginia*].

Because West Virginia is in the Fourth Circuit, it attempted to rely on an influential minority opinion in one of the very few prior cases in which a court found federal policy to conflict with the Spending Clause. In a 1997 en banc opinion, the Fourth Circuit invalidated a federal policy that would have denied Virginia all federal funding under the Individuals with Disabilities in Education Act (IDEA) because the Commonwealth did not provide a free and appropriate public education to disabled children who had been suspended or expelled for reasons unrelated to their disabilities. The judges in the en banc majority adopted (and in some cases, concurred with) part of an opinion written by Judge Luttig, the dissenting member of the original panel, n53 in which he concluded that the federal policy was not signposted sufficiently by the IDEA provision at issue in the case, that the Commonwealth did not have unambiguous notice of it, and it was thus unconstitutional under the Spending Clause. n54 Another portion of Judge Luttig's opinion, which was not endorsed by the en banc majority, concluded that the IDEA provision was also unduly coercive because violating it would cause the federal government to withhold "100% of an annual special education grant of \$ 60 million because of the Commonwealth's failure to provide private educational services to less than one-tenth of one percent . . . of the 128,000 handicapped students for whom the special education funds were earmarked." n55 In Judge Luttig's view, "a Tenth Amendment claim of the highest order lies where, as here, the Federal Government . . . withholds the entirety of a substantial federal grant on the ground that the States refuse to fulfill their federal obligation in some insubstantial respect rather than submit to the policy dictates of Washington in a matter peculiarly within their powers as sovereign States." n56

n53 *Va. Dep't of Educ. v. Riley*, 106 F.3d 559, 560 (4th Cir. 1997) (en banc).

n54 *Id.* at 562-68.

n55 *Id.* at 569.

n56 *Id.* at 570.

When the West Virginia case came before the Fourth Circuit, therefore, there was a chance that the court might take an approach to the coercion argument similar to that of Judge Luttig. In fact, the court in its decision acknowledged

that Judge Luttig's opinion in *Riley* "strongly indicates that the coercion theory remains viable in this circuit, and that federal statutes that threaten the loss of an entire block of federal funds upon a relatively minor failing by a state are constitutionally suspect." n57 However, it found that under the plain terms of 42 U.S.C. § 1396c--the same provision that was at issue in *NFIB*--the federal agency did not have to withhold *all* of West Virginia's Medicaid grant if West Virginia did not comply with the estate recovery provisions. Instead, as that provision states, the federal government has the option of withholding only that portion of funds that relates to the noncompliance. n58 Finding that the question of "whether the federal government could withhold all of West Virginia's Medicaid funds" was "a hypothetical one that is not properly before us," the court characterized West Virginia's challenge as a facial constitutional assault on the statute's estate recovery provisions. n59 It noted that for such a challenge to succeed, West Virginia must show that the statutory provisions "cannot operate constitutionally under any circumstance." n60 The court did not think that West Virginia could make such a showing because there was no guarantee that the federal government would actually withhold all of a state's Medicaid funds; it thus rejected the argument that the provision was coercive. n61 The court also rejected a related Tenth Amendment argument that the provisions unconstitutionally invaded an area of policy reserved to the states, largely because it was unconvinced by West Virginia's Spending Clause challenge. n62

n57 *West Virginia*, at 291.

n58 *Id.* at 292.

n59 *Id.*

n60 *Id.*

n61 *Id.* at 292-94.

n62 *Id.* at 295-96.

Although the West Virginia decision limited the effect of Judge Luttig's opinion in *Riley*, the Supreme Court's *NFIB* decision may have given that opinion new luster. Chief Justice Roberts did not cite *Riley* in his opinion in *NFIB*, but he reached the conclusion that the Medicaid expansion was unconstitutional by applying similar reasoning: "The threatened loss of over 10 percent of a State's overall budget . . . is economic dragooning that leaves the States with no real option but to acquiesce in the Medicaid expansion." n63

n63 *NFIB*, at 2605 (Roberts, C.J.).

2006--Medicare Part D challenge

In 2006, five states (joined by ten state amici) challenged a provision of the Medicare prescription drug benefit program (Medicare Part D) that required states to pay the federal Medicare program an amount based on their 2003 expenditures for prescription drugs provided to individuals eligible for both Medicare and Medicaid. Under the legislation enacting Medicare Part D, Medicare would cover prescription drug costs for this population in the future; the challenged provision, known as the *clawback* provision, would ensure that the full cost of providing services to this population would never be shifted entirely to the federal government. n64 The states petitioned the Supreme Court to hear their challenge to the provision under its original jurisdiction, but the Court summarily denied their request. n65 The states do not appear to have brought any later challenges to the provision in the lower federal courts. Accordingly, the merits of the states' case attacking this provision have yet to be resolved. In their petition, the states attacked the clawback provision as an impermissible tax on the state, and as unconstitutional "commandeering" of state budgetary and legislative authority. n66 They did not, however, advance the argument that the provision exceeded what was permissible under the Spending Clause because such an argument would have conflicted with their contention that the provision was not a condition on the receipt of federal funds, but rather an impermissible tax. n67

n64 See 42 U.S.C. § 1396u-5(c); ANDY SCHNEIDER, KAISER COMM'N ON MEDICAID AND THE UNINSURED, THE "CLAWBACK": STATE FINANCING OF MEDICARE DRUG COVERAGE (2004), available at www.kff.org/medicaid/upload/The-Clawback-State-Financing-of-Medicare-Drug-Coverage.pdf; see also Elizabeth A. Weeks, *Cooperative Federalism and Healthcare Reform: The Medicare Part D "Clawback" Example*, 1 ST. LOUIS U. J. HEALTH L. & POL'Y 79, 82 (2007) [hereinafter *Weeks*].

n65 *Texas v. Leavitt*, 547 U.S. 1204 (2006).

n66 See Motion for Leave to File Bill of Complaint, Supporting Brief, and Bill of Complaint, *Texas v. Leavitt*, No. 135 (U.S. Mar. 2, 2006), available at www.oag.state.tx.us/newspubs/releases/2006/030306medicare_complaint.pdf. Because of the differences between the program challenged in this lawsuit and the Medicaid expansion, this argument was not available to the *NFIB* state petitioners.

n67 See *id.* 14-16. A group of law professors who filed an amicus brief supporting the states considered making this argument, but ultimately decided not to do so in light of the conflict with the states' tax argument. See *Weeks*, at 113-14 ("In early drafts of the Professors' Brief, I argued that the clawback failed the *Dole* limits by operating as an ambiguous condition on states' receipt of federal Medicaid funds because the states were not notified of its consequences ... My argument, however, was incompatible with the States' intergovernmental tax immunity argument that the clawback operated as a mandatory tax on states qua states.").

Conclusion

The foregoing review of *pre-NFIB* state challenges to federal health and welfare policy illustrates just how difficult it has been for states to gain any traction with litigation based on federalism theories. Until now, the federal courts have been quite reluctant to find that Spending Clause legislation is unconstitutionally coercive, and states have been likewise reluctant to look a federal gift horse in the mouth. Moreover, until now, federal courts have been quite deferential to federal legislation and policy and disinclined to protect a zone of policymaking authority in which states may act independently of the federal government. In the wake of the Supreme Court's decision in *NFIB*, all this may change significantly because the Court took a much more protective stance toward the powers reserved to the states. This change in the Court's approach to state powers may explain why many of the prior cases raised the same theories at issue in *NFIB* (and one attacked the same statutory provision) but reached conclusions opposite to *NFIB*.

Despite the Court's refusal to provide future litigants and courts with a clear test for unconstitutionally coercive legislation, the *NFIB* decision opens up new opportunities for states to challenge federal policy in the federal courts. As Maine's recent challenge demonstrates, one possible new target under the coercion theory is the Affordable Care Act's maintenance of effort provision. It is even possible that some states that have grudgingly accepted prior changes to the Medicaid program (such as the expansion of Medicaid eligibility to certain pregnant women and children in the late 1980s or the provision of emergency services to immigrants) may now challenge those changes in federal court, particularly where Medicaid funding is held hostage to requirements that apply to a completely different program (such as the SSI funding requirements that the states challenged in 1981 and the Medicare Part D clawback). The coming years will show to what extent *NFIB* has ushered in a significant rebalancing of state and federal power in health policy.

REFERENCE: CITATION: Charles A. Miller and Laura E. Schattschneider, *State Challenges to Federal Health and Welfare Policy Prior to NFIB v. Sebelius*, J. HEALTH & LIFE SCI. L., February 2013, at 36. (c) 2013 American Health Lawyers Association, www.healthlawyers.org/JHLSL. All rights reserved.

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TITLE: Health Care Institutional Planning for Civil and Criminal Enforcement of Environmental Laws in the 1990s

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TEXT:

. Criminal prosecution was initiated by the city of Los Angeles against the Veterans Administration and its Administrator for improper disposal of hazardous medical waste. n1

. A clinical medical laboratory was suspended from the Medicaid program after being indicted in New Jersey for dumping hazardous waste into a river. n2

. A medical provider of oncology services asked a Pennsylvania trial court to dismiss a \$ 96 million dollar class action on behalf of 94 people exposed to a highly radioactive substance that was lost during a therapeutic application. n3

INTRODUCTION

Health care executives, as well as other business and community leaders, are being increasingly held responsible for the health and safety of their own communities and of the community at large. Health care clients could face millions of dollars in fines, penalties, and damages if they are not properly advised about their environmental obligations. n4 Moreover, as responsible corporate officers, health care executive clients could face civil and criminal liability for their decisions. n5

While there is exposure to civil liability under a variety of environmental laws, n6 this Article will mainly address the potentially devastating exposure to liability under the federal Superfund law. n7 It will then address how corporate executives, including health care managers, are increasingly vulnerable to criminal prosecution for violations of other environmental laws. n8

THE SUPERFUND LAW

The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) n9 was enacted by Congress in 1980 to establish a program for cleaning up the numerous toxic waste sites that threaten our nation's environmental health. The law, which contains the well-known Superfund provisions, was passed in response to public concerns over contaminated sites, such as the Love Canal area in upstate New York. n10

Congress created through the CERCLA statute a billion dollar fund, "Superfund," to finance cleanups for those toxic waste sites where parties responsible for the contamination could not be identified or simply lacked the economic

resources to fund the cleanup. n11 Superfund is financed through taxes on the petroleum and chemical industries. n12

In CERCLA's early years, liability was directed primarily toward large industrial polluters. n13 In recent years, however, the Superfund net has been cast more widely, and today there are few **companies**, small businesses, or municipalities that can feel comfortable that they can escape its reach. n14 Specifically, health care facilities typically generate the kinds of waste that could subject an entity to CERCLA liability. n15 Thus, hospital attorneys need to understand the CERCLA regulatory scheme and the action their clients must take to avoid creating CERCLA liability.

LIABILITY UNDER CERCLA

Under CERCLA, the Environmental Protection Agency (EPA) has the authority to investigate sites that may be contaminated, to rank the sites according to the threat to human health and the environment, and to place the most contaminated sites on a National Priorities List (NPL). n16 Once a site has been placed on the NPL, the EPA attempts to find potentially responsible parties (PRPs) to fund or conduct specified cleanup activities. n17

CERCLA establishes four categories of PRPs:

- . current owners and operators of a facility where hazardous substances are located;
- . past owners and operators of a facility at the time of disposal of hazardous substances;
- . anyone who arranged for the disposal of hazardous substances (generators); and
- . anyone who transports hazardous substances to the facility, if they selected it as a disposal site (transporters). n18

A "facility" is defined as any area where hazardous substances were placed. n19

A hospital's failure to dispose of its wastes properly or to ensure those responsible for disposing of its wastes are doing their jobs appropriately, can result in the imposition of an obligation to fund the entire cleanup of a Superfund site. n20 Thus, every hospital realistically should be concerned about and should be prepared for being named a PRP.

CERCLA's Definitions

CERCLA defines a hazardous substance as any one of approximately 800 chemicals and metals identified by the EPA as hazardous, because they are regulated by various federal environmental laws. n21 The only important substance explicitly not encompassed by the definition is petroleum, which includes crude oil. n22 Oil contaminated with a hazardous substance, however, may be covered by CERCLA. n23 Thus, petroleum contaminated with benzene, toluene, or lead may incur CERCLA liability.

Accordingly, any waste material, including ordinary garbage, may contain some, albeit a very small amount, of one or more hazardous substances. For this reason, CERCLA has a special significance to hospitals, whose waste streams may be contaminated with small quantities of hazardous substances, including materials from renovations and new construction.

Types of Liability

PRP liability can arise without negligence. n24 If a hospital's waste is sent to a disposal site that later becomes a Superfund site, the hospital may be liable for cleanup costs, regardless of how careful it was in disposing of or arranging for the disposal of its wastes.

Liability under CERCLA is joint and several. n25 This means that even in circumstances where many parties are responsible for contributing to the contamination, the government can elect to file suit against only a select few--or even one party--to recover the full costs of cleanup. However, the members of such an unfortunate group can initiate private

party cost recovery or contribution suits against their jointly liable counterparts. n26 Thus, actual liability ultimately may be apportioned through private civil litigation initiated by PRPs whom the government originally tagged with the entire bill for cleanup costs. Thus, other PRPs may ultimately be compelled to contribute financially to the cleanup. Experience has shown this litigation over contribution is staggeringly expensive. n27

The government does not need to identify or "fingerprint" an entity's waste to hold the entity responsible as a PRP. All the government has to prove is that the entity actually sent a hazardous substance to the site in question. n28

Waste Disposal: Independent Contractors

Hospitals (as well as clinics, **nursing homes**, and other health care providers) often rely on independent contractors for waste disposal, believing the use of independent contractors will free them from liability for violations of environmental statutes and regulations.

Unfortunately, a hospital's liability is not curtailed by the use of an independent contractor. Hospitals that generate waste containing hazardous substances are responsible for their waste from "cradle to grave." In the event of government action, the hospital's explanation that the waste was handed to a licensed hauler will not serve as a defense. n29

Hospitals can take steps, however, to set up contractual safeguards to transfer some of the risk of financial loss resulting from environmental liability attributable to a contractor's actions. Contracts with independent contractors should include some or all of the following protections:

- . the contractor's agreement to comply with applicable laws and regulations, specifically including environmental laws;
- . indemnification and duty-to-defend agreements from the contractor; and
- . financial assurances (in the form of insurance or otherwise) by the contractor to protect the hospital from loss.

Promises of Compliance. If a contractor does not properly dispose of the hospital's waste, the hospital will face liability. Thus, hospitals have a genuine economic stake in ensuring contractors comply with the law. The most effective way to ensure contractor compliance is for the hospital to monitor such compliance on a regular basis.

Consequently, compliance requires three elements from the contractor:

- . promise to obey the law;
- . agreement to periodic compliance inspections by the hospital; and
- . acknowledgement and agreement that failure to comply with the law is grounds for termination of the contract and payment of the hospital's damages.

Of course, the hospital must do more than simply create the contractual language; it must actively monitor the contractor and terminate the contract in the event of noncompliance.

Indemnification and Duty-to-Defend Agreements. Hospitals should attempt to limit their exposure through the inclusion of at least two specific legal devices in their contracts:

- . an indemnity clause n30 which requires the contractor to pay all judgments and costs arising out of the contract; and
- . a duty-to-defend agreement, which requires the contractor to pay the hospital's legal fees and other defense costs for all matters arising out of the contract.

Financial Assurances. All of the contract language in the world will not protect a hospital if the contractor does

not have the financial resources to satisfy a judgment or claim. Therefore, contracts should include specific requirements for liability insurance. The hospital should insist on being named as an additional insured.

Although contractual safeguards will not protect a hospital from CERCLA and other environmental liabilities, they may help shift some of the financial risk associated with CERCLA liability.

CRIMINAL ENFORCEMENT

These last several years, record numbers of corporations and individual officers have been indicted for damaging the environment. n31 Criminal prosecution for environmental offenses is a very real threat in today's world. Many individuals have been sent to jail. n32 Criminal enforcement of environmental laws and regulations is no longer limited to flagrant violations; it has become a routine part of the government's enforcement efforts. As of 1992, for example, over half of all the indictments and convictions -- and 94 percent of the fines and penalties ever collected for environmental crimes -- came during the preceding three years. n33

Whereas civil penalties for environmental violations are sometimes seen by corporate officers simply as a cost of doing business, criminal sanctions cannot be viewed in the same way. The fact that individuals, not organizations, will wind up in prison should encourage corporate officers to take their environmental responsibilities very seriously.

The Responsible Corporate Officer Doctrine

Under the "responsible corporate officer" doctrine, corporate executives face criminal liability solely on the basis of their status as a corporate officer; the criminal intent ordinarily necessary to convict someone of a crime does not apply to environmental violations. n34

Basis of the Doctrine. In recent years, a number of Supreme Court and federal appellate decisions have contained language that appears to support the proposition strict criminal liability applies to "public welfare" statutes involving danger to the community. n35 Many environmental laws arguably fit into this category, because they regulate health hazards, which are largely beyond the ability of the public to control. n36 The opinions written in these cases have appeared to support the idea of punishing persons who are in a "responsible relationship" to the harm in order to persuade such persons to pay closer attention to the relevant organization's environmental obligations; in any case, such imposition of liability is viewed as preferable to allowing a helpless public to be harmed. n37

Whether senior management will be held strictly liable based solely on its status within the organization, or whether there still must be some degree of personal involvement in order to hold a corporate officer personally accountable for a violation, continues to be the subject of much debate. n38 Whatever the correct answer turns out to be, it is important to realize it is not very difficult to find a corporate officer who had, or should have had, knowledge of facts sufficient to hold him or her responsible for the environmental violation of his or her organization.

Elements of the Doctrine. For liability to be imposed on an individual under the "responsible corporate officer" doctrine, three elements must be satisfied: (1) the individual must be in a position of responsibility that allows the person to influence corporate policies or activities; (2) there must be a sufficiently close connection between the individual's position and the violation in question so the individual could have influenced the corporate actions that constituted the violation; and (3) the individual's action or inaction must have facilitated the violation. n39

Avoiding Liability Under the Doctrine. Persons carrying the title "Environmental Manager" or "Environmental Coordinator" are obviously good candidates for imposition of the responsible corporate officer doctrine should environmental violations be discovered. However, following the prevailing wisdom, individuals will rarely be held liable when their organization has in place and actively carries out an effective environmental compliance program. Thus, it is important for these persons to take the initiative to help their organizations develop and to implement active and effective programs and systems which provide for environmental responsibility and accountability.

The ability to exercise power and the authority to control are two factors which are key to the imposition of personal liability. If this power and authority are used to establish and implement an effective environmental compliance program, responsible individuals within the corporation can go a long way toward avoiding personal liability. n40

Corporate Due Diligence for Avoiding Prosecution

In order to avoid exposure to criminal prosecution, organizations must have in place an environmental compliance program and must be diligent in carrying it out. It is no longer sufficient simply to leave compliance matters to the organization's legal department. Rather, someone in top management must be specifically responsible for environmental compliance at all levels within the organization.

Establishment of an Effective Environmental Compliance Program. An effective environmental compliance program should include, at minimum, the elements described below.

. Organizations must develop standards and procedures for environmental responsibility and compliance. This means adopting a written "code of environmental conduct" or similar compliance program.

. Organizations must assign overall responsibility for overseeing compliance to a specific individual or individuals within the organization's "high-level personnel," meaning those who have substantial control over the organization or who have a significant policy-making role.

. The compliance program must be communicated effectively to employees. As a first step, each employee should receive a copy of the compliance program and should be required to confirm in writing that he or she has read and understands it and will act in accordance with it. Annually, thereafter, each employee should certify he or she has acted in accordance with the compliance program throughout the past year and is not aware of any violations by others. It should be made clear to the employees in writing, that failure to tell the truth in this respect will be grounds for termination. Employees' regard for the organization's code of environmental conduct should be strengthened by periodic meetings with senior management to review the requirements of the compliance program. Regular evaluations of the employees' environmental performance should be conducted, with further education and training provided as necessary.

. Regular and thorough compliance inspections must be carried out, with documentation of the inspections and appropriate reporting of any environmental incidents. The person in charge of environmental compliance must be given adequate resources to follow up with any corrective actions necessary.

. The compliance program must be enforced. Organizations must employ appropriate disciplinary mechanisms consistently and must be willing to terminate employees who do not act in accordance with the organization's compliance program.

. The compliance program must be reviewed periodically to determine whether it needs to be updated or modified. An overall review must be conducted on an annual basis and a review for potential specific failures of the compliance program should be conducted after every incident of noncompliance. Corrective actions and further education and training must be undertaken as necessary. n41

Creation and Maintenance of a Sensible Document Retention Program. In the environmental area, just as in other areas of an organization's activities, many documents are generated. These documents are often of great interest to regulators and other parties. The establishment of an appropriate records retention (and destruction) policy is, therefore, very important.

Some records are required by law to be kept for a certain length of time. n42 However, there are many records, such as correspondence, notes, and memoranda that are retained indefinitely simply because the organization has no policy concerning records retention.

All documents going between an organization and its legal counsel, including those pertaining to environmental matters and especially those pertaining to environmental compliance, should be marked "Privileged and Confidential -- Attorney-Client Privilege." These documents should be kept separate from the organization's general files and should be accessible only on a need-to-know basis. The same applies to materials generated in connection with periodic internal compliance reviews. n43

Documents having a specific retention requirement (such as tax records, n44 employment records, n45 and health and safety records n46) must of course be retained in accordance with applicable requirements. Documents that have no specific retention requirement should be retained only so long as necessary to satisfy a specific organizational need and should then be destroyed. It is important, however, that destruction of documents be undertaken only pursuant to a written policy, and the policy should be consistently followed. n47 Should the organization become involved in a regulatory dispute or in litigation, all records pertaining to the dispute or the litigation must be maintained until the matter is concluded.

Internal Environmental Compliance Audits

In recent years, many organizations have performed some sort of internal environmental evaluation or audit. However, many other organizations have resisted doing so for fear potential violations uncovered in an audit will cause them to be exposed to civil and criminal liability. Much has been written and said about the advantages and disadvantages of performing an audit, particularly about the extent to which audit information can be protected from disclosure. The current view is the risks of an organization's disclosing environmental violations through an audit are outweighed by the advantages of knowing where the organization stands environmentally so that an effective compliance program can be developed. n48

Benefits and Risks of Performing an Internal Audit. All regulated entities are required to develop certain environmental compliance information. This information obviously can be and often is collected and reported without an organization's having performed an environmental audit. An audit, however, can go far beyond merely collecting compliance information. A comprehensive audit will include:

- . an assessment of environmental risks beyond those currently regulated;
- . an evaluation of internal control systems;
- . an assessment of health and safety concerns;
- . an assessment of whether mandatory reporting and disclosure requirements are being met; and
- . information necessary to budget appropriately for environmental activities. n49

As this list illustrates, the environmental audit can be extremely valuable not only as an aid to regulatory compliance, but also as a risk assessment guide. It can be an effective management tool for establishing, implementing, and maintaining a comprehensive compliance program. Still, it is viewed by many organizations as a dangerous undertaking because it can result in a written record of compliance problems that can be used against the organization and its employees if the information generated by the audit is not protected.

The risks of disclosure are obviously greatest with respect to potential criminal prosecution. Because almost every environmental violation can be charged as a criminal offense n50 and because there are no standard criteria defining the kinds of enforcement cases that will be handled as civil rather than criminal matters, the regulated community has no way of knowing for certain what kind of compliance, short of total compliance, is required to avoid criminal prosecution. As mentioned above, however, current thinking reveals the benefits of performing an audit outweigh the risks, provided the audit process is carefully structured to maintain, insofar as possible, confidentiality of the information and documents generated by the audit. n51

Protecting the Confidentiality of the Audit. There are three bases normally utilized to support the confidentiality of the audit. They are the attorney-client privilege, n52 the work product privilege, n53 and the self-evaluation privilege.

n54 Whether one or more of these bases will be successful in any given case is uncertain under present law. However, it is useful to understand each of these bases so that the argument can be made one or more of them applies.

Attorney-Client Privilege. The attorney-client privilege is defined as a communication made in confidence to an attorney by a client or potential client for the purpose of obtaining legal advice. n55 The four elements of the privilege are: (1) the use of a attorney to provide legal advice; (2) a communication between a client or prospective client and an attorney; (3) confidentiality of the communication; and (4) absence of conduct indicating the privilege has been waived. n56

In the context of an environmental audit, an organization will fulfill the first element by specifically requesting the services of an attorney to provide legal advice in connection with a contemplated environmental audit. The second and third elements will be fulfilled if an organization selects the auditing firm through the attorney, having all documents pass through the attorney to the client, and making sure the attorney is present for all conversations concerning the audit. If the audit is performed in-house, the attorney should oversee its performance. [*caveat*: If your client's organization has an in-house attorney involved in the audit, the attorney must act in his or her capacity as a legal advisor, not as a business advisor. Otherwise, the privilege will be lost.]

Finally, the privilege will be waived if audit information is disclosed. Thus, tight control must be kept over audit information; it should be circulated within the organization only on a need-to-know basis. Also, all copies of the audit report, whether a draft or final, and all copies of any correspondence, notes, memoranda, reports, or other documents generated in connection with the audit should be marked "Confidential--Attorney-Client Privilege" and should be filed separately from the general corporate files, with access restricted solely to a need-to-know basis.

Work Product Doctrine. The work product doctrine protects an attorney's work product prepared in anticipation of litigation from discovery. The doctrine is based on the policy a lawyer needs to be assured he or she can prepare for litigation with a certain degree of privacy. n57 Generally speaking, it is hard to obtain work product protection for an environmental audit since the audit is normally performed to obtain information on the organization's environmental compliance status and on the environmental risks posed by the organization's operations rather than in anticipation of litigation. Although potential lawsuits charging noncompliance are virtually always a possibility, the words "in anticipation of litigation" usually are interpreted to mean there must be a "substantial probability" or a "real prospect" of litigation for the protection of the work product doctrine to attach. n58

Self-Evaluation Privilege. This is a judicially created privilege designed to protect certain internal documents from discovery. The policy underlying this privilege is to encourage honest self-evaluation, which is generally thought to lead to the protection of the public interest. Thus, an environmental audit undertaken by an organization to determine its compliance status and to correct any noncompliances discovered therein might be protected from discovery. n59

It is important to understand, even if one of the three bases outlined above is applicable to the audit, it is only the *evaluative* portions of the audit that can be protected. The *facts* of the audit are not protected. Thus, the consultant's opinions about and the attorney's analysis of potential liability for environmental violations discovered in the audit should qualify for protection, but the fact that violations occurred cannot be protected.

Protecting environmental audits from discovery and disclosure is without question uncertain and difficult under the present state of the law. Nevertheless, with careful planning and the proper use of legal counsel, an organization can do much to protect itself from forced disclosures.

CONCLUSION

The volume and complexity of environmental laws and regulations in existence today, combined with the increased potential for corporate and individual civil and criminal liability, make it imperative that health care organizations take their exposure to liability extremely seriously. Such organizations must commit adequate personnel and resources towards establishing, implementing and maintaining an effective environmental compliance program. This, more than

anything else, can help a health care facility and its responsible individuals avoid civil and criminal liability for environmental violations.

REFERENCE: [n2.] Plaza Health Labs., Inc. v. Perales, 878 F.2d 577 (2d Cir. 1989).

[n1.] State v. Walters, 751 F.2d 977 (9th Cir. 1985).

[n3.] Joyner v. Omnitron Int'l Inc., 8 TOXICS REP. 299 (Pa. C.P. 1993).

[n4.] See, e.g., id.

[n5.] See Department of Justice Announces Third Straight Record Year for Environmental Enforcement, (Dep't Just. News Release May 8, 1992); see also Plaza Health Labs, supra note 2.

[n6.] See e.g., Emergency Planning and Community Right-to-Know Act (EPCRA) of 1986, 42 U.S.C. §§ 11001-11050 (1988 & Supp. V 1993); Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 7 U.S.C. § 136 (1994).

[n7.] 42 U.S.C. §§ 9604, 9606 (1988 & Supp. V 1993); see also Pennsylvania v. Union Gas Co., 491 U.S. 1 (1989).

[n8.] See R. Singer, The Responsible Corporate Officer Doctrine in Environmental Cases (Part 1), 6 TOXICS L. REP. (BNA) at 1405 (1992).

[n9.] 42 U.S.C. §§ 9601-9604, 9606-9610 (1988 & Supp V 1993).

[n10.] See Philip Shabecoff, 45 Toxic Waste Sites Listed as Health Risks, N.Y.TIMES, Jul. 24, 1982, sec. 1 at 8; Not So Super Superfund, N.Y.TIMES, Feb. 7, 1994, at A16.

[n11.] 141 CONG. REC. S 9856, 9875 (daily ed. July 10, 1995).

[n12.] Id.

[n13.] United States v. Price, 688 F.2d 204, (3rd Cir. 1982) (complaint for CERCLA violation against 35 corporations); Wehner v. Snytex Corp., 622 F.Supp. 302 (E.D. Mo. 1983) (complaint against Independent Petrochemical Corporation for CERCLA violation).

[n14.] See Westfarm Assoc. Ltd. Partnership v. Washington Suburban Sanitary Comm'n, 66 F.3d 669 (4th Cir. 1995).

[n15.] Kenneth W. Ayers, Health Care Facilities Cope with New Environmental Risks, RISK MGMT., Oct. 1993, at 83.

[n16.] 42 U.S.C. § 9604(a) (1988).

[n17.] 42 U.S.C. § 9607(a) (1988).

[n18.] Id.

[n19.] 42 U.S.C. § 9601(9) (1988).

[n20.] To avoid this result, hospitals enter into disposal contracts in which the medical waste firm carries the liability. Casey Bukro, Medical-Waste Firm Shoulders Hospitals' Liability, CHI. TRIB., Apr. 9, 1994, at Business 1.

[n21.] See 42 U.S.C. §§ 9601(14)(1988); 42 U.S.C. §§ 9602(1988); 40 C.F.R. 261 (1992).

[n22.] 42 U.S.C. § 9601(14) (1988); see also *Southern Pac. Transp. Co. v. California*, 790 F. Supp 983, 22 *Envtl. L. Rep.* 20,351 (C.D. Cal. 1991) (petroleum exclusion applies to all forms of petroleum); Leo O. Bacher, Jr., *When Oil is Not Oil: An Analysis of CERCLA's Petroleum Exclusion in the Context of a Mixed Oil Spill*, 45 *BAYLOR L. REV.* 233 (1993).

[n23.] But see *Niecko v. Emro Mktg. Co.*, 769 F. Supp 973 (E.D. Mich. 1991) (purchasers of property formerly used as a gas station had no CERCLA cause of action where evidence suggested benzene, toluene, ethyl benzene, and xylene removed from the property was the result of leaking gasoline because the petroleum exclusion excepts this type of spill from CERCLA coverage).

[n24.] *United States v. Alcan Aluminum Corp.*, 964 F.2d 252 (3d Cir. 1992).

[n25.] *United States v. A & N Cleaners & Launderers.*, 788 F. Supp. 1317 (S.D.N.Y. 1992).

[n26.] 42 U.S.C. § 9607, 9613 (1988).

[n27.] Bob Sablature, *Toxic Waste; For Little Guy, Cleanup Often Sizeable Worry; Owners of Drugstore Lived Legal Nightmare*, *HOUS. CHRON.*, Oct. 23, 1995, at A7.

[n28.] *Alcan Aluminum Corp.*, 964 F.2d at 252.

[n29.] 42 U.S.C. § 9607(b) (1988).

[n30.] *Jones-Hamilton Co. v. Beazer Materials & Servs.*, 973 F.2d 688 (9th Cir. 1992) (indemnification clause referring to all laws included environmental laws was enforceable).

[n31.] Singer, *supra* note 8.

[n32.] *Id.*

[n33.] Dep't of Justice Announces Record \$ 2 Billion Year for Environmental Enforcement, Dep't of Just. News Release (Oct. 29, 1992).

[n34.] See Richard G. Singer, *The 'Responsible Corporate Officer Doctrine' in Environmental Cases Part 2*, 6 *TOXICS LAW REP.* 1405 (1992).

[n35.] *Id.* Singer, *supra* note 8, at 1378-1379 (analyzing *United States v. Int'l Minerals & Chem. Corp.*, 402 U.S. 558 (1971), *United States v. Freed*, 401 U.S. 601 (1971), and *United States v. Balint*, 258 U.S. 250 (1922)).

[n36.] See generally, Singer, *supra* note 8.

[n37.] See *Id.* at 1380 (citing *United States v. Dotterweich*, 320 U.S. 277, 285 (1943) (the Court stated in balancing the hardships, Congress had chosen to place responsibility on those with the opportunity to inform themselves of a public danger rather than "to throw the hazard on the innocent public who are wholly helpless").

[n38.] *Id.*; see e.g., *United States v. MacDonald & Watson Waste Oil Co.*, 933 F.2d 35, 55 (1st Cir. 1991) (stating a mere showing of official responsibility . . . is not an adequate substitute for direct or circumstantial proof of knowledge).

[n39.] See generally, Singer *supra* note 34. The seminal cases regarding the "responsible corporate officer doctrine" are *United States v. Dotterweich*, 320 U.S. 277 and *United States v. Park*, 421 U.S. 658 (1975).

[n40.] See Kenneth D. Woodrow, *The Proposed Federal Environmental Sentencing Guidelines: A Model for Corporate Environmental Compliance Programs*, ENV'T REP. 325, 326 (BNA) (1994) (analyzing Factors in Decisions on Criminal Prosecutions for Environmental Violations in the Context of Significant Voluntary Compliance of Disclosure Efforts by the Violator, Dep't Just. News Release (July 1, 1991).

[n41.] RIDGWAY M. HALL, JR. & DAVID R. CASE, *ALL ABOUT ENVIRONMENTAL AUDITING*, 8-56 to 8-57 (1992); see also Woodrow, *supra* note 40, at 328-30.

[n42.] 42 U.S.C. § 9601; see also, 18 U.S.C. §§ 1503, 1505, and 1510 (federal statute mandating criminal prosecution for destruction of documents if it interferes with judicial, administrative, or legislative investigations).

[n43.] HALL & CASE, *supra* note 41, at 7-19 to 7-20.

[n44.] 26 U.S.C. § 6695(d) (1995).

[n45.] See e.g., KAN. STAT. ANN. § 44-714 (1994); ME. REV. STAT. ANN. tit. 19, § 777-C(5) (1994); MONT. CODE ANN. § 20-1-212(2) (1995); OHIO ADMIN. CODE § 1301:12-1-10 (1995); S.D. CODIFIED LAWS ANN. § 1-27-14.1 (1995).

[n46.] See, e.g., CAL. HEALTH & SAFETY CODE § 1795.28 (Deering 1995); IND. CODE ANN. § 8-2.1-11-1 (Burns 1995); LA. REV. STAT. ANN. § 40:1596.1 (West 1995).

[n47.] HALL & CASE, *supra* note 41, at 7-20.

[n48.] *Id.* at 5-1 to 5-24; see also Woodrow, *supra* note 40, at 326.

[n49.] See generally HALL & CASE, *supra* note 41.

[n50.] *Id.* at 8-6 to 8-7.

[n51.] *Id.* at 8-2 to 8-58.

[n52.] The attorney-client privilege protects the audit process itself; however, it mandates the involvement of the attorney in providing legal advice regarding liability of noncompliance. HALL & CASE, *supra* note 41, at 5-8 to 5-9; see also *Olen Properties Corp. v. Sheldahl*, 1994 U.S. Dist. LEXIS 7125 (D.C. Cal. Apr. 12, 1994).

[n53.] This doctrine protects material prepared by the attorney in anticipation of litigation. HALL & CASE, *supra* note 41, at 5-15 to 5-16; see also *Hickman v. Taylor*, 329 U.S. 495 (1947).

[n54.] This privilege is similar to the work-product doctrine. However, it has a narrow application; courts have held it does not apply to criminal enforcement actions. HALL & CASE, *supra* note 41, at 5-19; see also Thomas E. Lindley & Jerry B. Hodson, *Environmental Audit Privilege: Oregon's Experiment*, 24 ENV'T REP. (BNA) at 1230-1232 (1993) (discussion of Oregon's newly enacted Senate Bill 912, which generally excludes audit reports from admission in civil, criminal, or administrative proceedings).

[n55.] See e.g., *United States v. White*, 950 F.2d 426, (7th Cir. 1991).

[n56.] See HALL & CASE, *supra* note 41, at 5-5 to 5-15.

[n57.] *Hickman*, 329 U.S. at 497.

[n58.] HALL & CASE, *supra* note 41, at 5-15 to 5-19.

[n59.] *Id.* at 5-19.

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TITLE: The Summer of Union Discontent Portends a Season of Employer Discomfort

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TEXT:

ABSTRACT: The recent splintering of the unions of the Change to Win Coalition from the AFL-CIO has received a great deal of attention in the media. Few have watched these developments with greater interest than employers in a broad variety of employment settings. As union prospects in the manufacturing industries have dwindled, employers in the service industries such as healthcare have become especially sensitive to changes in the labor movement and the opportunities to organize. This Article explores the philosophical differences responsible for the AFL-CIO schism, the likely effect this division will have on union organizing efforts in the healthcare industry, and the negative consequences these organizing efforts could have on employee free choice within the industry. In addition, this Article outlines some of the steps healthcare employers can take to protect their ability to communicate freely and directly with their employees.

Many news accounts of the recent AFL-CIO schism have caught the attention of employers. Some have taken solace in the departure of the Service Employees International Union (SEIU) and the International Brotherhood of Teamsters (Teamsters) from the fold of their union brothers and sisters. n1 Other unions that have joined the Change to Win Coalition include UNITE-HERE, the Laborers and Carpenters unions, as well as the United Food and Commercial Workers (UFCW). n2

n1 Harold Meyerson, *One More Secession: The AFL-CIO Has Lost Another Member, Shrinking Its Numbers Even More*, AM. PROSPECT ONLINE ED., Sept. 15, 2005, at www.prospect.org/web/page.wv?section=root&name=ViewWeb&articleId=10285 (last visited Dec. 27, 2005).

n2 *See id.*

The recent division between the AFL-CIO and the Change to Win Coalition has brought to the public eye the most recent trends in union organizing. In the face of decreasing union membership, the unions of the Change to Win Coalition have adopted more aggressive organizing techniques, many of which have been brought to bear on hospitals and other employers in the healthcare industry. n3 With relatively low union representation and significant job growth projected well into the future in healthcare, n4 unions will no doubt continue to focus considerable resources and effort on organizing the healthcare industry.

n3 *See id.*

n4 *See* BUREAU OF LABOR STATISTICS, U.S. DEPT OF LABOR, BULL. NO. 2601, 2006-2007 CAREER GUIDE TO INDUSTRIES: HEALTH CARE (2005), at www.bls.gov/oco/cg/print/cgs035.htm (last visited Dec. 27, 2005).

This Article addresses the recent split between the AFL-CIO and Change to Win and suggests the split will generally increase union organizing efforts in the near term and will specifically increase the use of aggressive techniques that have gained popularity among successful union organizers. The position of the healthcare industry in the overall labor market makes it a prime target for union organizers.

Observers of the healthcare industry note several deleterious effects that the unionization of healthcare workers can create. Of first and obvious importance is the potential of strike action taken by those charged with patient care. Despite unique notice and cooling off periods imposed by federal labor law on strikes in healthcare settings, n5 hospital and **nursing home** strikes occur with alarming frequency and can last for extended periods of time, depriving communities of reliable healthcare services. n6 Additionally, the adversarial employee relations environment that too often accompanies workplace unionization is the antithesis of the collaborative work culture required for improved healthcare services and patient safety. n7

n5

A labor organization, before engaging in any strike, picketing, or other concerted refusal to work at any health care institution shall, not less than ten days prior to such action, notify the institution in writing and the Federal Mediation and Conciliation Service of that intention, except that in the case of bargaining for an initial agreement following certification or recognition the notice required by this subsection shall not be given until the expiration of the period specified in clause (B) of the last sentence of section (8)(d) of this Act. The notice shall state the date and time that such action will commence. The notice, once given, may be extended by the written agreement of both parties.

29 U.S.C. § 158(g)

n6 *See, e.g.*, Tim Bonfield, *Hospital Braces for Nurses Strike*, THE ENQUIRER, June 27, 2002, at <http://tinyurl.com/9jjvb> (last visited Feb. 18, 2006) (listing some of the services one hospital intended to discontinue should its nurses go on strike and observing that, the previous year, "770 nurses in Youngstown, Ohio, went on strike for 78 days"); Scott Deacle, *Butler Hospital Lays off 141*, POST-GAZETTE.COM April 5, 2002, at www.post-gazette.com/businessnews/20020405butler0405bnp2.asp (last visited Feb. 18, 2006) (reporting that Butler hospital began "denying admission to children as well as to patients requiring certain types of care" in preparation for a nurses strike).

n7 INSTITUTE OF MEDICINE, COMMITTEE ON THE WORK ENVIRONMENT OF NURSES AND PATIENT SAFETY, KEEPING PATIENTS SAFE: TRANSFORMING THE WORK ENVIRONMENT OF NURSES 211 (Ann Page, ed., National Academies Press 2004) (Interdisciplinary collaboration is a "key strategy [healthcare organizations] should undertake to improve patient safety."), available at <http://newton.nap.edu/books/0309090679/html/8.html>.

The steady decline of union membership nationwide has pushed many unions to reverse the trend by utilizing strategies to exploit perceived weaknesses in healthcare organizations in order to gain an advantage in their organizing efforts. As a primary example, unions have increasingly attempted to compel employers to agree to union representation outside of the election process traditionally favored by the National Labor Relations Act (NLRA). n8 As explained in detail below, when unions succeed in moving representation initiatives outside of the election process, employees lose the benefit of National Labor Relations Board oversight and its review of the positions of both their employers and the unions as the employees consider the costs and benefits of collective bargaining.

n8 National Labor Relations Act (NLRA), 29 U.S.C. §§ 151-169 (2005).

Part I of this Article addresses both the recent split between the AFL-CIO and the Change to Win Coalition and the philosophical and strategic differences responsible for the division. Part II addresses the reasons unions have and will continue to target the healthcare industry. Part III addresses some of the organizing tactics unions have opted to use in organizing healthcare employers, including corporate campaigns, card check and neutrality agreements, telephone surveys, and grassroots organizing. Part IV analyzes the effect these new union measures are having on employee free choice, a fundamental policy in American labor relations. Finally, Part V offers specific suggestions for healthcare employers intent on **protecting** their ability to communicate directly and effectively with their employees in a climate of increasingly energetic union activity.

I. The Split between the AFL-CIO and Change to Win: A Climate for Intense Organizing Activity

The National Labor Relations Act grants a majority of workers in the United States the right to bargain collectively. n9 For years, however, the number of employees represented by unions has been in steady decline. Today, approximately 12.5% of all public and private sector wage and salary workers are represented by unions. n10 In comparison, 20.1% of such workers were represented by a union in 1983. n11 In the private sector, less than 8% of employees are represented by a union today, down from 26% fifty years ago. n12 It is against this backdrop that the schism between the AFL-CIO and the Change to Win Coalition arose. At the crux of the divide was a fundamental difference in organizing philosophy.

n9

Employees shall have the right to self-organization, to form, join, or assist labor organizations, to bargain collectively through representatives of their own choosing, and to engage in other concerted activities for the purpose of collective bargaining or other mutual aid or protection, and shall also have the right to refrain from any or all of such activities except to the extent that such right may be affected by an agreement requiring membership in a labor organization as a condition of employment as authorized in section 158(a)(3) of this title.

See id. § 157.

n10 Press Release, Bureau of Labor Statistics, U.S. Dep't of Labor, Union Members in 2004, (Jan. 27, 2005), *available at* <ftp://ftp.bls.gov/pub/news.release/union2.txt> (last visited Dec. 21, 2005).

n11 *Id.*

n12 Jessica Marquez, *AFL-CIO Split May Invigorate Labor Efforts*, WORKFORCE MGMT., Sept. 1, 2005, at 15.

A. The Philosophical Divide

The AFL-CIO has traditionally devoted considerable resources to addressing labor issues by political means. Even in the face of declining union membership, leaders in the AFL-CIO remained committed to pursuing political solutions, arguing for the "huge role" political action plays in organizing. n13 According to Jerry McEntee, president of the American Federation of State, County & Municipal Employees (AFSCME), "Labor isn't going to have significant organizing until we're able to change people in political office and persuade them to change the nation's labor laws." n14 The AFL-CIO's commitment to political action only grew in reaction to what was perceived as an anti-labor, right-wing Republican administration. Indeed, by mid-2005, John Sweeney, president of the AFL-CIO, planned on raising political spending from \$ 7.5 million to \$ 30 million a year. n15

n13 Radio interview by WLWU 88.7 FM (Chicago, IL) with Stewart Acuff, National Organizing Director, AFL-CIO (July 24, 2005).

n14 Aaron Bernstein, *Struggle for the Soul of the AFL-CIO: Two Union Honchos Battle Over Reform, Power, and Turf on the Eve of Its Convention*, BUS. WEEK, July 25, 2005, at 54.

n15 Steven Greenhouse, *Among Dissident Union Leaders, The Backgrounds May Vary but the Vision Is the Same*, N.Y. TIMES, July 22, 2005, at A15.

In sharp contrast, Andrew Stern, president of the SEIU, advocated shifting resources from political campaigns to more intense organizing efforts. n16 James P. Hoffa, president of the Teamsters, advocated investing primarily in union membership growth. n17 According to Stern, labor laws, written with the industrial economy in mind, were outdated. n18 Stern and SEIU opted to confront outdated labor laws, not with increased political pressure, but by changing organizing tactics.

n16 Andrew L. Stern, *Unions Reinvented; The AFL-CIO has Failed to Recognize That Times are Changing and Workers' Lives are Evolving. That's Why the Labor Movement Must Split*, L.A. TIMES, July 29, 2005, at B13.

n17 See Thomas B. Edsall, *Two Top Unions Split from AFL-CIO; Other are Expected to Follow Teamsters*, WASH. POST, July 26, 2005, at A01 [hereinafter Edsall, *Top Unions Split*].

n18 Stern, *supra* note 16.

This fundamental difference in philosophy soon created a rift in the AFL-CIO. Union leaders, as well as whole unions, began gravitating to the philosophical poles represented by Sweeney and Stern. Union dues rebates soon became a primary point of friction between these two organizing philosophies. While Stern demanded that fifty percent of union dues be returned to the unions to invest in massive organizing efforts, the AFL-CIO leadership balked, protesting that massive rebates would "cripple the federation's efforts in political campaigns, job safety and other areas." n19

n19 Steven Greenhouse, *Ambitions Are Fueling a Division of Labor*, N.Y. TIMES, July 26, 2005, at A1 [hereinafter Greenhouse, *Division of Labor*].

B. The Split

It is no coincidence that the workforces traditionally represented by the Change to Win Coalition (hospitality, transportation, and healthcare) are unlikely to be victims of job outsourcing. In contrast, the mainstream AFL-CIO constituency (telecommunications, manufacturing, basic metals, and mining) is most threatened by offshore work relocation. The difference between an emphasis on organizing and focusing on political action becomes apparent when each segment of the labor movement is identified by the interest groups served.

The fabric of the federation, tightened by internal disagreement, finally tore in July 2005, when the SEIU and the Teamsters resigned from the AFL-CIO. n20 At about the same time, these two unions, along with the UFCW and UNITE-HERE, announced their plans to boycott the AFL-CIO convention. n21 According to Hoffa, "What was done at the AFL-CIO was not working. We're going to do something new. That is our message." n22

n20 Edsall, *Top Unions Split*, *supra* note 17.

n21 Thomas B. Edsall, *Four Big Unions Boycott AFL-CIO Convention and May Split Away*, WASH. POST, July 25, 2005, at A04.

n22 Greenhouse, *Division of Labor*, *supra* note 19.

The split became official in September 2005, when the Teamsters, the SEIU, the Laborers International Union of North America, the United Brotherhood of Carpenters and Joiners of America, the United Farm Workers, the UFCW, and UNITE-HERE combined to create Change to Win. n23 At the Change to Win convention, the Chair of Change to Win, Anna Burger, stated the primary focus of the new coalition: "Strategic, smart organizing is our core principle--our North Star--uniting workers by industry, not one shop at a time, but whole **companies** all the time. Wholesale--not retail. We will put our money where our mouth is--three-quarters of our resources to a groundbreaking organizing crusade." n24 In addition to focusing on organizing, Burger noted Change to Win's willingness to use aggressive measures where necessary: "We have always said that we like to use the power of persuasion, but if we can't, we will use the persuasion of power." n25

n23 Steven Greenhouse, *Breakaway Unions Start New Federation*, N.Y. TIMES, Sept. 28, 2005, at A17. Cf. CHANGE TO WIN COALITION, *Change to Win Constitution*, www.workinglife.org/FOL/news/CTWConstitution.pdf (last visited Dec. 27, 2005).

n24 Anna Burger, Chair, Change to Win Coalition, Address at the Change to Win Founding Convention (Sept. 27, 2005), *available at* www.workinglife.org/FOL/news/BurgerCTWconvpreparedremarks (last visited Dec. 22, 2005).

n25 Marquez, *supra* note 12.

The activities of the SEIU, a key member of the Change to Win Coalition, indicate the aggressive direction in which Change to Win is likely to proceed. SEIU currently has approximately 1.8 million members in various service industries in the United States, Canada, and Puerto Rico. n26 SEIU has been one of the fastest growing unions in the country. Instead of pursuing political remedies to declining union membership, SEIU has focused primarily on increasing membership, often by means outside of the traditional NLRB election model. The single industry most affected by the SEIU organizing success has been healthcare.

n26 SERV. EMPLOYEES INT'L UNION (SEIU), *SEIU Fast Facts*, at www.seiu.org/about/fast_facts/index.cfm (last visited Jan. 5, 2006).

C. Effects of the Split

No one is sure of the long-term effects of the split between the unions of the AFL-CIO and Change to Win. Sweeney described the split as a "tragedy for working people," lamenting that "a divided movement hurts the hopes of working families for a better life." n27 Despite Sweeney's dire prediction for workers, some commentators believe the split may "cause all unions to be more aggressive with their organizing and collective bargaining," ultimately invigorating the labor movement. n28

n27 SEATTLE TIMES NEWS SERV., *Labor Split Could Hurt Democrats' Campaigns; Unions Provide Political Foot Soldiers--Analysts Debate Consequences of Defections*, SEATTLE TIMES, July 26, 2005, at A1.

n28 Marquez, *supra* note 12.

The division between the AFL-CIO and Change to Win, rather than reducing the amount of union organizing, will serve to increase competition for employee sympathies by unions admittedly desperate for increased membership. As competition for employee sympathies increases between unions, unions of all philosophical persuasions will utilize organizing techniques that have proven effective and will target those industries offering the greatest return for their

efforts.

II. Union Designs for the Healthcare Industry

There can be little doubt that the healthcare industry is a prime target for union organizing efforts. Some unions, such as the SEIU, have clearly stated their intention to focus on organizing workers in the industry. n29 The healthcare industry currently holds a unique position in the labor market, making it a target for unions intent on increasing membership. It is considered a growth industry with consistent growth projected through at least 2014. n30 In 2004, health services included 13.5 million jobs. n31 Health service jobs are projected to grow by 3.6 million between 2004 and 2014, which would account for 19% of all new wage and salary jobs in that period. n32 This significant projected growth, coupled with historically low union representation, makes healthcare workers a natural target for unions.

n29 Christopher Rowland, *Union Looks to Organize at Hub's Top Hospitals*, BOSTON GLOBE, Aug. 31, 2005, at A1.

n30 BUREAU OF LABOR STATISTICS, U.S. DEPT OF LABOR, *supra* note 4.

n31 *Id.*

n32 *Id.*

In addition to continuing growth in jobs across the industry, several other reasons are often cited for union interest in the healthcare industry. First, service jobs in the healthcare industry are unlikely to be outsourced. Unlike some service jobs, such as product support, which can be provided from virtually any location worldwide, most healthcare service positions must be filled by local employees. One healthcare division director for SEIU noted, "You can't do bedside nursing for people in New York in Asia." n33 Similarly, healthcare jobs cannot be "shifted from state to state to defeat union mobilization efforts." n34

n33 Michelle Rogers, *Under Siege*, HEALTHLEADERS MEDIA, Jan. 2004, at 56, 57 available at <http://tinyurl.com/npxny> (last visited Dec. 27, 2005).

n34 Thomas B. Edsall, *Insurrection Is a Big Gamble for Labor*, WASH. POST, July 30, 2005, at A11.

There are other reasons the healthcare industry is a particularly attractive target for union organizers. According to Rick Wade, senior vice president for communications at the American Hospital Association, "You have one-third of hospitals in America operating in the red, another third are just getting by and one-third are doing okay. You have a medical liability crisis, a workforce shortage, a poor economy and you have the grumpiest medical staff in recorded history." n35 Some commentators suggest that the healthcare industry has become a more attractive union target because of reductions in traditionally unionized industries, like manufacturing, and the resultant relocation of workers to the growth industry of healthcare. n36

n35 Rogers, *supra* note 33.

n36 *Id.* (quoting Chris Cimino, executive vice president of Chicago-based Chessboard Consulting: "You have lost 2.5 million manufacturing jobs since the recession started. So hospitals represent a plum for these unions and especially the SEIU.").

III. New Union Goals, New Union Strategies

Organizing campaigns are nothing new to labor relations. Nevertheless, with a shift in focus to growth in membership one industry at a time, aggressive organizing methods are replacing the traditional methods unions have used in the past. Some of the more significant departures from traditional organizing tactics include the use of corporate campaigns to bring to bear enormous public pressure on employers, the demand for card check and neutrality agreements to circumvent traditional NLRB-supervised elections, increased use of telephone surveys and grassroots organizing, and stealth organizing techniques designed to catch employers unaware.

A. Corporate Campaigns

Unions have demonstrated an ability to use the media and government agencies as well as civic and religious institutions to put public pressure on employers to drop resistance to union organizational efforts. Charges filed with regulatory agencies, media reports concerning poor customer and employee relations, and rallies attended by local religious leaders are some of the methods unions recently have used in organizational campaigns. Although unions have put various types of pressure on employers during organizational campaigns in the past, the strategic use of significant public pressure is a newer development, known as the "corporate campaign."ⁿ³⁷

ⁿ³⁷ *Compulsory Union Dues and Corporate Campaigns: Hearing Before the S. Comm. on Workforce Protections*, 107th Cong. 45--46 (2002) [hereinafter *Hearing Workforce Protections*] (testimony of Jarol B. Manheim, Professor of Media and Public Affairs and Political Science, George Washington University).

Jarol B. Manheim, a professor who has studied over 200 corporate campaigns, defined "corporate campaign" in testimony before the Subcommittee on Workforce Protections.ⁿ³⁸ According to Prof. Manheim:

A corporate campaign is an organized assault--involving economic, political, legal, regulatory and psychological warfare--on a **company** that has offended a labor union or some other group. The attack usually centers around the media, where the protagonists attempt to redefine the image--and tarnish the reputation--of the target **company** until it yields on whatever the issue in dispute might be. The central idea is to undermine the **company's** relationships with its key stakeholders: customers, employees, shareholders, bankers, insurers, regulators and the general public, among others. In effect, the goal of the campaign is to define the target **company** as a corporate outlaw--a pariah institution--that must be stopped before it does further damage to our society, and to make anyone who deals with the **company** feel a sense of personal embarrassment for having done so.ⁿ³⁹

ⁿ³⁸ *Id.*

ⁿ³⁹ *Id.*

According to Charles I. Cohen, the hallmark of a corporate campaign is coercion of management, including the looming threat of corporate extinction:

One of the principal differences between the traditional forms of union expression and the corporate campaign is that while collective bargaining is premised on labor having some or all of its views adopted voluntarily by management after a period of collective bargaining, the corporate campaign often is premised on management either being coerced into accepting a union's demands or potentially being driven out of business.ⁿ⁴⁰

n40 *Emerging Trends In Employment and Labor Law: Labor-Management Relations in a Global Economy; Hearing Before the S. Comm. on Employer-Employee Relations*, 107th Cong. 99 (2002) (statement by Charles I. Cohen, Senior Partner, Morgan, Lewis & Bockius LLP).

An interesting feature of the corporate campaign is that the coercion is generally unrelated to the labor dispute. To pressure the employer, a union will "glom on" to an issue that has nothing to do with the labor dispute. n41 This strategy "takes the labor dispute outside of the merits and economics of that labor dispute and puts it in a whole new context, a whole new economic context that has nothing to do with the pros and cons of the respective economic positions of the parties." n42

n41 FEDERALIST SOC'Y L. & PUB. POL'Y STUD., *The Rise of the Corporate Campaign--Transcripts; Panel One: The Core Elements of the Union-Backed Corporate Campaign, Litigation and Regulatory Strategies*, at www.fed-soc.org/Publications/practice-groupnewsletters/PG%20Links/corporatecampaign.htm (last visited Dec. 27, 2005).

n42 *Id.*

In recent years, the healthcare industry has seen an increased number of corporate campaigns, waged primarily against hospitals. The SEIU began using some of the techniques common in corporate campaigns in its efforts to organize California hospitals. n43 The techniques developed there have been used in other organizational campaigns, most notably at Yale-New Haven Hospital, Advocate Health Care, and Catholic West Healthcare. n44 These campaigns illustrate some of the techniques unions have developed to organize healthcare organizations.

n43 Jorge Mancillas, *Jorge Macillas Replies*, to Kate Bronfenbrenner *Changing to Organize; Unions Know What Has to be Done. Now They Have to Do it*. NATION, Sept. 3, 2001, at 16, 24, available at www.thenation.com/doc/20010903/forum (last visited Dec. 31, 2005) ("SEIU launched an ambitious plan to organize 148,000 employees in 473 California hospitals.").

n44 See generally GRACE ROLLINS, CONN. CTR. FOR A NEW ECONOMY, UNCHARITABLE CARE: YALE-NEW HAVEN HOSPITAL'S CHARITY CARE AND COLLECTIONS PRACTICES (2003), available at www.ctneweconomy.org/Publications/UC.pdf (last visited Dec. 26, 2005); SEIU HOSPITAL ACCOUNTABILITY PROJECT, UNINSURED AND OVERCHARGED: How ADVOCATE HEALTH CARE OVERCHARGES CHICAGO HOSPITAL PATIENTS (2003) [hereinafter SEIU HOSPITAL ACCOUNTABILITY PROJECT], available at www.seiu.org/docUploads/Discriminatory_Pricing__DP_Advocate.pdf (last visited Dec. 18, 2005); James McCoy, *Catholic Healthcare for the Rich: Poor Take a Hit While Revenues Rise*, L.A. LAY CATHOLIC MISSION, July-Aug. 1999, available at www.losangelesmission.com/ed/articles/1999/0799jm2.htm (last visited Dec. 18, 2005).

1. Charity Care Reports

As noted by Professor Manheim, a central feature of a corporate campaign is a direct attack on the reputation of an employer. n45 Unions setting their sights on healthcare employers have developed specific means to achieve these ends. The SEIU in particular has adopted the strategy of attacking a hospital's perceived commitment to charity care. n46 Generally speaking, charity care refers to free or reduced-cost healthcare services provided to those who are uninsured and unable to pay the cost of the services they require. n47 The SEIU Hospital Accountability Project, along with organizations acting in conjunction with SEIU, has published several reports purporting to "expose" a lack of charity care and aggressive bill collecting by some of the nation's largest hospitals. n48 The publication of these reports has coincided with significant organizational efforts at the hospitals targeted in the reports.

n45 *Hearing Workforce Protections*, *supra* note 37 (testimony of Professor Jarol B. Manheim).

n46 See THE NEW ATTACK ON CHARITY CARE, NYHART HREPORT, Spring 2005, at 1, 1, available at www.nyhart.biz/NyhartHRNewsSpring.pdf (last visited Dec. 26, 2005).

n47 See *Charity Care*, WIKIPEDIA, at http://en.wikipedia.org/wiki/Charity_care (last visited Dec. 18, 2005) [hereinafter *Charity Care*].

n48 See SEIU, *Discriminatory Pricing--SEIU Action; SEIU: Taking on Discriminatory Pricing--and Winning*, at www.seiu.org/health/hosp/dp_seiuaction.cfm (last visited Jan. 2, 2006).

In January 2003, the Connecticut Center for a New Economy published a report entitled *Uncharitable Care: Yale-New Haven Hospital's Charity Care and Collections Practices*. n49 This report was researched and written by Grace Rollins, a research analyst for New England Health Care Employees Union, District 1199/SEIU. n50 The report purported to expose Yale-New Haven's reduction of offered charity care and aggressive collection practices, all while Yale-New Haven continued to show a profit. n51 The publication of this report followed extensive union efforts to organize workers at Yale-New Haven.

n49 See ROLLINS, *supra* note 44.

n50 *Id.*

n51 *Id.* at i.

Advocate Health Care in Chicago was the subject of a comparable report. *Uninsured and Overcharged: How Advocate Care overcharges Chicago hospital patients*, was strikingly similar in style to the Yale-New Haven report, and focused on an alleged disparity between what uninsured patients pay for hospital services compared to what insurance **companies** pay for insured patients. n52

n52 SEIU HOSPITAL ACCOUNTABILITY PROJECT, *supra* note 44, at 6.

Employers insisted that the assertions in these reports were not true. In regard to the charity care report published against Yale-New Haven, Katie Krauss, spokeswoman for Yale-New Haven Hospital states: "Most of these accusations are false. The fact is, Yale-New Haven Hospital provided the largest amount of free and charity care in the state of Connecticut." n53 Whether charity care reports are half-truths or patently false, employers are left scrambling to shore up their public image, often having to engage in the same sort of campaigning conducted by the unions. At Yale-New Haven, both the union and the hospital purchased billboard ads in an attempt to get their respective messages out to the public. n54

n53 Rogers, *supra* note 33.

n54 See Paul Bass, *Heartless Hospital: Yale-New Haven Breaks New Ground in Going after Patients' Homes*, NEW HAVEN ADVOCATE, Apr. 17, 2003, available at www.newhavenadvocate.com/gbase/News/content.html?oid=oid:12326 (last visited Dec. 18, 2005) (displaying pictures of both union and hospital billboards with a caption reading "Dueling billboards on the Route 34 Connector near the I-95/I-91 interchange").

These reports and others like them have not addressed organizing efforts. Rather, such reports sought only to tarnish the reputation of the hospital while endearing the union "whistle-blowers" to the community they claimed to be **protecting**.

2. Religious Pressure

Another feature of corporate campaigns in the healthcare industry has been the formation of alliances between

union organizers and local religious organizations. This technique was most notably used in the SEIU's campaign to organize Catholic Healthcare West.ⁿ⁵⁵ In addition to utilizing charity care reports similar to those noted above, the SEIU allied itself with organizations within the Catholic community in its efforts to put pressure on the hospital. Organizations like the Los Angeles Lay Catholic Mission echoed the message of the SEIU, giving further publicity to the SEIU's charity care report and intensifying the pressure on the hospital to not only address its charity care policies, but to concede representational rights to the union in order to alleviate the pressure.ⁿ⁵⁶ The union efforts against Catholic Healthcare West eventually resulted in a four-year contract with the SEIU, covering 14,000 employees in twenty-eight California facilities.ⁿ⁵⁷

ⁿ⁵⁵ See *Union, Catholic Healthcare West Reach Statewide Labor Agreement*, SACRAMENTO BUS. J., June 1, 2004 [hereinafter *Union, Catholic Healthcare West*], available at www.bizjournals.com/sacramento/stories/2004/05/31/daily9.html (last visited Dec. 19, 2005).

ⁿ⁵⁶ See McCoy, *supra* note 44.

ⁿ⁵⁷ *Union, Catholic Healthcare West*, *supra* note 55.

Unions have not waited to forge alliances with religious organizations until a particular organizing campaign is in progress. In recent years, unions have reached out to religious organizations of all faiths to promote the message of a common cause between faith and labor. Over the recent 2005 Labor Day holiday weekend, hundreds of union organizers and officials assumed the pulpits of many churches and synagogues to promote the premise that religion and labor organizing are mutually supportive efforts and ethically compelled by people of faith.ⁿ⁵⁸ This event is just one instance of programs like Labor in the Pulpits, a program sponsored in part by the AFL-CIO, to highlight the "shared goals of the faith community and the union movement."ⁿ⁵⁹ Since 1996, the Labor in the Pulpits program has encouraged congregations of all faiths to allow a labor organizer to deliver a message during religious services over the Labor Day weekend.ⁿ⁶⁰

ⁿ⁵⁸ AM. FED. OF LABOR-CONG. OF INDUSTRIAL ORGS. (AFL-CIO), *Labor in the Pulpits: 'Remembering the God-Given Dignity of Work'*, AFL-CIO NEWS (Aug. 30, 2005), at www.aflcio.org/joinaunion/faith/ns08302005.cfm (last visited Dec. 18, 2005).

ⁿ⁵⁹ *Id.*

ⁿ⁶⁰ *Id.*

The use of corporate campaigns has allowed unions to soften employer resistance to organizing efforts. Primarily, unions have used their corporate campaigns to gain two particular organizing advantages: neutrality and card check agreements.

B. Neutrality and Card Check Agreements

A neutrality agreement is an agreement by the employer that it will "remain neutral during a union organizing campaign."ⁿ⁶¹ A congressional report noted some of the forms neutrality agreements take:

The employer may agree not to attack or criticize the union, while the union may agree not to attack or criticize the employer. The agreement may allow managers to answer questions or provide factual information to employees. A neutrality agreement may give a union access to **company** property to meet with employees and distribute literature. An employer may also agree to give the union a list of employee names and addresses. A neutrality agreement may cover organizing drives at new branches of

the **company**. n62

n61 GERALD MAYER, CONG. RESEARCH SERV., LIBRARY OF CONG., LABOR UNION RECOGNITION PROCEDURES: USE OF SECRET BALLOTS AND CARD CHECKS 8 (May 23, 2005), *available at* <http://tinyurl.com/q3mh4>(last visited Dec. 29, 2005).

n62 *Id.*

Regardless of the form, the fundamental purpose of a neutrality agreement is to restrain an employer from exercising its right to communicate to its employees its view of the merits of organizing. n63

n63

The expressing of any views, argument, or opinion, or the dissemination thereof, whether in written, printed, graphic, or visual form, shall not constitute or be evidence of an unfair labor practice under any of the provisions of this subchapter, if such expression contains no threat of reprisal or force or promise of benefit.

29 U.S.C. § 158(c) (2005).

Neutrality agreements are often used in tandem with a card check agreement. n64 In a card check agreement, an employer agrees to forego an NLRB-supervised election recognize a union upon a majority of employees in a bargaining unit signing union cards. n65 There are several reasons that unions prefer card check recognition. First, as long as the union campaign can proceed outside of the NLRA's election procedure, unions can operate largely unsupervised, avoiding potential unfair labor practice violations. n66 Second, under a card check agreement, a union can claim victory the moment a majority of signatures is collected. n67 The time required to conduct an election allows both the union and the employer time to discuss their respective positions and deprives the union of the advantage of a quick, unopposed victory. n68

n64 MAYER, *supra* note 61.

n65 *See id.* at 13.

n66 *Id.*

n67 *Id.*

n68 *See id.* at 6.

Proponents of card check recognition have also lobbied for changes in the law to increase the frequency of card check recognition. In fact, both proponents and opponents of card check recognition have introduced bills in the House of Representatives. n69 Intensified union pressure for card check agreements has led to increased debate over the legitimacy of card check recognition. Proponents of card check agreements claim that such recognition neutralizes the unfair advantage employers have during the process leading up to an election. n70 Opponents, on the other hand, argue that card check recognition undermines employee choice. n71 Presently pending before the NLRB is the *Dana/Metaldyne* case, which questions the legality of neutrality agreements on the grounds that they effectively deprive employees of the free choice guaranteed by the NLRA. n72

n69 See H.R. 3619, 108th Cong. (2003) (A bill sponsored by Rep. Miller "[t]o amend the National Labor Relations Act to establish an efficient system to enable employees to form, join, or assist labor organizations, to provide for mandatory injunctions for unfair labor practices during organizing efforts, and for other purposes."); H.R. 874, 109th Cong. (2005) (A bill sponsored by Rep. Norwood "[t]o amend the National Labor Relations Act to ensure the right of employees to a secret-ballot election conducted by the National Labor Relations Board.").

n70 See MAYER, *supra* note 61, at 13.

n71 *Id.*

n72 Dana Corp., 341 N.L.R.B. 150 (2004), 2004 WL 1329345. In the combined cases of Dana Corporation and Metaldyne Corporation, both employers entered neutrality and card check agreements with the union and subsequently voluntarily recognized the union after card checks were conducted by neutral third parties. *Id.* at *1-2. Also in both cases, employees filed petitions for decertification elections shortly after the employers had voluntarily recognized the union. *Id.* at *3 (Members Liebman and Walsh, dissenting). The NLRB granted review of the Regional Directors' administrative dismissals of petitions in these combined cases. *Id.* at *1. The issue before the board is "whether voluntary recognition . . . should give rise to a recognition bar" where the employer and the union entered into a card check agreement before the union obtained authorization cards from a majority of employees. *Id.* at *2. See also *infra* Section IV, notes 77-85 and accompanying text.

Proponents of card check recognition believe the field is tilted in favor of employers who have both greater access to and greater leverage over their employees. n73 In advocating for card check recognition, proponents would address the inequality, not by leveling the playing field, but by removing the employer from the game altogether through reliance on authorization cards. The downside of this approach, however, is that authorization cards lack the protections of an NLRB-supervised election and may be signed in coercive circumstances or without accurate information. n74

n73 See MAYER, *supra* note 61, at 13.

n74 *Id.*

C. Telephone Surveys

Unions have successfully used polling techniques to gain information on local employers and gauge employee support for union organizing. Acting as political pollsters, union organizers will call employees at home and pose a series of sophisticated human interest questions with the purpose of ferreting out employers who are ripe for organizing and employees willing to assist. This target assessment device will objectively provide unions with a numerical score to indicate the likelihood of organizing success with a particular employer before the union is even identified or goes public with its intentions. n75 Among the various issues explored in the survey is the degree to which a specific employer is on record as being opposed to unionization and regularly articulates its reasons for that position. Employers who repeatedly express their reasons for remaining union-free are far less likely to be organized, and unions choose their targets accordingly. n76

n75 See Initial Assessment of Targets for Union Organizing Drive (document on file with authors, which was obtained in connection with a UAW organizing campaign in the early 1990s).

n76 CHIRAG MEHTA & NIK THEODORE, AM. RIGHTS AT WORK, UNDERMINING THE RIGHT TO ORGANIZE: EMPLOYER BEHAVIOR DURING UNION REPRESENTATION CAMPAIGNS 8 (2005), available at <http://tinyurl.com/zcsc2> (last visited Mar. 6, 2006).

D. Grassroots Organizing

Before employee organizing takes place, many unions work for long periods of time developing relationships with local civic leaders and politicians to build credibility and a power base from which to operate in the event a union membership campaign is resisted by a local employer. When an employer caught unaware attempts to oppose the union's organizing efforts, the area civic leaders can be counted on by the union to exert pressure with various degrees of subtlety.

IV. Employee Free Choice: A Casualty of New Union Strategies

Section 7 of the NLRA grants employees both "the right . . . to form, join, or assist labor organizations" as well as "the right to refrain from any or all of such activities." n77 The statutory model for **protecting** employee choice provides an election process that allows for a period of open discussion of conflicting opinions followed by a secret ballot election. n78

n77 29 U.S.C. § 157 (2005).

n78 *See id.* § 159.

A fundamental aim underlying many of the union tactics outlined above is to remove the organizing process from this statutory framework and government oversight. Securing card check and neutrality agreements allows the union to espouse its pro-union message free from any competing messages of the employer. When employers are forced to enter neutrality agreements, not only do employers lose the ability to communicate their position to employees, employees lose critical access to information as they determine whether they want to be represented by the union.

This phenomenon has serious implications for employees' rights under the NLRA. Several commentators have argued that card check and neutrality agreements are unlawful under the NLRA. n79 Some believe neutrality agreements violate Section 8(a)(2) because an employer's agreement to stay silent while the union expresses its opinion in an environment free from countervailing opinions is equivalent to contributing unlawful support toward a union's success. n80 Commentators have also suggested that neutrality agreements are an improper waiver of an employer's Section 8(c) rights. n81 Moreover, card check agreements have been attacked because of the unreliable circumstances under which a majority is recognized. n82 Even the NLRB has stated that card checks are "admittedly inferior to the election process" as a means of reflecting employee sentiment regarding organization. n83 Other commentators argue that both of these devices are lawful under the NLRA. n84 While pro-election and pro-card recognition advocates agree that employee free choice in organizing is the goal, they disagree completely as to the best method for reaching that goal. n85

n79 *See, e.g.,* James J. Brudney, *Neutrality Agreements and Card Check Recognition: Prospects for Changing Paradigms*, 90 IOWA L. REV. 819, 842 (2005) (addressing the three main aspects to commentator arguments regarding the unlawfulness of card check and neutrality agreements, but ultimately finding none to be persuasive).

n80 *See id.* at 844-45; Andrew M. Kramer, et al., *Neutrality Agreements: The New Frontier in Labor Relations--Fair Play or Foul?*, 23 B.C. L. REV. 39, 63-66 (1981). The legality of agreements that confer economic benefits on unions subject to the criminal provisions of 29 U.S.C. § 186 (2005) has yet to be decided.

n81 *See* Kramer, *supra* note 80, at 72-76.

n82 Daniel V. Yager & Joseph J. LoBue, *Corporate Campaigns and Card Checks: Creating the **Company** Unions of the Twenty-First Century*, 24 EMPLOYEE REL. L.J. 21, 29 (1999).

n83 *N.L.R.B. v. Gissel Packing Co., Inc.*, 395 U.S. 575, 603 (1969).

n84 Brudney, *supra* note 79, at 862.

n85 *See* MAYER, *supra* note 61, at 13.

As the perceived need to reverse the decline in union membership intensifies, it can be anticipated that unions will continue to employ methods that yield the greatest number of new members, not necessarily methods that most accurately reflect employee sentiment after being fully informed.

V. Measures to Meet the Challenge

As discussed above, the disaffiliation of the Change to Win coalition of unions from the AFL-CIO promises to increase the intensity of union competition for employee sympathies at a time when all unions are desperate to increase membership. More aggressive unions, such as SEIU, have already enjoyed relative success in their organizing efforts by relying on many of the techniques outlined above. n86

n86 *N.L.R.B. Election Statistics, Year-End 2004 Report*, Union Organizing in the Health Care Industry Rep. tbl. 1 (BNA) (2005).

Many of these efforts have serious implications for employee free choice, a primary right protected by the NLRA. If an employer concedes its right to inform employees of the overall effects likely to follow unionization, employees have only one biased perspective to consider when determining whether organizing is in their best interests.

Obviously, time is of the essence once a union targets an employer for organizing. There is often insufficient time to turn an engineered defeat into victory. Whether by card check or NLRB election, employers caught off guard are ill prepared to persuade employees of the alternatives to union organization. The organizing techniques outlined above are remarkably successful in achieving representational status by aggressive unions. Almost 60% of NLRB-supervised elections are now won by unions. n87 The SEIU in particular enjoys better than 70% success in its election efforts. n88

n87 *Id.*

n88 *Id.*

Individuals on both sides of the debate agree in principle that giving a voice to employees is an essential policy underlying labor relations. The means to foster employee choice, however, is hotly debated once union organizing efforts begin. Fortunately, employers and employees have an excellent opportunity to communicate prior to the first signs of union activity if employers make the necessary effort to reach out to their workforce.

Employers and employees must be forewarned in order to be forearmed and able to make informed decisions about unionization. Waiting until the union makes its presence known to formulate a response is often too late for unwary employers and uninformed employees. Among the steps proactive employers take in preparing for the potential of a union organizing effort, most are put in place far before the union seeks to target the employer for a campaign. Essential employer protection initiatives include: (1) identifying supervisory personnel, (2) training, (3) policy review and revision, (4) employee perception surveys, (5) pay and benefit parity reviews, (6) aggressive dispute resolution mechanisms, (7) employee communication, and (8) community outreach.

A. Identifying Supervisory Personnel

It should seem self-evident, but without knowing who the supervisors and managers are, employers are at risk of a

union's successful organizational effort. Not all who wear the title "supervisor" are in fact supervisory within the meaning of the NLRA. n89 Likewise, many employees exercise supervisory authority without the title. The labor laws prohibit union organization by and among supervisors and impose very specific rules on supervisory conduct during organizational campaigns. n90 Many elections are lost or unfair labor practices are committed by supervisors who follow their instincts and violate any of the countless NLRB election rules. Knowing who is "on the team" enables the employer to train these essential people in the technicalities of union organization and how to respond to them legally. Trained supervisors and managers communicate a consistent and trustworthy message of the reasons for maintaining a union-free status in a fashion that makes the likelihood of facing union organizational efforts far less likely.

n89 A supervisor is

any individual having authority, in the interest of the employer, to hire, transfer, suspend, lay off, recall, promote, discharge, assign, reward, or discipline other employees, or responsibility to direct them or to adjust their grievances, or effectively to recommend such action, if in connection with the foregoing the exercise of such authority is not of a merely routine or clerical nature, but requires the use of independent judgment.

29 U.S.C. § 152(11). The Supreme Court addressed the supervisory status of nurses in *N.L.R.B. v. Kentucky River Cmty. Care, Inc.*, 532 U.S. 706 (2001). The Court affirmed the Sixth Circuit's rejection of the N.L.R.B.'s rationale for not treating certain nurses as supervisors. According to the Court's analysis,

employees are statutory supervisors if (1) they hold the authority to engage in any 1 of the 12 listed supervisory functions, (2) their "exercise of such authority is not of a merely routine or clerical nature, but requires the use of independent judgment," and (3) their authority is held "in the interest of the employer."

Id. at 713 (quoting *N.L.R.B. v. Health Care & Retirement Corp. of Am.*, 511 U.S. 573, 574 (1994)). Analyzing supervisory status in this manner, whether particular nurses qualify as statutory supervisors requires fact-specific analysis and appellate courts have come to different conclusions as to whether substantial evidence supports a finding that nurses are or are not supervisors. *See Hospital Gen'l Menonita v. N.L.R.B.*, 393 F.3d 263, 267 (1st Cir. 2004) (RNs who assign work to employees by consensus do not exercise "independent judgment."); *Evergreen New Hope Health & Rehab. Ctr. V. N.L.R.B.*, 65 Fed. Appx. 624, 626 (9th Cir. 2003) ("substantial evidence in the record that the charge nurses exercise independent judgment and that they are 'responsible to direct' the other employees"). The NLRB continues to address the issue of the supervisory status of nurses as well. *See, e.g., Wilshire at Lakewood v. Jochims*, 345 NLRB No. 80 (Sept. 30, 2005) (Nurse who rendered disciplinary action, completed evaluations, and dismissed employees from work assignment was a supervisor under the NLRA.).

n90 *See* 29 U.S.C. § 152(3) (2005) (excluding from the definition of "employee" an "individual employed as a supervisor.").

B. Training

The supervisory and management team periodically must be reminded of the rules of the game. At least annually, proactive employers educate managers and supervisors on the latest trends in union organizing and how employers can lawfully maintain their union-free status. Union prevention is simply good management in action. Employees and employers alike benefit from a trained supervisory workforce.

Mock union campaigns are the best way to immerse supervisors and managers in the intricacies and nuances of campaign strategies and conduct. The techniques of lawful supervisory conduct can be learned in the pressure cooker of a simulated union campaign conducted over a few days in a particularized training program in ways that are never forgotten and often only learned "on the job" when a union organization effort begins. Supervisors and managers can undergo mock campaign training that can prepare them in ways classroom education can never accomplish. Equally important, employers should regularly educate their nonsupervisory employees on the value of remaining union-free and the reasons the employer promotes that status.

Healthcare employers who have confronted aggressive union campaigns know the importance of being prepared for the strategies these unions employ. Managers and supervisors are the real "front line" in the effort to remain union-free.

C. Policy Review and Revision

In the healthcare industry, a careful understanding of an employer's solicitation and distribution rules is vital because the law addresses with specificity solicitation and distribution rules for those areas of the hospital in which direct patient care is provided. n91

n91 See *Cooper Health Sys.*, 327 N.L.R.B. 1159, 1163 (1999).

The Board, with Supreme Court approval, has recognized that a health care facility can prohibit solicitation and distribution in immediate patient care areas. The Board has also held that prohibitions of lawful nonworktime solicitation and distribution in areas other than immediate care areas, to which patients and visitors have access, are invalid, absent a showing by the hospital that such a ban is necessary to avoid a disruption of patient care.

Id. See also *Doctors' Hosp. of Staten Island*, 325 N.L.R.B. 730, 735 (1998) ("Rules which prohibit employee solicitation and distribution in immediate patient care areas, such as patient rooms, operating rooms, places where patients receive treatment and adjacent corridors and waiting rooms have been found presumptively lawful."). For Supreme Court cases approving of these Board positions, see *N.L.R.B. v. Baptist Hosp.*, 442 U.S. 773, 791 (1979); *Beth Israel Hosp. v. N.L.R.B.*, 437 U.S. 483, 507 (1978).

The manner in which healthcare employers control access to working areas is not only a matter of medical and business concern, but has ramifications for union organizing as well. Without clearly defined and consistently applied rules regarding solicitation and distribution, employers can unwittingly open themselves up to unrestricted union access to their workplaces. n92 Knowing when and where nonwork-related verbal solicitation and literature distribution restrictions can be enforced is critical to productivity, safety, and patient care. Policies controlling such conduct cannot be devised after union activity begins without legal implications.

n92 For instance, an employer may enact a lawful no-solicitation policy, but if the policy is not consistently applied, the policy will not be enforced against union solicitation once an organizing campaign begins. See *Hammary Mfg. Corp.*, 265 N.L.R.B. 57, 57 (1982) (noting, however, that "an employer's tolerance of isolated beneficent solicitation does not by itself constitute sufficient evidence of disparate treatment of union solicitation"). In *Cooper Health Sys.*, an administrative law judge concluded that selectively enforcing a no-solicitation/no-distribution policy against a hospital employee distributing union flyers was an unfair labor practice. 327 N.L.R.B. at 1164.

Likewise, promotion, transfer, and overtime policies can be causes of employee unrest and suspicion of favoritism if viewed as inconsistent or unfair in operation. Prepared employers make sure that policies exist to meet business needs as well as reasonable employee expectations and are actually complied with and consistently applied.

D. Employee Perception Surveys

No less frequently than every two years, employers intent on maintaining their union-free status should conduct confidential interviews to help identify employee irritants that may give rise to union sympathies. Unions promote their value on the basis of giving employees "a voice" in the matters that affect them in the workplace. Employers who recognize and address employee concerns on a regular basis remove the union's strongest organizing tool. Employees who trust the value of their voice in the context of their employer's workplace practices are far less likely to look outside for assistance in being heard.

E. Pay and Benefit Parity

Very few **companies** are organized by unions because of pay inequity alone. Most employers understand the need to pay competitive wages and benefits. Appropriate levels of pay and benefits are unique to a particular industry and geographic locale. An employer's failure to understand and explain the reasons for employee wage and benefit levels, however, may lead to perceptions of unfairness by disenchanted employees. Noncompetitive wages and benefits are the key to avoiding costly retention problems as well as potential union organizing efforts. Proactive healthcare employers conduct periodic wage and benefit surveys, conform their pay practices to their industry and explain to employees the market forces that compel the compensation practices of that workplace. Employees well informed about the relevant

factors that comprise competitive wage and benefit packages are unlikely to believe union campaign promises of significant wage increases.

F. Aggressive Dispute Resolution Systems

Most successful union campaigns are driven by unresolved employee concerns. Proactive employers understand the value of flushing out employee grievances effectively and promptly. The standard "open door policy" rarely works well because most employees distrust the "pay back" potential of behind the scenes reprisal to employees who have circumvented the chain of command. Employers who maintain a high level commitment to conflict management will impose formal dispute resolution systems ranging from peer review to ombudsmen or human resource hot lines intended to solicit employee grievances and address them promptly. Training of supervisors in conflict management principles will assist in maintaining a workplace that is more productive and less susceptible to the costs of unresolved conflict such as litigation and unionization. It will be too late to alter the status or effectiveness of dispute resolution procedures after the union shows up. The law prohibits the employer from soliciting employee grievances and resolving them once a union organizing campaign begins. n93

n93 See 29 U.S.C. § 158(a)(1) (2005); N.L.R.B. v. Rich's of Plymouth, Inc., 578 F.2d 880, 883 (1st Cir. 1978) (holding that employer violated N.L.R.A. by soliciting employee grievances and promising benefits during pendency of union campaign).

G. Communication with Employees

Employers and consultants who have faced aggressive union campaigns identify communication with employees as a key part of meeting the challenge. n94 This is especially true in the healthcare industry, where employees may not fully understand all of the internal and external forces acting on the business. Chris Cimino, executive vice president of Chessboard Consulting, states:

What is amazing to me is that many CEOs assume that the average line-level employee really understands what is going on with the economics in healthcare today, and most of them don't. They see their healthcare costs going up, their wage increases narrowing . . . and at the same time they see the hospital building new wings. n95

n94 Rogers, *supra* note 33.

n95 *Id.* (alterations in original).

According to one attorney in Washington, D.C.:

Management all too often has a tendency to act in a vacuum without thinking about communicating with the entire work force, and that is a mistake. If your employees understand what the organization is going through both from a positive and a negative standpoint, then they will have a much better appreciation for the actions that management takes. n96

n96 *Id.*

H. Community Outreach

In campaigns to organize hospitals, unions have consistently waged corporate campaigns attacking, among other things, charity careⁿ⁹⁷ and collections policies.ⁿ⁹⁸ The efficacy of these measures is dependent in large part upon unions characterizing the employer's relationship with the community as poor or self-serving. A proactive employer will not only consider the opinion of its work force, but will also review its reputation in the community at large. This factor is especially important for many employers in the healthcare industry, where institutions are generally considered to have a moral and ethical responsibility to the community.

ⁿ⁹⁷ See *Charity Care*, *supra* note 47.

ⁿ⁹⁸ See *ROLLINS*, *supra* note 44, at i.

Healthcare employers should evaluate their reputation in the community and ensure that their community outreach programs are both widely known and well understood. In addition, healthcare employers should continue to develop relationships with other community groups, forestalling union organizers from adopting an "us against them" strategy with civic and religious leaders. Those employers best situated to remain union-free are those that have become vital community citizens and who have made their contributions to the community's well-being long before the union attempts to taint their reputation among local leaders. Isolation in local communities leaves employers susceptible to divisive public relations campaigns by unions with opinion shapers who can raise the public profile of a recalcitrant employer accused of insensitivity to the needs of the citizens who work and are patients there.

This principle is evident in the corporate campaigns against hospitals alleging poor charity care programs. If the union impugns an employer's contributions to the community, any change in policy, even if initiated prior to union involvement, becomes a union victory in the public mind.

VI. Conclusion

Employers intent on maintaining maximum protection from potential union organizing efforts will not adopt an "ostrich posture" in hopes that they will never have to deal with the unpleasantness of a union campaign. Proactive employers desirous of maintaining union-free status will create an internal union-free task force to educate the management team about today's organizing climate and remain updated on union organizational activity nationally and locally. Understanding current steps unions are taking to reverse their fortunes will help **companies** lawfully resist the well-financed and finely-tuned efforts of the Change to Win coalition and other unions dedicated to organize the unorganized.

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TITLE: Articles: The Collision of Healthcare and Corporate Law in a Hospital Closure Case

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TEXT:

ABSTRACT: This Article analyzes potential conflicts that arise from both the judicial and administrative approval processes that govern the closure of charitable hospitals through a sale of all or substantially all of their assets. Examining the recent closure attempt by the Manhattan Eye, Ear & Throat Hospital as an example, the Article highlights the various public health and corporate law issues that are raised when a not-for-profit hospital seeks closure. The Article thoroughly discusses both the statutorily and judicially required approval schemes applicable to the closure of charitable hospitals. The Article also suggests ways in which these conflicts might be avoided or remedied, as well as gives advice regarding hospital board decisionmaking.

An important recent case involving the attempt to close a New York City hospital, *In re Manhattan Eye, Ear & Throat Hospital v. Spitzer*, n1 illustrates a serious clash of corporate law and public health issues. Two related bodies of law--a state's Not-for-Profit Corporation Law and regulations of the state's health department--are involved.

n1 Manhattan Eye, Ear, & Throat Hosp. ("*MEETH*") v. Spitzer, 715 N.Y.S.2d 575 (Sup. Ct. 1999). For commentary on *MEETH*, see Michael W. Peregrine & James R. Schwartz, *Nonprofit Corporations: The M & A Process and the Meaning of MEETH*, 28 HEALTH LAW DIGEST 3 (2000); Leo T. Crowley, *Hospital Case: Significant Governance Questions*, N.Y.L.J., Feb. 10, 2000, at 1; William Josephson, *Guiding the Way Through Changes in Charities Law*, N.Y.L.J., Sept. 18, 2000, at 1.

The provisions relating to hospital closure in both areas of law, one based in legislative judgment, the other in administrative determination, are fairly undeveloped, having received little attention from the courts in the past. The attempt to close the Manhattan Eye, Ear & Throat Hospital ("*MEETH*") highlights the conflicts and the potential serious harm to both the valuable charitable asset of a hospital and important public health concerns resulting from the separate corporate law and public health standards that govern a hospital closure under the dual approval requirements. The attempt to close *MEETH* and the resulting litigation also speak volumes about another important issue: the process by which the board of directors of a charitable institution decides on closing the institution, and how that process can go wrong.

MEETH is a specialty care hospital located on the Upper East Side of Manhattan, which exists as a charitable

not-for-profit corporation. n2 In early 1999, MEETH's Board of Directors decided to close MEETH as a hospital and sell its real estate, expecting to receive about \$ 40 million. n3 The Board planned to use the sale proceeds to develop an undetermined number of small clinic-like facilities, known as "diagnostic and treatment centers," in outlying areas around New York City. n4 Closing MEETH required approval of the Commissioner of New York State's Department of Health ("DOH") pursuant to DOH regulations. In addition, since the closure would result from MEETH selling substantially all of its assets and MEETH is a charitable corporation, the sale needed court approval under New York's Not-for-Profit Corporation Law ("N-PCL"). n5 Two approval regimes thus governed MEETH's proposed closure.

n2 *MEETH*, 715 N.Y.S.2d at 577.

n3 *Id.* at 581.

n4 *Id.* at 578.

n5 *Id.* at 592.

Against various parties' opposition, MEETH eventually sought both DOH and judicial approval for its proposed closure and asset sale. Although MEETH vigorously pressed for administrative approval, the DOH never decided MEETH's request to close. On the judicial path, however, after a lengthy trial on MEETH's N-PCL petition, the state trial court disapproved MEETH's proposed asset sale, thereby preventing the closure. n6

n6 *Id.* at 597.

But before the court ended the Board of Directors' attempt to close it, MEETH--caught in a kind of regulatory purgatory--teetered on the brink of collapse.

This Article discusses, from the benefit of the MEETH experience, how conflicts can arise from the dual approval process that governs when a charitable hospital wants to close through a substantial asset sale. The separate approvals are grounded in very important, albeit different, public policy considerations. Yet the lack of consistency and coordination in the approval regimes can threaten the very existence of a hospital--which typically "belongs" to the public as a charitable asset--and can pose serious public health risks that should always be evaluated when a hospital wants to close. As a result, there is great need to harmonize these related, yet different, decisionmaking and approval processes to protect charitable assets and promote health concerns in future hospital closings both in New York and elsewhere.

After first discussing the circumstances of MEETH's attempt to close, this Article describes the separate administrative and judicial approval schemes that apply to a hospital closure. Against the backdrop of the troubling conflicts and inconsistencies manifested in the MEETH situation, the Article then proposes some ways to address these problems. This discussion also illuminates some important considerations in achieving sound decisionmaking when a nonprofit board considers a transaction that will close its institution.

I. The Circumstances of MEETH's Attempted Closure

A. MEETH Before the Closure Events

MEETH was created by special state legislation in 1869. n7 Throughout its 130-year existence, MEETH's medical mission, as stated in its corporate charter, has been to operate a hospital devoted exclusively to the specialty fields of ophthalmology, otolaryngology (ear, nose and throat, or "ENT," care) and, more recently, plastic and reconstructive

surgery. n8 MEETH mainly provides secondary and tertiary care in its specialties--meaning more sophisticated care involving complicated and difficult health problems, requiring high levels of medical expertise.

n7 See *MEETH*, 715 N.Y.S.2d at 577.

n8 MEETH's charter stated its charitable corporate purposes as follows:

"to establish, provide, conduct, operate and maintain a hospital in the City, County and State of New York for the general treatment of persons suffering from acute short-term illnesses; performing general plastic surgery; treating persons suffering from diseases of the eye, ear, nose or throat; and maintaining a school for post graduate instruction in the treatment of such illnesses, performing such surgery, and the treatment of such diseases, and conducting associated and basic research."

Section 5.1(a) of MEETH's Certificate of Amendment of the Certificate of Incorporation, *quoted in MEETH*, 715 N.Y.S.2d at 577.

While MEETH operates an inpatient hospital for surgical cases and acute illness, outpatient clinics, ambulatory surgery, and an emergency room provide much of MEETH's specialized care. Of particular significance to the issue of MEETH's closure, MEETH for many years afforded care to the community through its in-house Eye and ENT Clinics (as well as through those clinics' subspecialty facilities treating patients needing even more highly specialized care). Over the past several years, MEETH's clinics have handled about 80,000-90,000 patient visits per year, with the majority of patients being indigent and elderly. n9 Beyond providing patient care in its specialty fields, MEETH has long undertaken basic and clinical research and provided postgraduate medical education in its fields. These activities are also stated purposes under its charter. n10

n9 In addition to its "in-house" clinics, MEETH operates a small extension center facility in Harlem, which treats a small portion of its total clinic patients, many of whom are then referred to the hospital itself for necessary follow-up care.

n10 *MEETH*, 715 N.Y.S.2d at 577.

In its opinion disapproving MEETH's proposed asset sale, the court found that MEETH "has outstandingly realized" its medical care purposes. n11 The court noted that MEETH's physicians "have achieved world acclaim for their advancements in medical care and for their provision of acute care in these specialty areas," that MEETH has developed premier residency and fellowship training programs in ophthalmology, otolaryngology and plastic surgery, and that MEETH, in short, "has consistently been ranked among the top specialty hospitals in the United States." n12

n11 *Id.*

n12 *Id.*

Nonetheless, like most of the healthcare industry, MEETH in recent years has encountered serious financial problems as a result of changes in healthcare economics. n13 Based upon its own detailed analysis, the medical staff by 1998 had concluded that MEETH's Board and administration were not addressing these changes adequately and were mismanaging MEETH. The medical staff thus submitted a lengthy memorandum to MEETH's Board, which described MEETH's operational and financial problems and recommended specific steps to correct them. n14 Shortly thereafter, in late 1998, members of the medical staff addressed these problems at a meeting with Board members. n15 But instead of trying to solve the problems, the Board soon set upon a course to sell MEETH's real estate and close MEETH as a functioning hospital.

n13 *Id.* at 577.

n14 *Id.* at 578.

n15 *Id.*

B. The Board's Decision to Sell MEETH's Real Property and Close the Hospital

In January 1999, MEETH received a bid from Memorial Sloan-Kettering Cancer Center ("MSKCC"), another New York City hospital, to buy MEETH's real estate. n16 MEETH then hired a financial advisor to consider the MSKCC offer, and also to assess MEETH's "strategic options." n17

n16 *MEETH*, 715 N.Y.S.2d at 579.

n17 *Id.*

The advisor concluded that MEETH's business as a specialty care hospital had no ongoing economic value. n18 The advisor also opined that MEETH's real estate--located on Manhattan's Upper East Side--had considerable value and should be sold as part of "refocusing" MEETH's mission into new "diagnostic & treatment centers." n19 When the *MEETH* court subsequently evaluated these events based on the trial evidence, the court held: "it was this mindset, that the real estate was the only asset of MEETH with value, which determined the future course of events. As [MEETH's advisor] put it, the Board wanted to 'monetize the assets,' rather than seek to preserve MEETH as its main priority." n20

n18 *Id.* at 580.

n19 *Id.*

n20 *Id.*

Thus, in late February 1999, the Board voted to sell MEETH's real estate for a price as near as possible to \$ 45 million. n21 The Board also authorized filing the necessary applications for regulatory and judicial approvals. n22 The medical staff and other affected parties were not informed about these major decisions at the time. Significantly, the *MEETH* court found that prior to these decisions, "there was interest from other medical institutions in seeking to preserve MEETH as a world-class teaching and research hospital, which [was] ignored by the Board" in accepting the advisor's recommendation to sell the real estate. n23

n21 *Id.* at 581.

n22 *MEETH*, 715 N.Y.S.2d at 581.

n23 *Id.* at 583.

On April 25, 1999, *The New York Times* reported that MEETH's directors "are getting out of the hospital business" and "have put their hospital up for sale." n24 The article stated that the Board expected that more than \$ 40 million would be received for selling MEETH's real estate to a developer and that the Board planned to use the sale proceeds "to open outpatient clinics in several poor neighborhoods." n25 The *Times* article was the first widespread notice that

MEETH's Board had decided to sell MEETH's real estate and close the hospital.

n24 Randy Kennedy, *A Hospital Expands by Closing Its Doors*, N.Y. TIMES, Apr. 25, 1999, § 1, at 37.

n25 *Id.*

A few days after that article, at a meeting on April 29, the Board made several important decisions to advance its plans. First, it voted again to sell the hospital, at a price in excess of \$ 40 million. n26 It authorized MEETH's administration to prepare for closing the hospital and to give notice of termination to MEETH's residents (the recent medical school graduates receiving specialized training in MEETH's fields, who were integral to MEETH's day-to-day functions). n27 It again authorized the administration to seek regulatory and judicial approvals for its decisions, and it also authorized (but did not actually submit or file) an amendment to MEETH's corporate charter to encompass running the new clinics, which were to be the main use under its plan for the sale proceeds. n28 Significantly, although authorized by the Board, MEETH did not make any filings for approval to close at this time.

n26 *MEETH*, 715 N.Y.S.2d at 584.

n27 *Id.* at 585.

n28 *Id.* at 584.

After hearing the trial evidence, the *MEETH* court found that in late April the Board had not performed or obtained any study or management plan to support establishing new clinics, even though closing MEETH as a hospital to create these clinics was a "momentous decision." n29 Indeed, the Board did not engage healthcare consultants to evaluate this new clinics plan until much later, at a meeting on July 26. The court found that the Board's doing so at that late date simply resulted in the consultants endorsing the Board's already determined plan. n30

n29 *Id.*

n30 As the court described the Board's conduct during late July:

As of July 26th, the Board had neither received nor commissioned any study with regard to the Board's planned use of the sales proceeds to establish [diagnostic & treatment] centers, the necessity for such centers, or the viability of such centers. It was an idea in progress. . . . There had been no consultation with the medical staff or other medical experts or health care experts or anyone else concerning its feasibility or viability. . . .

. . . .

. . . Significantly, [the consultants hired on July 26] were charged with supporting the already decided upon plan. [Their] study . . . not unsurprisingly supported closure of the Hospital, and the transformation of MEETH from a world-class teaching hospital to operating two [diagnostic and treatment] "sites in under-served areas in Harlem and Brooklyn." . . . Neither [consultant] looked at or evaluated, or were asked to look at or evaluate, any of the proposed alternatives to closing MEETH. . . .

. . . .

. . . A careful evaluation of whether there was a basis for changing the corporate purposes should have determined the need to sell, not vice versa. The total absence of any study beforehand, concerning the [diagnostic and treatment] centers, and the retention of healthcare experts, only after submission of the proposal to the DOH, and only to prepare a business plan "for fulfillment" or in "support" of the D & T proposal, not to independently evaluate the plan's feasibility, buttresses the conclusion that the sale drove the change in purpose.

Id. at 586-88, 596.

By early May, MEETH had received several proposals to purchase its real estate. On May 5, the Board voted to accept a joint bid of \$ 41 million from MSKCC and a real estate developer. n31 That same day, MEETH executed a "letter of intent" to sell its real estate to MSKCC and the real estate group. n32 MEETH subsequently described this document (including in court proceedings) as a "binding" commitment that included a "no-shop" clause, therefore invoking it as grounds not to negotiate with other bidders. n33 After considering the proof at trial, the *MEETH* court held that "the letter of intent was not binding, . . . that it did not contain a no-shop clause . . . [and that] there was nothing in the non-binding letter which would have prohibited MEETH from actually seeking to preserve its mission [by negotiating with other bidders]." n34

n31 *Id.* at 585.

n32 *MEETH*, 715 N.Y.S.2d at 585.

n33 *See id.* at 587.

n34 *Id.*

The *MEETH* court also noted that on May 5 the Board discussed the issue of closing the hospital only *after* having approved the sale, and that, according to the meeting minutes, "*no* actual decision had been made to close the Hospital." n35 Criticizing the approach to pursuing closure, the court noted that on April 29 the Board had terminated MEETH's residency programs and had authorized its administration to prepare for possible closure, but that "even as of May 5th . . . the Board did not seem to believe that it was actually closing the Hospital. One has to wonder exactly what the Board thought it was doing." n36

n35 *Id.* at 585 (emphasis in original).

n36 *Id.*

Also, shortly after the *Times* article, New York's Attorney General actively entered the picture. n37 Typically, before a petition under the N-PCL is filed in court, the Attorney General informally reviews the proposed transaction. n38 The Attorney General considers both the proposed sale itself and the proposed disposition of any sale proceeds. Starting early on, the Attorney General thus sought information about MEETH's proposed transaction and met with MEETH's representatives to try to learn more about it. n39

n37 *Id.* at 587.

n38 *MEETH*, 715 N.Y.S.2d at 587.

n39 Shortly after learning that the Board planned to close MEETH, the medical staff, on May 10, filed a special proceeding against MEETH's individual Board members and its executive director, seeking to enjoin the proposed real estate sale and the closure of the hospital. *In re* Board of Surgeon Directors of the Manhattan Eye, Ear & Throat Hospital v. Board of Directors of the Manhattan Eye, Ear & Throat Hospital, Index No. 109692/99 (Sup. Ct. NY 1999); *see MEETH*, 715 N.Y.S.2d at 586. A group of MEETH's residents also brought a separate action arising from the termination of their employment and joined in the medical staff's special proceeding. On May 28, the same court that ultimately rejected the sale dismissed the medical staff's petition and denied the requested injunctive relief, principally for lack of standing. In its subsequent decision, the *MEETH* court noted that, while being dismissed, "the [special] proceeding demonstrated . . . that the

medical staff played no role in the decision to sell and close the hospital: it was not consulted and the Board did not respond to written entreaties on behalf of the doctors," even though "it was the medical staff that distinguished MEETH." *Id.*

In accord with DOH regulations, MEETH also needed regulatory approval to close. Although authorized weeks earlier, MEETH did not file its plan for closing the hospital with the DOH until June 14. n40 Noting that since the Board previously had decided to terminate MEETH's residents effective June 30, the closure plan proposed discontinuing the patient care services affected by resident staffing, including the outpatient clinics, the emergency services covered by residents and the inpatient activities covered by residents on call, as of June 30--barely two weeks after the DOH filing was finally made.

n40 *MEETH*, 715 N.Y.S.2d at 585.

On a Sunday evening in late June, MEETH, having accepted the bid in early May, entered into a contract with MSKCC and the real estate developer to sell its real property to them. n41 Under the terms of the proposed transaction, MSKCC intended to develop MEETH's newer facilities into a breast cancer center, and the real estate developer expected to develop the remaining older property into apartments or other residential units. n42 The contract required MEETH to file its petition for judicial approval of the sale within sixty days or, in other words, by late August. n43 Nonetheless, MEETH failed to do so. The *MEETH* court determined that there had been no explanation for failing to file in accordance with the contract, but it stated that "there is no doubt that MEETH was putting off instituting the judicial petition while awaiting the hoped-for DOH approvals for the closure and [diagnostic and treatment center] plans." n44 As it turned out, MEETH would not file its petition for judicial approval until late September. n45

n41 *See id.*

n42 *Id.* at 591.

n43 *Id.* at 587.

n44 *Id.*

n45 *Id.*

C. The Subsequent Events Surrounding the Board's Efforts to Sell and Close

Despite the sales contract with MSKCC, several institutions and others remained extremely interested in transactions to acquire MEETH that would enable MEETH to continue its basic medical care mission. As a result, in June and July, Lenox Hill Hospital and Continuum Health Partners, Inc., (which includes Beth Israel Medical Center, St. Luke's-Roosevelt Hospital and other prominent New York City healthcare facilities) made new proposals to acquire MEETH. n46 Although these new proposals differed significantly from one another, both shared one salient aspect: to preserve MEETH substantially as it existed and thus continue MEETH's core charitable medical purposes set forth in its charter. n47

n46 *MEETH*, 715 N.Y.S.2d at 588-91.

n47 For a discussion of these new proposals and more details about their terms, see *id.*

Also during the summer of 1999, the Attorney General, through his Charities Bureau, became increasingly involved in monitoring and reacting to MEETH's conduct and plans. n48 Over time, the Attorney General became increasingly concerned about the propriety of the Board's actions. Indeed, the medical staff and others had complained to the Attorney General that MEETH was not providing information to various interested buyers and, generally, was not acting in MEETH's best interests. n49

n48 *Id.* at 587-88.

n49 *Id.* at 588.

The Attorney General soon concluded that MEETH's Board was not properly considering the new proposals to acquire MEETH that would preserve MEETH's charitable mission. For example, in a June letter, the Attorney General advised MEETH that "we are not aware of . . . one single shred of evidence that MEETH is actively exploring in good faith all or even any of these expressions of interest [which would preserve MEETH]"--a statement that the MEETH court found "proved to be accurate." n50 The Attorney General subsequently continued to advise MEETH that it objected to the Board's decisionmaking process and expressed concern that the Board was not furthering MEETH's charitable mission. n51

n50 *Id.* at 587.

n51 The medical establishment at the national, state and local levels--the American Medical Association; the Medical Society of the State of New York; and the New York County Medical Society--also all supported preserving MEETH, as did numerous major elected government officials.

MEETH's plan to sell and close, and various parties' efforts opposing it, also involved another front over the summer months--the DOH. Shortly after MEETH filed its closure plan with the DOH in mid-June, the medical staff filed objections to the plan. Also soon after the filing, the DOH informed MEETH that until the DOH approved the plan, MEETH was not permitted to discontinue operation. The DOH instructed MEETH that it must assure adequate staff coverage, equipment, and supplies so as to maintain its operation as a licensed healthcare facility, including sufficient emergency room and clinic coverage.

Despite this admonition, and even while the DOH was considering the closure plan, MEETH's Board and administration took numerous steps over the summer to "wind down" MEETH's operations. For example, in addition to having previously decided to terminate the residents, n52 the medical staff asserted that from July into September the Board and administration: (a) terminated other employees, including some with important patient care responsibilities; (b) failed to provide adequate staffing for patient care, particularly for the clinics and at times even the emergency room; (c) curtailed the availability of care in the clinics and cancelled patients' appointments; (d) reduced the availability and hours for operating rooms and made it difficult for physicians to schedule surgery; (e) failed to maintain some important surgical equipment; (f) evicted from the hospital certain physicians who had long maintained offices there; (g) instructed security personnel to search people's bags as they entered and left the hospital; (h) reportedly failed to order necessary drugs, neglected hazardous waste, and came close to causing the hospital's computer operations to be shutdown for failing to pay the hospital's service contract vendor; and (i) eventually, sent a letter to patients stating that the Board had decided to close MEETH and listing supposed alternate healthcare providers. Indeed, as a dynamic, living institution, these actions--like the announced plan to close itself--threatened a self-fulfilling prophecy of collapse, causing many of MEETH's physicians, residents, nurses, other professionals, and staff to seek other professional affiliations and new jobs. And all of this occurred without the DOH approving MEETH's closure plan and before MEETH had even filed its judicial petition for approval of its asset sale.

n52 *MEETH*, 715 N.Y.S.2d at 585. Once the Board decided in April to terminate the residents, their last day of employment was June 30. MEETH's residents performed many essential patient care functions in the hospital, particularly in the clinics and emergency room. Nonetheless, even shortly before June 30, the administration had made no plan to cover for residents' services come July 1. When the medical staff learned of this in late June, it immediately contacted the DOH. As a result, emergency arrangements were made, largely with the help of the medical staff and employees, to provide physician coverage for MEETH's essential medical care services after June 30.

Throughout the summer, MEETH's medical staff and employees thought that MEETH was very near to closing *de facto*--that is, even though the DOH had not approved closure, MEETH's operations had been so severely curtailed and its basic functioning so severely harmed that MEETH would be forced to close its doors. n53 As an obvious consequence of the Board and administration so substantially limiting the hospital's activities, MEETH's financial condition rapidly deteriorated. Another serious consequence was the potential effect on the existing bids for MEETH. The other institutions wanted to acquire MEETH as a going concern, so that MEETH's failure probably would have killed those bids.

n53 *Id.* at 588.

While MEETH seemed on the brink of a shutdown over the summer, the medical staff and others constantly communicated with the DOH, urging that it prevent MEETH from pursuing a course of conduct that would lead to MEETH's collapse. Significantly, while events were leading to MEETH's collapse during this time period, MEETH still refrained from filing its petition for judicial approval of its real estate sale.

Finally, on September 21, 1999, no doubt due to continuing pressure from the Attorney General, MEETH filed that necessary N-PCL petition. n54 With the matter of MEETH's real estate sale and closure then within a court's jurisdiction, the Attorney General promptly moved for a preliminary injunction to enjoin MEETH from taking any action to wind down operations, reduce its services, or implement a closure plan before obtaining DOH and court approval. The Attorney General also moved for leave to file a third-party complaint against MEETH's Board members and its executive director, seeking money damages and an accounting based on claims for waste of MEETH's charitable assets from an alleged breach of fiduciary duties. n55

n54 *Id.* at 587.

n55 MEETH's directors were required to carry out their duties "in good faith and with that degree of diligence, care and skill which ordinarily prudent men would exercise under similar circumstances in like positions." N.Y. NOT-FOR-PROFIT CORP. LAW § 717(a) (McKinney 1990). The Attorney General had to move for leave to file his third-party complaint asserting breach of fiduciary duty claims because MEETH's petition commenced a special proceeding, and additional parties generally cannot be joined in a special proceeding without court permission. *See* N.Y. C.P.L.R. 401 (McKinney 1990).

In connection with the Attorney General's motion, the court entered a temporary restraining order on September 30 that prohibited MEETH from taking any action to wind down its operations or to stop operating as a fully functioning hospital, pending the hearing on the motion. That TRO helped stabilize MEETH's operations somewhat, and it lessened the immediate threat of a *de facto* closure.

D. The Court's Decision and Its Aftermath

In October, having considered MEETH's N-PCL petition very promptly, the court merged the preliminary injunction application with a trial on the merits of the N-PCL petition. n56 Other than one half-day deposition of MEETH's executive director, there was no discovery preceding the N-PCL trial. Various interested parties, including MEETH's medical staff, the union representing its employees and the union pension fund, the institutions that had submitted competing bids, and MSKCC and the developer group, joined in the litigation and participated in the trial. The trial lasted thirteen days, and the court issued its decision on December 3. n57

n56 *MEETH*, 715 N.Y.S.2d at 577.

n57 *Id.*

Based upon detailed fact-findings and a thorough legal analysis, the court denied MEETH's petition for approval of the real estate sale. n58 The court held that the proposed sale failed to meet the N-PCL Section 511 two-part test of proper consideration and furtherance of MEETH's charitable purposes. n59 The court found that the proposed use of the charitable assets--establishing new clinic-like facilities with the sale proceeds--involved "a new and fundamentally different corporate purpose" than prescribed under MEETH's charter. n60 The court emphasized that in the first instance, the board of a not-for-profit must seek to preserve the corporation's original mission, but MEETH's Board did not make a "reasoned and studied determination" that MEETH could not survive as a hospital. n61 Instead, as the court held, MSKCC's original offer caused the Board to recognize the underlying value of MEETH's real estate, and the realization that the Board could "monetize" this asset drove the decision to change MEETH's purposes and the other subsequent events. n62 The court found it very significant that the Board might not have received disinterested advice because its strategic advisor had a financial interest in its recommendation, which posed a conflict of interest. n63 The court also emphasized that the Board had failed to consider properly the various alternative proposals that would have preserved MEETH's mission. n64

n58 *Id.* at 597.

n59 *Id.*

n60 *Id.* at 595.

n61 *Id.*

n62 *MEETH*, 715 N.Y.S.2d at 595.

n63 *Id.* at 596.

n64 *Id.*

In short, the court held that the proposed sale did not meet MEETH's corporate purposes because MEETH first decided to sell and "then evolved its new or 'reprioritized mission,'" and only then sought DOH approval to close and "judicial imprimatur of this plan." n65 Further, under the N-PCL test, the court found that the Board had improperly disregarded important components of MEETH's value in deciding to "monetize" by selling its real estate. n66 This was an additional ground for disapproving the proposed real estate sale. n67

n65 *Id.* at 597.

n66 *Id.* at 594.

n67 *Id.*

After the court issued its decision, the Board agreed to undertake a new bidding process for offers to acquire MEETH. At the Attorney General's urging, the Board formed a special committee that considered several formal bids received in late December, and shortly afterwards recommended one of the bids to the Board. In mid-January 2000, the Board voted to accept the new proposal from Lenox Hill Hospital.

Soon thereafter, MEETH and Lenox Hill entered into a sponsorship transaction under which Lenox Hill acquired control of MEETH as MEETH's sole corporate "member." This kind of sponsorship arrangement enables one not-for-profit medical institution (generally, the financially stronger entity) to acquire another (weaker) not-for-profit facility. Under the agreement, Lenox Hill committed to maintain MEETH as a specialty care hospital and to continue MEETH's charitable mission. Throughout the post-decision events, the Attorney General actively and carefully oversaw and monitored the process. Today MEETH has a new Board of Directors (which, unlike most of the previous boards, includes physicians from MEETH's medical staff) and new management furnished by Lenox Hill. In light of this transaction, MEETH should continue as a specialty care hospital substantially as it has functioned in the past, now under Lenox Hill's auspices and management.

II. The Regulatory Process Governing Hospital Closure

A. The DOH Regulations

Regulatory approval for closing a hospital is required because healthcare is a heavily regulated industry with broad and important public policy concerns. Just as establishing a hospital requires administrative approval for a license to operate, so too must closing the hospital be administratively approved. Scrutiny to assure that closure meets the public interest should be critical. While very little reported case law deals with regulatory approval for closing a hospital or other medical facility, one important New York Court of Appeals case, *Birnbaum v. State of New York*, n68 considered such approval against public health considerations.

n68 541 N.E.2d 23 (N.Y. 1989).

In *Birnbaum*, the State obtained receivership over a **nursing home** (a medical facility governed by DOH regulations similarly applied to hospitals) to prevent the **nursing home** from being closed precipitously, in contravention of a DOH regulation requiring approval to close. n69 The **nursing home's** owners asserted that the state-imposed receivership, which effectively required the facility to remain open against their will, constituted a "taking" of property entitling them to be compensated under the federal and state constitutions. n70

n69 *Id.* at 28-29 (discussing DOH Regulation § 401.3(g)).

n70 *Id.* at 25.

The court rejected that argument, holding that even though the facility continued to run at a deficit, applying the DOH closure-approval regulation to require the **nursing home** to remain open under receivership did not constitute an immediate taking of the owners' property. n71 The court emphasized that a **nursing home**, like a hospital, exists based on an administratively-determined public need for its services and through a regulatory scheme designed to match supply with demand. Thus, closing the facility can create a medical care shortage that poses public health risks:

[The owners] possessed the exclusive right to operate a **nursing home** solely because the public interest, as assessed by the Legislature and the Department of Health, required exclusivity. This grant by the State, while benefiting the [owners], also put them in the position to create an immediate scarcity of medical care if services were terminated abruptly. When the State confers an exclusive franchise upon an individual incidental to providing a public good, it need not subject itself to the uncontrolled discretion

of the individual to instantaneously create a public emergency. Instead, we conclude that the State may enforce the obligation, embodied in a regulation, that there shall not be immediate termination of **nursing home** services, because that use of the property threatens an imminent injury to the public. n72

n71 *Id.* at 27-28.

n72 *Id.* at 28.

Although receiving regulatory approval before a medical facility can close is crucial to avoid harm to the public health, New York's DOH has promulgated only very limited standards for a closing. The applicable provisions are under a regulation entitled "Changes in existing medical facilities." n73 The basic closure-approval provision states simply: "No medical facility shall discontinue operation or surrender its operating certificate unless 90 days' notice of its intention to do so is given to the commissioner [of the DOH] and his written approval obtained." n74 As the court noted in *Birnbaum*, this provision imposes a time constraint to prevent an immediate closing of a healthcare facility, without first obtaining the DOH's approval.

n73 N.Y. COMP. CODES R. & REGS. tit. 10, § 401.3 (1995-1999). Title 10 of New York State's *Official Compilation of Codes, Rules & Regulations* pertains to the DOH; Part 401 governs operating certificates for medical facilities. Part 401 is promulgated under Section 2803 of the Public Health Law and was adopted in 1976.

n74 *Id.* § 401.3(g). A facility must also obtain the DOH's approval to reduce its certified bed capacity. *Id.* § 401.3(e).

Only two other DOH provisions specify what a hospital actually must do for closure. First, upon obtaining approval for a "voluntary surrender" of a hospital's operating license, the hospital must so notify each patient (or a patient's relatives or physician) and "shall discharge or transfer all patients or residents to other appropriate facilities prior to discontinuing operation." n75 Second, before a medical facility can discontinue operation or surrender its operating certificate, it must also obtain the commissioner's written approval "of a plan for the maintenance, storage and safekeeping of its patients' medical records." n76 The plan must "provide adequate safeguards for these records, make them accessible to the patients and their physicians, and may provide for their ultimate disposition." n77

n75 *Id.* § 401.3(h).

n76 *Id.* § 401.3(i).

n77 *Id.*

These few provisions are the sum total of New York's DOH regulations that govern a hospital closure. In a nutshell, a hospital seeking to close needs to: (a) obtain the Commissioner's approval ninety days before closing; (b) tell patients of the intention to close and, as an obvious necessity, discharge or transfer all patients before closing; and (c) offer an acceptable plan for preserving and accessing patients' medical records. n78 Other states, similarly, provide few criteria in either their legislation or regulations for closing a medical facility. n79

n78 *Id.*

n79 *See, e.g.*, FLA. ADMIN. CODE ANN. r. 59A-3.203(5) (2001) (hospital must notify state's Agency for Health Care Administration ninety days before impending closing and hospital "shall be responsible for advising the licensing agency as to the placement of patients and disposition of medical records"); ME. REV. STAT. ANN. tit. 22, § 1822 (West 1992) (person operating hospital must give thirty days notice of voluntary closing to patients and to parties primarily responsible for patients' welfare, "so that adequate preparation may be made for the orderly transfer of said patients to another qualified facility"); MINN. STAT. ANN. § 144.555 (West 1998) (when a medical facility "voluntarily plans to cease operations," facility's controlling persons "must notify the commissioner of health at least 90 days before the scheduled cessation" and commissioner "shall cooperate with the controlling persons and advise them about relocating the patients"); OR. ADMIN. R. 333-500-0055, -0060 (2000) (closure provisions require only that if "the operation of any licensed hospital is discontinued, . . . the licensee shall notify the [state health department] of the fact in writing within 14 days of such discontinuance;" and that hospital voluntarily discontinuing operation must initiate press release notifying public of closure and stating procedure for patients to obtain medical records, and must give notice of closure and plan for disposal of records to state health department); 28 PA. CODE § 101.196 (2001) (notice of closure provision states in full: "A hospital shall give written notice of an intent to close to the Department [of Health], not later than 90 days prior to the anticipated date of closing.").

Some states have more detailed provisions concerning closure, which require some generalized assessment on delivery of healthcare to the community. *See, e.g.*, MD. CODE ANN., HEALTH-GEN. § 19-123(e)(1), (i)(1), (2) (Supp. 1999) (specifying certificate of need requirements for various hospital changes, but providing that no certificate of need is necessary for closing hospital where notice is given to public health commission and public hearing is held; or where there are few hospitals in county, commission finds that proposed closing "is not inconsistent with the state health plan or an institution-specific plan developed by the Commission" and is in the public interest). Other states now have requirements that could relate to a closing, enacted as part of recent legislation dealing with the "conversion" of a nonprofit hospital to a for-profit institution or with the sale of a nonprofit hospital's assets to another nonprofit. *See, e.g.*, R.I. GEN. LAWS § 23-17.14-18 (Supp. 1999) (under state's Hospital Conversions Act, prior to eliminating emergency department or primary care services, hospital must provide health department director with written plan that describes impact on access to and delivery of healthcare and impact on other hospitals); *cf.* ARIZ. REV. STAT. ANN. § 10-11253(F) (West 1999) (state "conversion" legislation requires public hearing concerning proposed sale/transfer, at which parties are to present information "whether the intended transaction creates or has the likelihood of creating an adverse effect on the access to or availability or cost of health care services"); CAL. CORP. CODE §§ 5917(h), 5923(e) (West Supp. 2000) (under state "conversion" legislation governing sale or transfer of hospital assets, Attorney General may consider whether "the agreement or transaction may create a significant effect on the availability or accessibility of health care services to the affected community").

In short, while closing a hospital raises many serious issues, the formal regulations do not provide meaningful guidance for the closure; consequently, they do not provide meaningful protection for the public from harm that closure might cause. While "approval" of the DOH Commissioner is required, the regulations do not specify any criteria, standards, or factors to govern that approval determination. In the MEETH medical staff's dialogue with the DOH during the closure events, the agency's personnel acknowledged the sparseness of the written regulations. Indeed, although regulatory agencies generally are given wide discretion and flexibility in setting licensing standards within a statutory framework, it could be argued that the DOH closure regulations are so vague and uncertain as to be invalid.

n80

n80 *See* *Levine v. Whalen*, 384 N.Y.S.2d 721 (1976) (while statutory authority sufficiently sets standards for DOH to promulgate regulations, certain DOH regulations themselves, which were based on requirements specified by DOH Commissioner, were impermissibly vague and subjective); *Slocum v. Berman*, 439 N.Y.S.2d 967, 970 (App. Div. 1981) (DOH regulations, modified in light of prior cases, upheld as not impermissibly vague and subjective; "the standard whereby the sufficiency of the statute or regulation is measured is whether men of common intelligence must necessarily guess at what conduct is prohibited"); *Koelbl v. Whalen*, 406 N.Y.S.2d 621, 623 (App. Div. 1978) (certain DOH regulations were impermissible because they "imposed no objective standard, but ultimately required the facilities and services to meet the 'approval' or 'satisfaction' of the Commissioner," or were "subjective and, therefore, invalid"). *See generally* 1 MICHAEL G. MacDONALD ET AL., TREATISE ON HEALTH CARE LAW § 4.03[6][a] (2000).

Undoubtedly because of this lack of specificity, the procedures a New York hospital follows for closure, and the DOH's resulting consideration, appear *ad hoc*. It is customary for a hospital seeking the Commissioner's approval to close to submit a "plan of closure." Again, however, there are no formal guidelines for the showing to be made in a closure plan. As a result, in the MEETH situation, an evolving *ad hoc* approach was employed to address the issues that repeatedly arose concerning the closure.

A critical issue for the DOH in any hospital closure situation should be the assurance of continuity of patient care. As the court of appeals emphasized in *Birnbaum*, a medical facility operates as a state-created "franchise" that exists in a carefully weighed balance of patient needs and economic considerations. The patient-care need exists for the facility's

services, but an excess of services creates unnecessary healthcare costs. In this delicate regulatory milieu of care versus costs, a closure poses important patient care issues. How will the hospital's patients receive care in the future? Will they receive the same quality of care? Can the existing medical facilities in the area absorb them as new patients? How will patients know where they can get care? Is there a risk that some patients simply will not receive care if the facility is closed? These are vital public health concerns, and should be addressed in any hospital closure situation. The MEETH situation illustrated these concerns, and how they were nearly short-changed in a precipitous and unnecessary closure.

B. The MEETH Experience with the DOH

As noted, MEETH's administration submitted a closure plan to the DOH in mid-June 1999.ⁿ⁸¹ The plan formally notified the DOH that MEETH intended to close, stating that MEETH would institute the closure plan once the Commissioner had approved it.

ⁿ⁸¹ *MEETH*, 715 N.Y.S.2d at 585.

In varying degrees of detail, MEETH's plan addressed the following issues and subjects: (a) notifying patients, physicians, employees, and others of the closure; (b) discharging patients to other facilities; (c) maintaining, storing, and safekeeping patients' medical records; (d) maintaining continuing contacts with the DOH; (e) disposing of drugs and refuse; (f) setting up a closure "headquarters"; (g) providing plans for security and engineering/maintenance; (h) establishing staffing and personnel policies; and most importantly, (i) closing patient care services. Generally, however, the plan set forth proposed procedures for winding down MEETH's operations based upon the already-made determination to close and the assumption that approval would be quickly forthcoming.

MEETH's medical staff commented on the closure plan to the DOH. The medical staff addressed various particulars of the closure mechanics, such as monitoring and handling patient care matters as the hospital was shutting down, the nature of the hospital's proposed "closure team," and the notification process to patients.

Much more importantly, however, the medical staff addressed fundamental patient care issues that would arise from closure itself--how the medical community would absorb the large volume of MEETH's patients who would need care in the future, and how MEETH's patients would be able to receive the appropriate quality of care that they needed. Indeed, in commenting on the closure plan, the medical staff presented data to show that the existing medical facilities in the community could not absorb the large volume of MEETH's patients, particularly given the specialized nature of care MEETH afforded. In essence, the medical staff believed that all of MEETH's patients would not be able to receive appropriate care should MEETH be closed and, thus, that closure itself posed a serious public health risk.ⁿ⁸²

ⁿ⁸² Of particular significance, for example, was access to adequate substitute care for the 80,000 to 90,000 annual patient visits provided through MEETH's clinics; much of this care is for elderly and indigent patients with serious vision, hearing, and other ENT problems that required highly specialized treatment and continuing care and monitoring. Another important concern was the availability of emergency care in MEETH's specialty fields.

As the DOH considered MEETH's closure further, it requested additional information from MEETH's administration about the various issues the medical staff had raised. Significantly, the DOH required MEETH to provide information that would address continuity of care issues, such as where MEETH's patients would be able to receive continuing treatment and the basis for believing that MEETH's patients could be assimilated into the medical community's other facilities. In support of the position that MEETH should not be closed, the medical staff also continued to address these issues, asserting to the DOH that MEETH was a unique medical facility whose role in the medical community could not be replicated by other facilities. It also continued to insist that MEETH's patients simply would not obtain adequate comparable care elsewhere if MEETH were closed. In short, the medical staff asserted to the DOH that MEETH's closing would harm the delivery of needed medical care to the community and threaten the public

health, with profound and far-reaching ramifications.

The DOH never approved MEETH's closure. Indeed, although the DOH regulation prohibits a hospital from closing sooner than ninety days after giving notice that it intends to do so, that language does not appear to require the DOH to act within any specified time--and in MEETH's case, DOH took the position that it did not have to act within the ninety-day period.

Once MEETH finally filed the N-PCL petition for judicial approval of the proposed real estate sale in late September 1999, the DOH held its further consideration of closure in abeyance, pending the N-PCL trial. Closure from the regulatory standpoint became moot--indeed, impermissible--when the court subsequently disapproved MEETH's proposed real estate sale.

The circumstances of MEETH's seeking regulatory approval to close underscore two important issues. First, there are very few criteria that apply to closure under the DOH regulations, and no explicit requirement that patient care needs be assessed in determining whether a hospital may close. In the MEETH situation, patient care became a central issue largely because the medical staff made it so by showing that the healthcare needs of MEETH's patients and the community in general would be harmed if MEETH were closed. However, in the absence of an influential group pressing the issue in the regulatory process, there is no certainty that this vital public health consideration will be appropriately considered. Simply put, given the lack of specificity in the DOH regulations, a hospital might be permitted to close without due and informed consideration of the closure's adverse effects.

Second, MEETH sought DOH regulatory approval to close well *before* it sought the required judicial approval for the sale of its real estate that would necessitate closure. No formal mechanism required, or even facilitated, that these two approval processes, although related in important ways, be coordinated. As a result, there was the real possibility that the DOH would have permitted MEETH to close, even though the court had not yet determined--or even had the opportunity to determine--whether the sale of assets was permissible under the N-PCL.

III. The Statutory Framework and Considerations Governing a Not-for-Profit Corporation's Sale of Assets

A. The Not-for-Profit Corporation Law Provisions (and Their Common-Law Roots)

MEETH is a charitable not-for-profit corporation, and thus is governed by the N-PCL's special statutory framework. n83 As noted, New York's N-PCL requires that a charitable corporation which wants to sell all or substantially all of its assets must obtain judicial approval of the proposed sale. n84

n83 The N-PCL provides for four types of not-for-profit corporations, defined by the purposes for which the corporation is formed. N.Y. NOT-FOR-PROFIT CORP. LAW § 201 (McKinney 1990). MEETH is a "Type B" corporation--a charitable not-for-profit--under N-PCL § 201(b). The "Type B" corporation is the traditional charitable organization, which can qualify for a federal tax exemption under Section 501(c)(3) of the Internal Revenue Code. However, not all nonprofit corporations are charitable corporations; for example, trade associations, unions, business organizations and civic, political and fraternal groups might exist as nonprofit corporations or organizations. This Article generally uses "nonprofit" or "not-for-profit" to refer only to charitable nonprofit corporations.

n84 N.Y. NOT-FOR-PROFIT CORP. LAW §§ 510-511.

The N-PCL sets forth several key elements for such a sale. First, a two-part test must be met. The consideration and terms of the transaction must be "fair and reasonable to the corporation," and the "purposes of the corporation" must be "promoted" by the sale. n85 Second, this test must be met "to the satisfaction of the court." n86 Third, the Attorney General must be given notice of the petition for court approval, and other interested parties can also be afforded notice and are entitled to appear at the hearing. n87 Thus, for scrutinizing a charitable corporation's proposed asset sale, the N-PCL spells out a test to be met, the review standard for the court, and necessary and permissible parties to the proceeding.

n85 *Id.* § 511(d); see *MEETH*, 715 N.Y.S.2d at 576, 591-92. If the charitable corporation has members, the second prong of the test includes whether the sale will promote "the interests of the members."

n86 N.Y. NOT-FOR-PROFIT CORP. LAW § 511(d).

n87 *Id.* § 511(b). In addition to requiring notice to the Attorney General, Section 511(b) states that the court, in its discretion, shall direct that notice of the petition be given "to any person interested therein, as member, officer or creditor of the corporation"; and it also provides that "any person interested, whether or not formally notified, may appear at the hearing" and contest the petition for approval. Those provisions are fairly read to permit the participation of any party interested in the proposed asset sale (not just participation of a member, officer, or creditor of the not-for-profit). As noted, several interested parties were permitted to join in the *MEETH* litigation, and they participated fully in the trial; most did not fall within the discrete categories of members, officers, or creditors of *MEETH*. Like the other elements of the N-PCL provisions relating to an asset sale, this intervention-like provision has common-law roots. See 4A AUSTIN W. SCOTT & WILLIAM F. FRATCHER, *THE LAW OF TRUSTS* § 391, at 379 (4th ed. 1989).

Court approval of major changes for a not-for-profit corporation, such as a substantial asset sale, is required because a not-for-profit has fundamental structural differences from a for-profit corporation. As the *MEETH* court succinctly explained,

in the for-profit context, shareholder power ensures that boards make provident decisions, while in the not-for-profit context, this internal check does not exist. To put it another way, a nonprofit corporation has no "owners" or private parties with a pecuniary stake to monitor and scrutinize actions by the directors. This distinction is even more significant in the case of charitable corporations, such as *MEETH*, where there are no members, because the board is essentially self-perpetuating. n88

n88 *MEETH*, 715 N.Y.S.2d at 592.

Thus, "the Not-for-Profit Corporation Law addresses this lack of accountability by requiring court approval of fundamental changes in the life of a . . . charitable corporation, such as a disposition of all or substantially all assets, since there are no shareholders whose approval can be sought." n89 The *MEETH* court emphasized that the Attorney General is deemed a "statutorily necessary party" to the petition for judicial approval and that "his 'active participation' is presumed." n90 The purpose of that participation is to assure that the corporation's ultimate beneficiaries--members of the public--are adequately represented and protected "from improvident transactions." n91

n89 *Id.*

n90 *Id.*

n91 *Id.* at 592-93 (citing *Rose Ocko Found., Inc. v. Lebovits*, 686 N.Y.S.2d 861, 864 (App. Div. 1999)). See also VICTORIA B. BJORKLUND ET AL., *NEW YORK NONPROFIT LAW AND PRACTICE: WITH TAX ANALYSIS* § 8-2(a), at 238 (1997):

What the law seeks to do in each case, consistent with New York's *quasi-cy pres* doctrine, is to preserve charitable assets to serve public purposes. This is assumed, in each case, by making these transactions subject to court approval, on notice to and, presumably, with the active participation of the Attorney General, and because these are transforming events, to require board and member approval when there are members.

New York's N-PCL details requirements for a charitable corporation's asset sale that go beyond what most other

states' nonprofit corporation statutes prescribe. Many states have enacted statutory schemes for regulating nonprofit corporations based on model legislation drafted by the American Bar Association. n92 Under the *Revised Model Nonprofit Corporation Act*, a nonprofit corporation can sell substantially all of its assets other than in the regular course of business, as would be the case for a closure of the nonprofit's operations, based principally on only board approval (and for nonprofits having members, with the members' approval). n93 Notice to the state's Attorney General of the proposed sale is required for the asset sale by a public benefit corporation. n94 However, the *Revised Model Nonprofit Corporation Act*--and thus many states' legislation--does not expressly subject the sale to court approval as does New York's N-PCL, nor does it (or many states' laws) impose the two-part fair-and-reasonable-terms and promotion-of-corporate-purposes test set forth in New York's law. n95

n92 Numerous states' laws regulating nonprofit and charitable corporations are based either on the MODEL NONPROFIT CORPORATION ACT (promulgated in 1952) or the subsequent REVISED MODEL NONPROFIT CORPORATION ACT (adopted in 1987). However, the states often have adopted their own extensive variations to the model legislation, so that even among states that follow the model laws, provisions differ significantly. See 1 MARILYN E. PHELAN, *NONPROFIT ENTERPRISES: LAW AND TAXATION* § 1:11 (1995). Other states, particularly New York and California, have unique nonprofit corporation acts that differ substantially from the model acts. *Id.* at note 2. For a summary of all the states' nonprofit corporation acts, see *id.* §§ 1:12-1:62.

n93 REVISED MODEL NONPROFIT CORPORATION ACT § 12.02 (1987). Specifically, if the nonprofit does not have any members, such an asset sale can be authorized by the approval of a majority vote of the directors. *Id.* § 12.02(c). For a nonprofit with members, the transaction is permissible if it is approved by the board, by a members' vote of two-thirds of the votes cast or a majority of voting power, and by any person whose approval is specifically required under the corporation's articles of incorporation or bylaws. *Id.* § 12.02 (a)-(b).

n94 *Id.* § 12.02(g) (1987). A public benefit corporation includes corporations with the charitable-entity federal tax exemption under Section 501(c)(3) of the Internal Revenue Code, as well as corporations organized for public or charitable purposes. See *id.* §§ 1.40(28), 17.07. Some states adopt this notice-to-the-Attorney-General provision for an asset sale in their nonprofit corporation acts. See, e.g., CAL. CORP. CODE § 5913 (West Supp. 2000); MASS GEN. LAWS ANN. ch. 180, § 8A (West 1998); TENN. CODE ANN. § 48-62-102(g) (1995). Other states, even after adopting a sale of assets statute that generally tracks the Revised Act, nonetheless omit this notice provision. See, e.g., CONN. GEN. STAT. ANN. § 33-1166 (West 1997); FLA. STAT. ANN. §§ 617.1201, 617.1202 (West 1993); 805 ILL. COMP. STAT. ANN. § 105/111.60 (West 1993); N.J. STAT. ANN. § 15A:10-11 (West 1984); TEX. REV. CIV. STAT. ANN. art. 1396-5.09 (West 1997); WIS. STAT. ANN. § 181.1202 (West Supp. 1999). Cf. OHIO REV. CODE ANN. § 1715.39 (Anderson 1997) (requiring court approval for charitable organization's proposed sale or other disposition of real estate).

n95 In addition to the regulation of asset sales by all nonprofit corporations, in recent years many states have enacted legislation dealing specifically with asset sales that involve the "conversion" of nonprofit healthcare facilities into for-profit institutions. As the *MEETH* court observed, while these conversions are not permitted in New York, there has been a "nationwide spate" of such conversions, which has generated much commentary. See 715 N.Y.S.2d at 593. (citations omitted). For a compilation of legislation regulating hospital conversions (enacted as of recently in 16 states and the District of Columbia), see *The Sale and Conversion of Not-For-Profit Hospitals: A State-by-State Analysis of New Legislation* (1998) (publication available from the Volunteer Trustees Foundation for Research and Education, Washington, D.C.). For a discussion of nonprofit hospital conversions generally, see James J. Fishman, *The Checkpoints on the Conversion Highway: Some Trouble Spots in the Conversion of Nonprofit Health Care Organizations to For-Profit Status*, 23 J. CORP. L. 701 (1998); David A. Hyman, *Hospital Conversions: Fact, Fantasy, and Regulatory Follies*, 23 J. CORP. L. 741 (1998).

Discussion of this conversion legislation is generally beyond the scope of this Article. However, it is worthwhile to note California's approach. California has longstanding legislation dealing with substantial asset sales by all nonprofit corporations, which requires notice to the Attorney General. Recently, California also enacted separate legislation governing an asset sale by a nonprofit health facility to both a for-profit corporation (enacted in 1996), see CAL. CORP. CODE §§ 5914-19 (West Supp. 2000), and to another nonprofit corporation. *Id.* §§ 5920-25 (enacted in 1999). (Several other states' hospital conversion laws also cover nonprofit-to-nonprofit asset transfers. See *The Sale and Conversion of Not-For-Profit Hospitals*, *supra* at 3.) California's laws require notice of the health facility's proposed transaction to California's Attorney General and the Attorney General's written consent to it, CAL. CORP. CODE §§ 5914, 5920, and they set forth factors that the Attorney General may consider that are akin to New York's N-PCL test. *Id.* §§ 5917, 5923. Significantly, because this legislation specifically addresses a health facility's asset sale, the Attorney General may consider whether "the agreement or transaction may create a significant effect on the availability or accessibility of health care services to the affected community." *Id.* §§ 5917(h), 5923(e).

Although other states' nonprofit corporation acts do not set forth the same statutory requirements as New York's

N-PCL, the principles codified in the N-PCL are derived from fundamental common-law charitable trust principles. Charitable nonprofit corporations typically exist to achieve benevolent public purposes; they generally receive tax-exempt grants and contributions, as well as other public financial support; and they commonly are exempt from federal and state taxation. As a result, charitable corporations are deemed to hold their assets in trust, being dedicated to the specific charitable purposes set forth in the corporation's charter or articles of incorporation. The public is considered to be the beneficiary of this trust, which the board members manage for the public's benefit as "trustees." Under traditional charitable trust law principles, a state Attorney General is permitted to bring an action on behalf of the public to protect these charitable assets and is entitled to represent the public interest in the sale or other transfer of the nonprofit's assets. n96

n96 RESTATEMENT (SECOND) OF TRUSTS § 348 & comment f, § 391 (1957); SCOTT & FRATCHER, *supra* note 87, § 348, at 7, § 348.1, at 9, 15, § 379, at 315-16, § 391, at 357, 360-61; *see also* Mary Grace Blasko et al., *Standing to Sue in the Charitable Sector*, 28 U.S.F. L. REV. 37, 42-47 (1993); Lawrence E. Singer, *The Conversion Conundrum: The State and Federal Response To Hospitals: Changes in Charitable Status*, 23 AM. J.L. & MED. 221, 237-38 (1997); Philip M. Gassel & Jay E. Gerzog, *Conversions of Not-for-Profit Organizations Proliferate*, NATL. L.J., Aug. 26, 1996. *Cf.* RESTATEMENT (SECOND) OF TRUSTS § 372 (1957) ("A trust for the promotion of health is charitable."); Fishman, *supra* note 95, at 703 ("From the time of the Elizabethan Statute of Uses [in 1601], the promotion of health has been considered a charitable purpose . . .").

Thus, even aside from a state's particular statutory provisions governing a charitable nonprofit's asset sale, these common-law principles mean that a nonprofit must use its assets to further its charitable purposes and that a substantial asset sale must be consistent with the nonprofit's main charitable purposes. If not, a state Attorney General can challenge the nonprofit's proposed asset sale in court. As a result, the core issues in the MEETH situation arising under New York's express N-PCL requirements could arise for a court to address in any jurisdiction when a charitable hospital wants to close or significantly change its activities through an asset sale. n97

n97 *See* Greil Mem'l Hosp. v. First Alabama Bank, 387 So. 2d 778 (Ala. 1980) (parties sought right to will bequest made to charitable hospital, after hospital changed its original sole purpose of treating tuberculosis to become grant-making foundation funding various projects; court held that bequest lapsed when recipient hospital changed its sole corporate purpose, since bequest was gift in trust for that purpose); Holt v. College of Osteopathic Physicians & Surgeons, 394 P.2d. 932 (Cal. 1964) (plaintiffs sought to enjoin, as diversion of assets, nonprofit trustees' plan to change osteopathic medical college to allopathic medical school; court upheld cause of action for threatened breach of charitable trust, because complaint sufficiently alleged acts not within the nonprofit's charitable purpose); Queen of Angels Hosp. v. Younger, 136 Cal. Rptr. 36 (Ct. App. 1977) (nonprofit hospital could not lease its property and then use lease proceeds to establish outpatient clinics which were not equivalent to a hospital; court accepted Attorney General's argument that using those assets exclusively for outpatient clinics would be an abandonment of nonprofit's primary charitable purpose and an impermissible diversion of charitable trust assets); Attorney General v. Hahnemann Hosp., 494 N.E.2d 1011 (Mass. 1986) (Attorney General sought to enjoin nonprofit hospital's sale of all its assets to for-profit hospital; court held that even though board had amended charter to change corporate purposes, nonprofit could not use the sale proceeds for these new purposes because doing so would violate terms of a trust which had provided the hospital's original funding and whose terms were incorporated in the hospital's bylaws); Taylor v. Baldwin, 247 S.W.2d 741 (Mo. 1952) (Attorney General sought to enjoin charitable hospital from affiliating with and relocating at university medical center, asserting violation of hospital's charter as well as of certain gifts and trusts; stating that courts should not interfere with nonprofit board's decision unless there is "substantial departure" from the charity's "dominant purpose," court permitted affiliation and relocation because hospital would continue to fulfill and not depart from its specified charitable purposes under affiliation/relocation); City of Paterson v. Paterson Gen. Hosp., 235 A.2d 487 (N.J. Super. Ct. Ch. Div. 1967) (plaintiffs sought to prevent charitable hospital from relocating to adjacent community because hospital's charter stated that hospital was to be located within city of Paterson; court upheld board's decision to relocate because residents would have continued access to the hospital, sound evidence supported need to move, and move did not constitute a "substantial departure" from corporate purposes). *See also* Bossen v. Woman's Christian Nat'l Library Ass'n, 225 S.W.2d 336 (Ark. 1949) (nonprofit permitted to sell land held in charitable trust for library purposes because it was unable to use land for those purposes but could use proceeds of sale to build new library at another site); Riverton Area Fire Prot. Dist. v. Riverton Volunteer Fire Dep't, 566 N.E.2d 1015 (Ill. App. Ct. 1991) (Attorney General and others sued to prevent nonprofit corporation fire department from selling its assets after corporation changed its corporate purposes; court affirmed judgment for Attorney General, emphasizing that nonprofit held its assets as trustee of charitable trust and that because nonprofit changed its purposes, assets should be delivered to another party to continue their use for original charitable purposes).

Despite these common-law roots to the N-PCL provisions, there are, as the MEETH court noted, few reported cases dealing with the approval requirements for an asset sale under New York's N-PCL. n98 The MEETH court thus

confronted the issues arising from the proposed asset sale and closure with little case law guidance. Its decision is now the leading one in this area, which can guide parties and other courts in addressing another nonprofit's asset sale in the future. n99

n98 *MEETH*, 715 N.Y.S.2d at 592.

n99 Departing from the statutory and common-law standards, one commentator has argued that only the sale price should be considered, asserting that a nonprofit board selling its corporation's assets in a change-of-control transaction has a duty to accept the highest bid offered. Colin T. Moran, *Why Revlon Applies to Nonprofit Corporations*, 53 BUS. LAW. 373 (1998). This argument derives from a well-known corporate law case, *Revlon, Inc. v. MacAndrews & Forbes Holdings, Inc.*, 506 A.2d 173 (Del. 1986). *Revlon* held that the board of a for-profit corporation undertaking a change-of-control or break-up sale of the corporation should perform an auction-like market check on price to maximize value to the shareholders, so that generally the board has a duty to accept the highest price offered. The argument runs that *Revlon* should be applied even to the sale of a nonprofit corporation. This position mainly rejects the notion that a bidder's commitment to the nonprofit's charitable purposes would justify the board's accepting a lower purchase price; the contention is that "deferring to a board's 'charitable purpose' for accepting a low bid . . . leaves any board free to accept whatever deal it chooses"--and that nonprofit boards and the courts cannot be relied upon to determine whether the charitable attributes of a low bidder and a commitment to continue the nonprofit's charitable purposes justify the lower price. Moran, *supra*, at 388-89. (The article nonetheless notes that no court has yet applied *Revlon* to nonprofits and that other commentary has not advocated doing so; *id.* at 375.) The argument, in effect, is that at least so long as some protections are implemented to safeguard the corporation's charitable purposes, the highest offer necessarily is the best transaction for a nonprofit corporation undertaking to sell its assets.

The *MEETH* case showed the error of this theoretical argument. Under New York's N-PCL, as well as under common-law charitable trust principles, whether a proposed asset sale promotes the nonprofit corporation's charitable purposes is fundamental to the permissibility of the sale. This determination inherently involves more than a pure monetary valuation of assets. In evaluating the *MEETH* Board's proposed asset sale, the court rejected the proposition that only price mattered. Indeed, obtaining a high purchase price--and seeking to "monetize" *MEETH*'s assets--did not assure integrity of the Board's decision; instead, doing so led the Board to abandon *MEETH*'s long-established corporate purposes. *MEETH*'s Board thus proposed a transaction that did not promote *MEETH*'s charitable purposes but instead would have involved very different purposes. While the highest offer that does promote a nonprofit's charitable purposes should, of course, be the preferred transaction, there must be very careful scrutiny to assure that the proposed transaction does, in fact, promote the required charitable purposes. The *MEETH* case illustrated the problem: the Board contended that its proposed transaction--which would have closed *MEETH* as a hospital, then using the asset-sale proceeds to establish new clinics--promoted *MEETH*'s corporate purposes; however, when that transaction was scrutinized, the court found that it really did not do so. Importantly, *MEETH* demonstrated that a court, through the regular trial process, is fully able to evaluate the competing transactions for acquiring a nonprofit corporation and whether a proposed transaction furthers the nonprofit's charitable purposes. See Fishman, *supra* note 95, at 720-21 ("In the nonprofit context the board's responsibilities should be to maximize the return to the public, including benefits to the community. This does not necessarily mean that the board must accept the highest price." Fishman also contends that board's business judgment applies to acceptance of a bidder.).

Significantly, the result in *MEETH* suggests that the business judgment rule, which substantially limits judicial review of the decisions by for-profit corporate boards, does not apply to the judicial evaluation of a nonprofit corporation's asset sale. The business judgment rule "bars judicial inquiry into actions of corporate directors taken in good faith and in the exercise of honest judgment in the lawful and legitimate furtherance of corporate purposes." n100 Generally, to overcome the business judgment rule and permit judicial scrutiny of directors' decisions, there must be a showing of fraud, bad faith, or lack of disinterested independence. n101 The business judgment rule affords a presumption of regularity to a corporate board's decisions, and courts will not second-guess corporate decisionmaking where disinterested and independent directors, on an informed basis, adopt a course of action that they honestly and reasonably believed would benefit the corporation. n102 "In essence, the business judgment rule provides that courts should not examine the quality of the directors' business decisions, but only the procedures followed in reaching that decision . . ." n103

n100 *Auerbach v. Bennett*, 47 N.Y.2d 619, 629 (1979); see *Levandusky v. One Fifth Ave. Apartment Corp.*, 75 N.Y.2d 530, 537-38 (1990). *Accord Smith v. Van Gorkom*, 488 A.2d 858, 872 (Del. 1985); *Aronson v. Lewis*, 473 A.2d 805, 812 (Del. 1984) (The business judgment rule is "a presumption that in making a business decision the directors of a corporation acted on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the **company**"). While the courts of other states may explain or state the business judgment rule using somewhat different language, the formulation and application are essentially the same as in New York and

Delaware. See 1 WILLIAM E. KNEPPER & DAN A. BAILEY, LIABILITY OF CORPORATE OFFICERS AND DIRECTORS § 2-1, at 48 (6th ed. 1998).

n101 *Auerbach*, 47 N.Y.2d at 631.

n102 See 1 DENNIS J. BLOCK, ET AL., THE BUSINESS JUDGMENT RULE: FIDUCIARY DUTIES OF CORPORATE DIRECTORS 4-6 (5th ed. 1998).

n103 KNEPPER & BAILEY, *supra* note 100, § 2-1, at 47.

New York's N-PCL requires that a not-for-profit corporation meet the two-part test for a substantial asset sale "to the satisfaction of the court." n104 While the New York cases are sparse, they explain that the courts must determine the effect of the proposed sale on the corporation's charitable purposes and whether the sale would benefit the corporation. n105 Thus, a court is authorized to protect the charitable corporation's beneficiaries "from loss through unwise bargains and from perversion of the use of the property." n106 In short, Section 511 is fairly read to give the court *de novo* review of the not-for-profit board's decision to sell all or substantially all of the corporation's assets and to empower the court to determine itself whether the proposed sale meets the two-part statutory test.

n104 N.Y. NOT-FOR-PROFIT CORP. LAW § 511(d) (McKinney's 1990).

n105 See *In re Agudist Council v. Imperial Sales Co.*, 551 N.Y.S.2d 955, 957 (App. Div. 1990); *Church of God of Prospect Plaza v. Fourth Church of Christ, Scientist*, 431 N.Y.S.2d 834, 838 (App. Div. 1980), *aff'd*, 442 N.Y.S.2d 986 (1981); *Manhattan Theatre Club, Inc. v. Bohemian Benevolent & Literary Ass'n*, 467 N.Y.S.2d 143, 146 (Sup. Ct. 1983), *aff'd*, 478 N.Y.S.2d 274 (App. Div. 1984), *aff'd*, 489 N.Y.S.2d 877 (1985).

n106 *Rose Ocko Found., Inc. v. Lebovits*, 686 N.Y.S.2d 861, 864 (App. Div.) (citation omitted), *appeal dismissed and mot. for leave to appeal denied*, 696 N.Y.S.2d 107 (1999). See N.Y. NOT-FOR-PROFIT CORP. LAW § 511 (McKinney 1997) ("Generally, each court will decide on a case by case basis whether the contract is in the best interest of the corporation.").

Apart from the N-PCL's language, there is sound basis for not applying the business judgment rule to a nonprofit's substantial asset sale. When a for-profit, business corporation wants to sell all or substantially all of its assets not in the regular course of business, shareholder consent generally is required under state corporate law. n107 "The purpose of the consent statutes is to protect the shareholders from fundamental change, or more specifically to protect the shareholders from the destruction of the means to accomplish the purposes or objects for which the corporation was incorporated and actually performs." n108 Furthermore, the shareholders of a for-profit corporation have ways to challenge an incumbent board of directors, or to contest board decisions like change-of-control or substantial-asset-sale transactions: they can seek to replace management and the board through a proxy fight, start (or sell their shares in) a hostile tender offer, or bring derivative lawsuits.

n107 6A WILLIAM MEADE FLETCHER ET AL., FLETCHER CYCLOPEDIA OF THE LAW OF PRIVATE CORPORATIONS § 2949.20.10 (perm.ed.rev.vol.1997) ("Every state requires in some or all instances where all, or substantially all, of the corporate assets are sold or transferred that there be shareholder consent."). See, e.g., N.Y. BUS. CORP. LAW § 909 (McKinney 1986 & Supp. 2000).

n108 6A FLETCHER, *supra* note 107, § 2949.20.10. Indeed, in determining whether a sale constitutes "all or substantially all" of the assets of a corporation, courts look to whether "the fundamental purpose for which the corporation was formed was eliminated as a result of the transfer." *Id.* § 2949.40.

But these rights and remedies available to the shareholders of for-profit, business corporations are lacking in the charitable corporation context. A main attribute of a nonprofit corporation is the absence of owners. n109 The typical

charitable corporation, like MEETH, lacks even members (who might have some say in a nonprofit's decisions), so that, as the *MEETH* court observed, the nonprofit's board is entrenched, being self-perpetuating. n110 The board thus has pervasive control over a sale of the charitable corporation's assets. Indeed, the required shareholder check on a business corporation's substantial asset sale cannot exist for a charitable corporation. n111 In short, because a charitable corporation does not have shareholder-like owners with a pecuniary interest in the corporation, there generally is no outside party with a strong interest in examining and challenging the board's decisionmaking. n112

n109 *MEETH*, 715 N.Y.S.2d at 592.

n110 *Id.*

n111 *Id.*

n112 *Id.*

As a result, a nonprofit board can act more freely than the usual for-profit board, being largely immune from both critical scrutiny and the conventional tools so important for policing for-profit corporations. Thus, there is much less reason to apply the hard-to-overcome presumption of regularity of board decisionmaking afforded by the business judgment rule.

While not explicitly so holding, the *MEETH* court in effect determined that the business judgment rule did not apply to a charitable corporation's asset sale. The court did not defer to the Board's decision to sell MEETH's assets, but instead thoroughly analyzed the decision itself--carefully making a *de novo* determination under the statutory criteria. Indeed, the court held that several factors derived from another state's hospital "conversion" legislation, factors that concern both the procedures and merits of a board's decision, should be considered in evaluating an asset sale under the N-PCL. n113 The court also considered the directors' duties without reference to the business judgment rule. n114 Thus the *MEETH* analysis confirmed that a court should examine the grounds for the board's sale decision, without adopting a presumption of regularity from the business judgment rule. The *MEETH* decision is further and compelling authority that the business judgment rule does not apply to the judicial process for approving or evaluating a nonprofit's asset sale. n115

n113 *Id.* at 594 (employing factors enumerated in the Nebraska statute, as summarized in Mark Krause, "First, Do No Harm": An Analysis of the Nonprofit Hospital Sale Acts, 45 UCLA L. REV. 503, 550 (1997)).

n114 *See MEETH*, 715 N.Y.S.2d at 593.

n115 It has been noted that confusion exists in regulating nonprofit hospital sales within various jurisdictions because nonprofit hospitals are governed by both statutory corporate law and charitable trust law; thus, commentary has observed a "modern trend" from certain jurisdictions to apply corporate fiduciary standards rather than generally more rigorous trust principles to gauge nonprofit directors' duties--so that the business judgment rule would apply to nonprofit directors' decisions involving nonprofit hospital sales. *See* KNEPPER & BAILEY, *supra* note 100, § 12-2(b), at 418-19; Rachel B. Rubin, *Nonprofit Hospital Conversions in Kansas: The Kansas Attorney General Should Regulate All Nonprofit Hospital Sales*, 47 U. KAN. L. REV. 521, 536-49 (1999). *See also* Stern v. Lucy Webb Hayes Nat'l Training Sch., 381 F. Supp 1003, 1013 (D.D.C. 1974). The model nonprofit legislation accepts the business judgment rule and rejects the stricter trustee standard of care. REVISED MODEL NONPROFIT CORP. ACT § 8.30 & cmt 3 (1987) ("While the application of the business judgment rule to directors of nonprofit corporations is not firmly established by the case law, its use is consistent with section 8.30 [setting forth general standards of conduct for directors of a nonprofit corporation]."); *id.* § 8.30(e) ("A director shall not be deemed to be a trustee with respect to the corporation or with respect to any property held or administered by the corporation . . ."). *See* Fishman, *supra* note 95, at 735-39 (recognizing business judgment rule for nonprofit decisionmaking but recommending enhanced scrutiny for conversion transactions); Harvey J. Goldschmid, *The Fiduciary Duties of Nonprofit Dirs. and Officers: Paradoxes, Problems, and Proposed Reforms*, 23 J. Corp. L.

631, 648-51 (1998) (recommending judicial review more rigorous than business judgment rule, such as a fairness test, for matters implicating nonprofit directors' duty of loyalty, like interested-director transactions; but suggesting business judgment rule should apply for conversions and similar transactions).

Nonetheless, New York's statutory scheme governing a not-for-profit's asset sale specifies, in straightforward language, that the two-part test must be met "to the satisfaction of the court." As a result, the *MEETH* court emphasized that its "mandate" under the N-PCL was to review the proposed sale to assure that the interests of the public, as the corporation's ultimate beneficiaries, are "protected from improvident transactions." *MEETH*, 715 N.Y.S.2d at 592-93. Such judicial review precludes justifying a sale solely under the business judgment rule. While *MEETH*'s Board initially argued that the business judgment rule applied to its sale decision, it did not pursue that contention, effectively abandoning it by the end of the trial. (In any event, the facts in *MEETH* probably would have overcome even the protection afforded by the business judgment rule.) And aside from the N-PCL express language, there are, as discussed above, valid reasons why a court should not apply the business judgment rule in evaluating any nonprofit board's sale-of-assets decision.

B. Considerations Under the N-PCL/Charitable Trust Law Versus the DOH Regulations

Despite some overlap, the considerations under the N-PCL and charitable trust law for judicial approval of a hospital's asset sale causing a closure differ significantly from the considerations before the DOH for regulatory approval of the closure. As a result and as occurred in the *MEETH* case, there is real potential for harmful conflicts to arise in determining whether a hospital may close. n116

n116 In New York, virtually all hospitals (other than public hospitals organized and operated through government or government-like agencies) exist as charitable corporations. The reason for this is that the statutory provisions by which New York permits a hospital to be established effectively prohibit a public for-profit **company** from owning a hospital. *See* N.Y. PUB. HEALTH LAW § 2801-a (McKinney Supp. 2000); *see also* Gassel & Gerzog, *supra* note 96; Hyman, *supra* note 95, at 766. As a result, a New York hospital that wants to sell all or substantially all of its assets as part of a closure plan (or which will cause a closure) will likely need judicial approval for the transaction under the N-PCL; thus, the problems so manifest in *MEETH*'s situation will reoccur.

As emphasized, DOH regulatory approval for a hospital closure involves the delicate balance of **protecting** patients' well being in the context of state-created limits on healthcare facilities. Despite the important need to promote economic healthcare by limiting excess facilities, considerations of patient care, continuity of care, and the public health generally should be critically important to the DOH in assessing whether (and if so, how) a hospital may close.

The main purpose of judicial approval under the N-PCL, as well as under the common-law principles, is very different. It is, essentially, to protect the not-for-profit corporation as a charitable asset. This charitable asset "belongs" to no one in particular. In effect, it belongs to the whole community. Thus, the responsibility and obligation are vested with the courts, and with the Attorney General in a *parens patriae* role and by statute, to protect charitable assets for the benefit of the public. n117 After the board of a not-for-profit corporation has decided to sell all or substantially all of the corporation's assets, both the Attorney General and the courts are bound to scrutinize that decision. The ultimate approval authority is then vested in the courts, to assure that the transaction favored by the board is sound. That is, that the consideration and terms are "fair and reasonable," and, very importantly, that the transaction also meets the corporation's charitable purposes--in other words, that those purposes are "promoted" by the transaction. n118

n117 In addition to approval for a substantial assets sale, a petition for judicial approval, with notice to the Attorney General, is required for numerous other significant corporate changes by a New York not-for-profit corporation, such as merger and dissolution (*see* N-PCL Articles 9, 10 & 11) and amendment of corporate purposes. (*See* N.Y. NOT-FOR-PROFIT CORP. LAW § 804(a).) With regard to the Attorney General's statutory authority, *see* N.Y. NOT-FOR-PROFIT CORP. LAW §§ 112(a), 720(b) (right to bring lawsuit); N.Y. EST. POWERS & TRUSTS LAW §§ 8-1.1, 8-1.4 (McKinney 1992 & Supp. 2000) (relating to disposition and supervision for charitable trusts); N.Y. EXEC. LAW § 63 (McKinney 1993 & Supp. 2000) (general duties of Attorney General, including duty to prosecute and defend actions in which state is interested).

n118 *MEETH*, 715 N.Y.S.2d at 591-92.

In the context of a hospital's asset sale, the N-PCL determination might implicate healthcare issues, but the

fundamental issue is different: the Attorney General and the court must protect the charitable asset and the charitable corporate mission. Thus, the DOH's decision on closure of a hospital, albeit possibly relevant to the Attorney General and court's review, should not determine the outcome of review under the N-PCL. For example, it is possible that the DOH would permit a closure if healthcare needs are not harmed or are otherwise protected, but that an asset-sale closure would nonetheless be impermissible under the N-PCL because it would not advance the corporation's charitable purposes. In the *MEETH* case, even though the DOH never decided the closure issue under its regulations, the Attorney General opposed MEETH's sale of assets (which necessarily would cause a closure), and the court disapproved it after trial, precisely because the proposed asset sale did not meet the N-PCL criteria.ⁿ¹¹⁹ While based in the statutory provision before it, the court's ruling also preserved MEETH as an important healthcare facility and assured its ability to continue its public healthcare role. In short, the considerations under the DOH regulations and the nonprofit corporation laws are intertwined, but must be considered independently.

ⁿ¹¹⁹ *Id.* at 592.

IV. The Lessons from *MEETH*, and Some Recommendations

In the *MEETH* situation, a not-for-profit corporation's Board of Directors voted to close a hospital, which required regulatory approval, based upon a transaction that also required judicial approval. The Board and its administration then took steps to effectuate a closing without having obtained either regulatory or judicial approval. Despite this absence of approvals, the winding down led MEETH to the brink of an irreversible shutdown, simply from the collapse of its own operations and finances. Only aggressive, sustained, and costly opposition to closure by various parties, and diligent action by the Attorney General, prevented that from happening. But in the dynamic and rapidly changing healthcare environment, we can expect other MEETH-like situations to arise. It is therefore very important that attention be given to reconciling the dual approval process that applies when a not-for-profit medical institution wants to close, to assure that important public policy concerns are protected.

Closing a charitable hospital presents an amalgam of issues. Public health concerns--which MEETH's potential closure highlighted so forcefully--are of course vested in the DOH, as the agency with expertise over those issues. But in a MEETH-like situation in which charitable assets are also at risk, the Attorney General and, ultimately a court, have very important roles that are quite different from the DOH's. Because of the unique charitable attributes of a not-for-profit corporation, New York's legislature has determined that the judiciary (with the Attorney General's important input) bears the final decisionmaking authority over major events in the not-for-profit's life. A court must make a determination, based upon the legislative requirements, whether a proposed transaction that might close a hospital is permissible. Because the court itself is vested with a statutorily-prescribed decision, the court need not--indeed, should not--defer to determinations made by the administrative agency, whose role and expertise involve different considerations. Simply stated, even if the DOH were to approve closing a hospital, a court might decide that the closure is impermissible under the N-PCL. And because New York's legislation comes from common-law charitable trust principles that prevail generally, the issues and problems under New York's statutory scheme and administrative regulations mirror what can occur in a closure approval process anywhere.

Achieving better reconciliation of the approval process involves the not-for-profit's board itself, more effective DOH regulations, and greater appreciation of the overriding N-PCL and charitable trust law considerations.

A. The Responsibilities of the Board

The starting point for achieving a better reconciliation of approvals is with the board of directors itself. Most states have incorporated many nonprofit corporations, and the state Attorneys General cannot effectively police even a small portion of them. (New York, for example, has about 38,000 registered charities, a number that excludes the many not-for-profits exempt from registration.) Diligent and responsible decisionmaking by their boards thus is critical. A board considering a closure should undertake--obviously without any prejudgment--an independent detailed study of the

facility's operations, finances, market-place, and the like to assist in deciding whether to close.

A decision to close should be supported by a thorough showing of justification and need, which can then be submitted to the DOH, the Attorney General, and the court. In seeking approvals, a board should be able to show that its decision is warranted, based on the most compelling circumstances, and is permissible based on public health considerations. Particularly from the public health perspective, a showing of the need to close should be thoroughly justified, as opposed to trying to achieve another course of action. In almost all cases, the analysis and advice of a truly independent, and disinterested, advisory firm or consultant will be necessary. The advisor/consultant's mandate cannot be restricted in advance and its compensation cannot be based on the nature of its recommendation. To promote the advisor/consultant being independent and disinterested, the terms of the retention should be expressly agreed upon in writing, carefully adhered to afterwards, and disclosed at the outset. In short, both agencies (the DOH and the Attorney General) and, eventually a court will need to consider in detail *how* the board decided to close or sell assets-and the board itself should take the proper steps to establish the integrity of that decision. n120

n120 The *MEETH* court noted that the process of converting a not-for-profit hospital into a for-profit hospital was "analytically useful" to the N-PCL determination before it. The court thus found that several of the factors from another state's hospital conversion legislation should be considered in the N-PCL determination: (a) whether the not-for-profit used due diligence in deciding to sell, selecting the purchaser and negotiating the sale's terms and conditions; (b) whether the procedures used in making the sale decision, including whether an appropriate expert was used, were fair; (c) whether conflicts of interest (including that of board members or retained experts) were disclosed; and (d) whether the hospital will receive reasonably fair value for its assets. *MEETH*, 715 N.Y.S.2d at 594. These factors go to the integrity of the board's decision, and they should be foremost in the board members' minds as they go about their decisionmaking process

The *MEETH* situation showed how a board, without obtaining independent advice and adhering to careful consideration at the outset, could decide to close improperly. The court found it significant that the Board's retention of *MEETH*'s original strategic advisor, who eventually recommended the assets sale, had harmed the decisionmaking process:

[The advisor] had a direct and substantial interest in a sale of the real estate, *i.e.*, the 1% transaction fee. This arrangement . . . resulted in a situation where the Board put its reliance upon a strategic advisor which had an actual interest in the recommendations of its strategic study. It is not necessary for me to conclude that this conflict of interest compromised the result; the fee arrangement [between *MEETH* and the advisor] certainly gives the appearance that the integrity of the process was flawed and that the Board had not obtained the assistance of a truly independent expert. Moreover, there does not appear to have been full disclosure to the Board of the potential for a conflict of interest in the expert. n121

n121 *MEETH*, 715 N.Y.S.2d at 595-96.

Similarly, the Board's retention of healthcare consultants, who subsequently supported the Board's new clinic plan (and who were different from the original strategic advisor), was problematic, making the Board's decision further suspect. The court found it significant that these consultants were engaged months after the Board's closure decision had been made and, thus, "were charged with supporting the already decided upon plan." n122

n122 *Id.* at 586.

The failings of the *MEETH* Board's decisionmaking process were revealed by cross-examination at the N-PCL trial. (Even the contingency-fee-like retention of *MEETH*'s strategic advisor evidently had not been disclosed to outside parties until the courtroom proceedings.) A trial should not be the time or place for these matters to first come to light.

Without a board acting diligently and objectively at the outset, there is great potential for abuse and manipulation. A not-for-profit board needs to be attuned to these important decisionmaking issues from the start, and it needs to approach the important decision of closing a charitable institution in an open-minded and objective way, with the aid of disinterested advisors. Indeed, to facilitate the subsequent dual approval process, the board needs to be able to demonstrate that it has done so.

In making this important decision, a core question to the board is the hospital's finances. While a charitable hospital lacks shareholders (and thus is not accountable to them for the profit expectations which face a for-profit corporation), if the hospital is continually losing money, surely something is wrong, and it might not be able to remain open. Simply put, while a not-for-profit hospital does not have the same moneymaking component of a for-profit **company**, it cannot be expected to survive if it remains significantly in the red.

The *MEETH* court, again cogently, answered this point. A not-for-profit corporation has a charitable mission, defined by its charter, and its board has a duty of obedience to that mission. As the court put it:

the duty of obedience . . . mandates that a Board, in the first instance, seek to preserve [the not-for-profit's] original mission. Embarkation upon a course of conduct which turns it away from the charity's central and well-understood mission should be a carefully chosen option of last resort. Otherwise, a Board facing difficult financial straits might find sale of its assets, and "reprioritization" of its mission to be an attractive option, rather than taking all reasonable efforts to preserve the mission which has been the object of its stewardship. n123

n123 *Id.* at 595.

When a not-for-profit hospital (or, for that matter, any nonprofit institution) confronts financial failure, *all other options* need to be evaluated fully and carefully before it abandons or even changes its mission through a complete asset sale and closure. For example, the *MEETH* case highlighted that the Board and its administration had not managed *MEETH* soundly and had repeatedly rejected the medical staff's recommendations for addressing the hospital's serious economic issues. Better management, enhancement of the services and business, and adaptation to marketplace changes always need to be thoroughly considered.

The *MEETH* case also highlighted--which was critical to the court--that the Board did not adequately consider various other proposals that would have continued *MEETH*. n124 As eventually occurred in the *MEETH* situation, it is common in the healthcare industry for a financially stronger entity to take over a weaker one. Before a board ever votes for closure, it should explore every possibility of achieving a merger or acquisition that will enable another institution to carry on the failing hospital's charitable mission. Again, the *MEETH* court hit the nail on the head: "the Board has no independent vitality. It appears that the Board confused preservation of the Hospital with preservation of the Board, when the appropriate calculus should be what is good for the Hospital is good for the Board." n125

n124 *Id.* at 596.

n125 *Id.*

Another important countervailing closure consideration is philanthropy. Few charitable hospitals meet their expenses based on revenue alone (and, indeed, unlike other businesses, profit admittedly is not their purpose). Philanthropy plays an important role in our healthcare system in helping hospitals make ends meet. Not surprisingly, for years before *MEETH*'s efforts to close, its Board and administration had done little fund-raising and generally had not

successfully generated charitable contributions that might have helped its finances significantly. Every conscientious not-for-profit board confronts fund-raising regularly, but for a hospital in financial difficulty, the board assuredly must be especially aggressive on this front.

It also bears emphasizing that the DOH can and should play a meaningful role in assisting a board on these countervailing closure issues. The DOH can lend some level of administrative expertise, in appropriate circumstances, to assist a beleaguered hospital administration. More significantly, the DOH can help to facilitate a merger or acquisition, or other workout-type transaction, based on its detailed knowledge of the industry and its extensive relationships with major hospitals and other healthcare providers. In MEETH's case, when it became evident that the Board was not properly considering other transactions as alternatives to closure, the medical staff urged the DOH to try to facilitate such a transaction. A conscientious board could well enlist the help of the DOH in seeking to survive, rather than just seeking the necessary approval to close.

Finally, it is very important that the board approach a sale-of-assets and closure decision rigorously and thoroughly, with careful consideration of all options, because subsequent judicial review might not apply the business judgment rule to presume that the board's decision is valid. Instead, a court might--indeed, should--review *de novo* the board's decision to close through an asset sale. Thus, judicial review should not be limited to considering the board's procedures in adopting its decision, but would involve scrutinizing the merits and quality of the decision itself, and, particularly, whether the transaction decided upon would legitimately further the institution's charitable purposes.

The bottom line is that a not-for-profit board must recognize--as the *MEETH* court held--that closing its institution is only justifiable as a last resort, after very principled, fully-informed, and objective decisionmaking process. The *MEETH* case spelled out the many ways in which MEETH's Board did not adhere to this concept. The court's decision should be required reading for all not-for-profit boards, both in New York and elsewhere.

B. The Guidance from Administrative Regulations

The DOH needs to promulgate much better regulations governing hospital closures. The MEETH situation underscored the lack of specificity--and the resulting deficiency--of the DOH's regulations. Promulgating more explicit provisions would both better inform a hospital's board about criteria to consider in deciding whether to close and, if the board votes for a closure, what must then be done in the closing process. More explicit regulatory provisions will, of course, improve the closure approval process in other states whose regulations are, like New York's, also undeveloped.

Fundamentally, the DOH needs to ask much more than its regulations now address when confronted with a hospital closure. In the first instance, regulations should require detailed, specific, and documented findings that establish the need to close. Even more importantly, DOH regulations should also require a careful and detailed assessment of the likely effects of a closure on delivery of medical care to the community and on continuity of medical care for existing patients. Indeed, the DOH could require an impact statement, which could solicit and include the views of the public and other knowledgeable and interested parties, in assessing an application for approval to close. In the MEETH situation, the serious public health concerns from closing MEETH emerged as major issues only through an *ad hoc* campaign to inform the DOH, not as a result of compliance with DOH regulations. Regulations should also require that a hospital seeking to close must address alternatives to closure, such as merger or acquisition transactions with other institutions. If, and only if, a proposed closing complies with these regulations, then further specific regulations should spell out, in much more detail than exists presently, the concrete requirements for actually shutting down the facility and assuring that patients' medical needs will continue to be met without interruption.

As the DOH regulations in New York now stand, the meager requirements almost presume permissibility of closing when the board seeks it: they set forth no criteria for the DOH's approval, state no requirements to be followed during the ninety-day notice period, and only briefly address a few specifics for an actual closing. The MEETH situation, once the proposed closing was finally subjected to judicial scrutiny, showed how wrong that approach is.

Also very importantly, the DOH needs to be able to freeze the status quo when confronting a closure application. That means that the DOH should not permit a hospital to wind down its operations while the closure application is pending. A winding down will invariably harm the facility significantly, causing major disruptions, dislocation, loss of patients and employees, diminution of procedures performed, and decline of the commitment of its physicians and staff--resulting, in short, in a kind of self-fulfilling prophecy leading to a shutdown. And the DOH should require the hospital to adhere to this requirement strictly, so as not to allow a hospital board and administration, having decided to close, to chip away, bit-by-bit, at the hospital's ongoing operations.

As almost happened in the MEETH situation, winding down can cause the hospital to fail *before* the DOH decides whether closure is permissible. If that occurs, the regulatory determination (as well as the judicial one) will be moot and the result assuredly will be irreversible, since once a hospital is shuttered, it is never going to be salvaged as an ongoing medical facility again.

C. The Importance of Coordinating the N-PCL and Charitable Trust Law

When closing a hospital involves an asset sale that requires review under the N-PCL, as will likely be the case, the DOH needs to work with the Attorney General to assure that the DOH's review process does not compromise the N-PCL considerations. In an asset-sale-based hospital closure, there are two policemen on the block, two regulators, both part of the executive branch of state government, who need to work together for the public good. The DOH needs to know and appreciate the Attorney General's position. There should be a constant and open dialogue between the DOH and the Attorney General about all of the issues surrounding closure, because the considerations under the N-PCL may be intertwined with the public health issues before the DOH. Most importantly, the DOH needs to know--and appreciate the ramifications of--whether the Attorney General objects to closure based on the N-PCL criteria. For example, if the Attorney General objects to an asset-sale-based closure, the DOH needs to recognize that its consideration of closure under its regulatory authority could harm the charitable institution that the Attorney General is charged with **protecting**. And again, these considerations apply in any jurisdiction, because the principles embodied in the N-PCL are based on charitable trust law concepts under common law, which a state Attorney General can enforce in court.

Put simply, if the DOH gives a green light to closure based on the public health issues it considers, its doing so could destroy the charitable asset, even though the criteria under the N-PCL might not be met. And without coordination between the DOH and the Attorney General, the integrity of the judicial approval process under the N-PCL could be undermined.

In analyzing the Board's conduct, the *MEETH* court recognized the crux of this problem:

MEETH began to act . . . upon the assumption that it would receive DOH approvals for closure and establishment of the [diagnostic and treatment] centers. It executed a letter evidencing its intent to sell to MSKCC, and chose to take steps to effectuate closure and receive regulatory approval for its plan, to enter into a contract for sale, and then to seek court approval under section 511. *This would have had the effect of presenting the court with what would have been essentially a fait accompli.* To put it another way, if everything went as-hoped-for, MEETH would have been able to present the section 511 petition pertaining to an *already* closed hospital, with DOH approval for the [diagnostic and treatment] centers, and it would have asked the court to find "that the purposes of the corporation . . . will be promoted." This would have effectively neutralized, or substantially compromised any meaningful judicial role in the section 511 process. Indeed, under the scenario envisaged by MEETH, denial of the petition would have been a pyrrhic victory for its opponents: the hospital would already be closed; under such circumstances, a court order could hardly have restored MEETH. n126

n126 *Id.* at 586 (first emphasis added).

The court's analysis of the MEETH Board's conduct was no doubt significant to its determination to disapprove the sale-of-assets contract under review. More generally, however, that analysis highlighted the potential harm from the uncoordinated dual regulatory regime that exists.

Coordination between the DOH and Attorney General in a hospital closure situation should be the norm, and achieving it should not be difficult. One sensible approach would be for the two agencies to agree upon a memorandum of understanding, or simply a written protocol of procedure, for addressing hospital closures that implicate both DOH regulations and the N-PCL.

Another significant change could be a requirement that the petition under the N-PCL be filed prior to, or at least contemporaneously with, the application under DOH regulations. DOH regulations could effectively mandate this--for example, by conditioning the DOH's consideration of a closure approval application on the applicant's contemporaneously or previously filing any required N-PCL petition. Once that petition is filed, the closure matter will be in court, and the Attorney General can appear formally to assert the public's position. Indeed, in MEETH's situation, for a significant period of time the Attorney General and the court could not address the *de facto* closure problem because there was no judicial application, but as soon as the Board finally filed its N-PCL petition, the Attorney General moved for, and the court ordered, injunctive relief to stop the Board's winding down process.

MEETH also demonstrated how the delay in filing the N-PCL petition, as the court noted, was so harmful to the hospital as a charitable institution. In particular, when the court considered the proposed asset sale, it found the sale unlawful (having tried the case and ruled very expeditiously once MEETH eventually filed its petition), but the Board's months-long winding down process preceding the filing had greatly harmed MEETH. Requiring that regulatory and judicial approvals be sought at the same time, thereby at least starting them on a concurrent time track, can help solve this problem. Significantly, requiring the not-for-profit to go to court when it also applies for DOH approval will prevent an institution from preempting the court and will allow the court to control the overall process. Thus, the court, as informed by the parties' advocacy and depending on the particular circumstances, can act to protect the charitable asset and guard against an impermissible closure, allow all interested parties to be heard, determine whether any stays or injunctive relief are warranted, address issues of winding down if necessary, and generally regulate the often multiple and competing issues involving closure.

The coordination between the dual regulatory regimes that govern a hospital closure raises important public policy issues. While regulators could agree among themselves to coordinate the process for evaluating a closure, legislation governing a hospital's closure (as now exists in some states) is also appropriate. Legislation could prescribe the procedures for a state's Attorney General and its department of health to work together on their respective review and approval functions and specify the requirements that the hospital seeking to close must meet. More broadly, legislation could also mandate that detailed administrative regulations be promulgated to govern a proposed hospital closure; require that the healthcare issues arising from a closure be evaluated; impose a "freeze" period that could protect against a *de facto* closing; and apply provisions for **protecting** charitable assets and enforcing charitable trust law principles. This kind of legislation would go a long way to ameliorate the problems that became manifest in the MEETH situation.

n127

n127 Various states' conversion legislation may be instructive for coordinating regulation. California's statutes provide that the Attorney General must review the conversion transaction but do not require direct review by the state Department of Health Services. Rather, the Attorney General is authorized to seek assistance from any state agency (which would include the Department of Health Services), as he or she "deems appropriate." See CAL. CORP. CODE §§ 5919, 5924 (West Supp. 2000). Review by the Department of Health Services was included in an earlier version of a California conversion bill but evidently was eliminated because the bill's sponsors decided that another level of review would overly burden the conversion process. See Mark Krause, "*First, Do No Harm*": An Analysis of the *Nonprofit Hospital Sale Acts*, 45 UCLA L. REV. 503, 550 (1997). Taking a different approach, another state's statute dealing with these conversions requires Department of Health review, mandating it to consider healthcare issues. NEB. REV. STAT. §§ 71-20,107, 71-20,109

(1996); *see* Krause, *supra*, at 551. Yet another state's statute regulating nonprofit hospital sales provides that *the Attorney General*, as part of his or her evaluation of the transaction, should consider whether the proposed transaction has sufficient safeguards "to assure the affected community continued access to affordable care" and to protect other health-care related concerns. *See* LA. REV. STAT. ANN. § 40:2115.18 (West Supp. 2000). Legislation could be crafted that gives both the state's Attorney General and its public health department significant input and authority, with each agency using its particular expertise, into the determination whether a charitable hospital may close.

V. Conclusion

Closing a not-for-profit hospital presents numerous complex problems that intertwine serious public health issues involving the delivery of medical care and important corporate law concerns involving the preservation and appropriate disposition of a valuable charitable asset. As a result, separate regulators and different approval schemes are involved. Also as a result, closing a charitable hospital requires very disciplined and careful decisionmaking, to assure that the institution's charitable mission and public healthcare role are not short-changed. A basic lesson of the *MEETH* case--in which a renowned charitable hospital was almost lost because of flawed decisionmaking--is that the regulation and approval under the different schemes governing closure of a not-for-profit hospital must be better harmonized, so that the important public policy considerations underlying both schemes are best protected.

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LENGTH: 15464 words**TITLE:** Articles: HIPAA Privacy: The Compliance Challenges Ahead**AUTHOR:** Kristen B. Rosati *

* Coppersmith Gordon Schermer Owens & Nelson PLC. I wish to thank Donna Eden, Senior Counsel, Department of Health and Human Services (DHHS), for her helpful suggestions and input. This Article does not represent the views of DHHS; any mistakes herein are mine.

TEXT:

ABSTRACT: This Article reviews the HIPAA Privacy Standards' impact on healthcare organizations. It discusses whether a healthcare organization is a "Covered Entity" under the regulations, what information the Privacy Standards protect, what restrictions the regulations place on the use and disclosure of protected health information, what individual rights the Privacy Standards create, and what agreements they require between healthcare organizations and their business associates. The author provides relatively extensive guidance to organizations that are embarking upon their voyage of compliance with these broadly applicable regulations, but notes that the full extent of necessary compliance remains unclear, pending DHHS issuance of the next iteration of the rulemaking in this area. The Article was finalized in January 2002, before HHS issued any modifications to the Privacy Standards.

Everyone involved in healthcare has a privacy horror story. An organization called "Dumpster Divers" contacts a hospital and offers to return medical records found in the garbage for a "handling fee" of \$ 25,000. n1 Aetna health insurance claim forms blow out of an open pickup truck during evening rush hour on the way to the recycling center. n2 A physician orders a genetic test on a woman without first warning her of its consequences: the results would be added to her record and could obliterate her chances of obtaining health insurance. n3 A Congresswoman's records of depression and a suicide attempt are faxed from a hospital to a local newspaper and television station just weeks before her election primary; she wins nonetheless. n4 A woman battling leukemia discovers she is pregnant, and must make the terrible choice between continuing chemotherapy or continuing her pregnancy. Only her physician and husband know of her pregnancy; a week later, she receives a stack of maternity magazines in the mail after filling a prescription for prenatal vitamins. n5

n1 Author interview with hospital's attorney, 2001.

n2 Kenneth R. Gosselin, *Careless Disposal of Records Imperils Privacy*, THE HARTFORD COURANT, May 14, 1999, at D1.

n3 Rick Weiss, *Ignorance Undercuts Gene Tests' Potential*, THE WASHINGTON POST, Dec. 2, 2000, at A1.

n4 Alissa J. Rubin, *Records No Longer for Doctors' Eyes Only*, LOS ANGELES TIMES, Sept. 1, 1998, at A1.

n5 Author interview with individual, 2001. For additional stories, see Georgetown University Institute for Health Care Research and Policy, *Medical Privacy Stories* (Nov. 14, 2001), at www.healthprivacy.org/usr_doc/mprivacystories%2Epdf.

Clearly, **protecting** the privacy of individual health information is an important public goal. How to regulate this protection, however, is anything but simple. Not surprisingly, the final Standards for Privacy of Individually Identifiable Health Information (Privacy Standards) n6 produce a complex and tangled web of regulation that makes **protecting** health information decidedly complicated.

n6 Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462 (Dec. 28, 2000) (to be codified at 45 C.F.R. pts. 160 and 164).

These regulations will have a profound effect on how healthcare providers, health plans, and healthcare clearinghouses do business. The Privacy Standards comprehensively regulate the internal use and external disclosure of protected health information (PHI), creating rules for when patient permission is required for use and disclosure, what that permission must contain, and how much of the PHI may be used or disclosed. n7 The Privacy Standards also create individual patient rights-some of which are new in many states-to inspect and copy one's own PHI, to amend erroneous or incomplete information, to obtain an "accounting" of many disclosures of information, to request restrictions of uses or disclosures for treatment, payment, or healthcare operations, to receive confidential communications, and to receive notice of a healthcare organization's privacy practices. n8 Further, the Privacy Standards establish a number of administrative requirements, which mandate covered healthcare organizations to have an extensive set of policies to protect the privacy of health information, to appoint a "privacy official" to develop those policies, and to conduct workforce training on those policies. n9 Finally, these regulations mandate contracts with "business associates" to ensure that they also protect health information. n10 Complying with these regulations will require a sustained, concentrated, and expensive effort by healthcare organizations.

n7 45 C.F.R. § 164.502 (2001).

n8 *Id.*

n9 *Id.* § 164.530.

n10 *Id.* § 164.502(e) (2001).

These regulations clearly are intended to impose strict requirements on the use and disclosure of individual health information. At the same time, the Department of Health and Human Services (DHHS) recognized that providers and payors must have prompt access to complete medical information to provide quality medical care. DHHS attempted to balance these concerns in the Privacy Standards; whether DHHS achieved this goal is debatable. n11

n11 *Id.*

One thing is certain: The Privacy Standards will impose substantial expense and operational change on the healthcare industry. The government estimates the cost of implementing the Privacy Standards at \$ 17.6 billion over ten years (2003-2012), n12 while the American Hospital Association's estimate comes in much higher at \$ 22 billion over five years. n13 Moreover, because of the substantial reworking of internal operations and business relationships that the Privacy Standards will require, it is questionable whether many covered healthcare organizations will meet the current compliance deadline of April 14, 2003. n14

n12 Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,760 (Dec. 28, 2000) (to be codified at 45 C.F.R. pts. 160 and 164).

n13 See American Hospital Association, *HIPAA Privacy Final Rule: An Overview* (Nov. 14, 2001), at www.aha.org/hipaa/advocacy.asp.

n14 45 C.F.R. § 164.534 (2001). Healthcare providers, healthcare clearinghouses, and most larger healthcare plans have 24 months after the effective date of the regulations (April 14, 2001) to comply with the rule. "Small" health plans--those with less than \$ 5 million in annual receipts--have 36 months to comply. *Id.* § 160.103.

This Article provides a brief survey of the origination of the Privacy Standards and recent developments pertaining to them, summarizes the major provisions of the final Privacy Standards, and suggests ways to tackle compliance.

I. Origins and Recent Developments

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), n15 contains an "Administrative Simplification" subtitle, the primary purpose of which is to adopt national standards to facilitate the electronic exchange of health information to make financial and administrative healthcare transactions more efficient. n16 On August 17, 2000, DHHS published regulations implementing these standard transactions, called the Standards for Electronic Transactions, n17 which DHHS calculates will result in over \$ 29.9 billion in net savings for the healthcare industry over the next ten years. n18 DHHS plans to issue additional regulations to implement the remaining Administrative Simplification provisions, possibly by the summer of 2002. n19

n15 Health Insurance Portability and Accountability Act of 1996 (hereinafter HIPAA 1996), Pub. L. No. 104-191, 110 Stat. 1936.

n16 HIPAA 1996, §§ 261-264, 110 Stat. at 2021-34 (enacting the Social Security Act §§ 1171-1179). See Health Insurance Reform: Standards for Electronic Transactions, 65 Fed. Reg. 50,312 (Aug. 17, 2000) (to be codified at 45 C.F.R. pts. 160 and 162); see also 42 U.S.C. § 1320d-2 (2001).

n17 Health Insurance Reform: Standards for Electronic Transactions, 65 Fed. Reg. at 50,312.

n18 *Id.* at 50,355.

n19 These include final Security Standards, which will govern the security of computer systems for specialized transactions (see Security and Electronic Signature Standards, 63 Fed. Reg. 43,242 (Aug. 12, 1998) (to be codified at 45 C.F.R. pt. 142)), and regulations governing national "identifiers" assigned to various participants in the health care system, such as: providers (see Health Insurance Reform: Standards for Electronic Transactions, 63 Fed. Reg. 25,272 (proposed May 7, 1998) (codified at 45 C.F.R. pt. 142)); employers (see Health Insurance Reform: National Standard Employer Identifier, 63 Fed. Reg. 32,784 (proposed June 16, 1998) (codified at 45 C.F.R. pt. 142)); and health plans (not yet proposed). National identifiers for individuals are on hold due to the controversy spurred by that proposal.

Encouraging electronic transmission of health information through standard transactions, however, may lead to widespread dissemination of this private and sensitive information. As DHHS has noted:

The same technological advances that make possible enormous administrative cost savings for the industry as a whole have also made it possible to breach the security and privacy of health information on a scale that was previously inconceivable. The Congress recognized that adequate protection of the security and privacy of health information is a sine qua non of the increased efficiency of information exchange brought about by the electronic revolution, by enacting the security and privacy provisions of the law. n20

n20 Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,474 (Dec. 28, 2000) (to be codified at 45 C.F.R. pts. 160 and 164).

In HIPAA, Congress thus called for the issuance of regulations to protect the privacy and security of personal health information. n21 DHHS issued the proposed Privacy Standards on November 3, 1999. n22 After sorting through approximately 52,000 comments in response to the publication of the proposed rule, n23 DHHS issued the final Privacy Standards on December 28, 2000, with an effective date of February 26, 2001. n24 As expected, the response from the healthcare industry was explosive.

n21 HIPAA 1996, Pub. L. No. 104-191, § 264, 110 Stat. 1936, 2033-34.

n22 Standards for Privacy of Individually Identifiable Health Information, 64 Fed. Reg. 59,918 (proposed Nov. 3, 1999) (to be codified at 45 C.F.R. pts. 160-164).

n23 *See Privacy Standards: Issues in HHS' Proposed Rule on Confidentiality of Personal Health Information*, 106th Cong. 5 (2000) (statement of Janet Heinrich, Associate Director of Health Financing and Public Health Issues, Health, Education, and Human Service Division), at www.gao.gov/new.items/00106t.pdf [hereinafter "April 26, 2000, GAO Report"].

n24 Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,462.

After President Bush took office and appointed Tommy G. Thompson as Secretary of DHHS, the lobbying began in earnest to derail or delay the final Privacy Standards. Interestingly, under the terms of the Congressional Review Act, the effective date of the Privacy Standards was delayed from February 26, 2001, until April 14, 2001, because DHHS did not provide a copy of the rule to Congress until after the rule's publication in the Federal Register on December 28, 2000. n25 Taking advantage of the delay in the regulation's effective date, Secretary Thompson reopened the Privacy Standards for public comment until March 30, 2001. n26

n25 *See* 5 U.S.C. § 801(a)(3)(A) (2001) (The effective date of a major rule is "the later of the date occurring 60 days after the date on which . . . Congress receives the [required] report . . . or . . . [on which] the rule is published in the Federal Register."). *See also* Standards for Privacy of Individually Identifiable Health Information, 66 Fed. Reg. 12,738 (Feb. 28, 2001) (to be codified at 45 C.F.R. pts. 160 and 164).

n26 *See* Standards for Privacy of Individually Identifiable Health Information, 66 Fed. Reg. 12,738.

DHHS this time received over 24,000 comments on the final regulations. n27 Many providers, health plans, and professional associations pressed to delay the Privacy Standards to allow more time for compliance and to coordinate the compliance date of the Privacy Standards with the other Administrative Simplification provisions. Most providers and health plans also pressed for substantive changes in identified problem areas. n28 The privacy advocacy community, on the other hand, urged DHHS not to dilute any patient protections provided by the final rule and not to delay the regulations.

n27 *See* Secretary Tommy G. Thompson, Statement Regarding the Patient Privacy Rule (April 12, 2001), at www.hhs.gov/ocr/hipaa. *See also* comments posted at the Administrative Simplification Web site, at www.aspe.dhhs.gov/admsimp.

n28 *See, e.g.*, American Hospital Association, *Comments* (Nov. 14, 2001), at www.aha.org.

Despite early indications that Secretary Thompson planned to delay the rules for revision, on April 12, 2001, the Secretary announced that the Privacy Standards would go into effect as planned. n29 Healthcare organizations then

began to take a serious look at compliance.

n29 *See* Thompson, *supra* note 27.

Since April of 2001, DHHS has indicated its willingness to adopt a reasonable enforcement posture and to assist the healthcare community with its compliance efforts. On July 6, 2001, the DHHS Office of Civil Rights (OCR), the DHHS section delegated authority to enforce the Privacy Standards, issued a "Guidance" to clarify various aspects of the Privacy Standards and to telegraph the changes it intended to make to the regulations before the end of 2001. n30 In this Guidance, the OCR emphasized that covered entities are not required to guarantee the privacy of PHI; rather, they must make "reasonable" efforts to protect the confidentiality and security of that information. n31 The Guidance provides valuable assistance in determining what efforts the OCR regards as "reasonable."

n30 *See* Office for Civil Rights, *Standards for Privacy of Individually Identifiable Health Information* (July 6, 2001), at www.hhs.gov/ocr/hipaa/index.html [hereinafter Guidance].

n31 *Id.* at 15.

The Guidance also provides useful explanations and examples concerning some of the more confusing aspects of the Privacy Standards, including: consent, the minimum necessary standard, oral communications, business associates, parental access to children's medical records, health-related communications and marketing, research, governmental access to protected health information, and payment. n32 For each of these areas, the OCR includes a brief explanation of the Privacy Standards' requirements (thus providing useful background information for those readers just becoming familiar with the Privacy Standards), followed by answers to frequently asked questions. n33

n32 *See* Guidance, *supra* note 30.

n33 *Id.*

Finally, and perhaps most importantly, the Guidance previews at least some of the modifications to the Privacy Standards the OCR will propose through a Notice of Proposed Rule Making in the *Federal Register*. n34 The OCR will seek to fix some of the more problematic areas of the Privacy Standards, such as the current prohibition against provider use of protected health information for patient treatment without signed consent before a face-to-face meeting. n35 Healthcare organizations have identified a number of areas in which the Privacy Standards will disrupt day-to-day operations and negatively impact patient care, and the OCR's Guidance shows it is listening.

n34 *Id.*

n35 *Id.* at 7-14.

II. An Overview of the Regulatory Requirements

This Article provides a bird's-eye view of the Privacy Standards. It discusses whether a health care organization is a "Covered Entity" under the regulations, what information the Privacy Standards protect, what restrictions the regulations place on the use and disclosure of protected health information, what individual rights the Privacy Standards create, and what agreements they require between healthcare organizations and their business associates. Since the

Privacy Standards' administrative requirements are closely related to necessary compliance steps, those administrative requirements are discussed in connection with the compliance recommendations at the end of the Article.

In as much as the Privacy Standards contain detailed requirements that cannot be properly discussed in an Article of this length, healthcare organizations should consult the text of the regulations and any modifications to the regulations before designing policies and procedures to implement the Privacy Standards. n36

n36 For an in-depth discussion of the Privacy Standards, see AMERICAN HEALTH LAWYERS ASS'N, SPECIAL MEMBER HIPAA BRIEFING COLLECTION, STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION, (Elisabeth Belmont et al. eds. Apr. 2001) (hereinafter AHLA).

A. Is the Organization or Individual a "Covered Entity"?

As an obvious threshold question, a healthcare organization must determine whether it is required to comply with the Privacy Standards. Organizations (and individuals) required to comply with the regulations (Covered Entities) include health plans, n37 healthcare clearinghouses, n38 and healthcare providers n39 that transmit health information electronically in connection with a standard transaction, such as an electronic claim for payment. n40 A provider also will be required to comply if it instructs other entities—such as third-party billing **companies** or healthcare clearinghouses, to submit electronic claims or other standard transactions on its behalf. n41

n37 *See* 45 C.F.R. § 160.103 (2001). The Privacy Standards contain an extensive definition of "health plan," essentially defined as an individual or group plan that provides or pays the cost of medical care. This includes the federal Medicare and state Medicaid programs.

n38 *Id.* A healthcare clearinghouse is an entity that processes information from nonstandard format to standard format (or vice versa) for purposes of conducting a Standard Transaction. This would include many billing services, repricing **companies**, community health management information systems, and value-added networks and switches.

n39 *Id.* Generally, a "provider" is defined as a provider of medical or health services and any other person or organization that furnishes, bills, or is paid for healthcare in the normal course of business. This broad definition includes a wide range of individuals and organizations in the healthcare system, such as hospitals, physicians, nurses, pharmacists, pharmaceutical **companies** (in certain circumstances), individuals who sell durable medical equipment, clinical social workers, nurse midwives, **nursing homes**, assisted living facilities, home health **companies**, dentists, chiropractors, and many others.

n40 *Id.* The Standard Transactions include health claims and equivalent health encounter information, health plan enrollments and disenrollments, health plan eligibility, healthcare payment and remittance advice, health plan premium payments, health claims status, referral certification and authorization, and coordination of benefits. DHHS will publish a separate rule governing claims attachments and first report of injury at a later date.

n41 45 C.F.R. § 160.103 (2001).

If an organization provides or pays for healthcare, but its primary function is *not* as a healthcare provider, health plan, or healthcare clearinghouse, then it is a "hybrid entity" and only the "health care component" of the organization must comply with the Privacy Standards. n42 For instance, if an employer maintains an on-site health clinic, only the health clinic must comply with most provisions of the Privacy Standards. However, the hybrid entity itself still has some limited responsibilities, such as ensuring that its healthcare component does not disclose PHI to another component of the **company**. n43

n42 *Id.* § 164.504(b)-(c).

n43 *Id.* § 164.504(c)(2).

The Privacy Standards contain other categories of organizations that may affect compliance. For instance, **companies** with common control or at least five percent common ownership can designate themselves "Affiliated Entities" to be treated as a single Covered Entity for most purposes. n44 However, if an Affiliated Entity contains any combination of healthcare providers, health plans, and healthcare clearinghouses (i.e., if they have multiple covered functions), each component of the entity must follow the requirements applicable to it. n45 In addition, if a Covered Entity functions as both a care provider and a health plan, the provider may not disclose PHI to the plan unless the patient is also a member of the plan. n46

n44 *Id.* § 160.504(d).

n45 *Id.* § 164.504(g).

n46 *Id.* § 164.504(g)(2).

The final special category of Covered Entity--an "Organized Health Care Arrangement" (OHCA)--may share a consent form and notice of privacy practices. n47 An OHCA includes a clinically integrated care setting in which patients typically receive care from more than one provider (such as in a hospital), an organized system in which Covered Entities hold themselves out as participating in a joint arrangement and conduct joint activities such as quality assessment (as in a joint venture or independent practice association), or various combinations of group health plans and plan sponsors. n48

n47 45 C.F.R. § 164.501 (2001) (defining OHCA).

n48 *Id.* See *id.* § 164.506(f).

B. What Type of Information Is Protected by the Privacy Standards?

The Privacy Standards protect virtually all "individually identifiable health information" handled by a Covered Entity, n49 including information transmitted or maintained electronically, paper records, and oral communications. n50 "Individually identifiable health information" is defined as information that meets all of the following requirements: (1) it is "created or received by a health care provider, health plan, employer, or health care clearinghouse"; (2) it "relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual"; and (3) it either identifies an individual or "there is a reasonable basis to believe the information can be used to identify the individual." n51

n49 *Id.* § 164.501 (defining protected health information).

n50 *Id.*

n51 *Id.*

"Individually identifiable health information" can be "deidentified" (and used without restriction) if a person with appropriate statistical knowledge concludes the risk is very small that the information could be used to identify an

individual. n52 Alternatively, information is de-identified if the "identifiers" listed in the regulations are removed (such as names, geographic designations, dates of service, telephone, fax, addresses, URLs and IP addresses, biometrics, photographs, and other information), as long as the Covered Entity has no knowledge that the information could be used to identify an individual. n53 For instance, even if a patient's name and all other listed identifiers are removed, information could be identifiable if the patient's diagnosis and provider could lead to identifying that individual in a small community. Organizations also can "de-identify" information by removing, coding, encrypting, or concealing specified information that would lead to identifying an individual, as long as they do not reveal the code. n54

n52 45 C.F.R. § 164.514(a)-(c) (2001).

n53 *Id.*

n54 *Id.*

The inclusion of oral communications as PHI in the final Privacy Standards spurred a great deal of criticism, in part because the Standards' application to conversations about healthcare pose real problems. Clearly, healthcare organizations have a duty to keep a patient's health information confidential. But how does the minimum necessary standard apply to oral communications? Is prior consent required for a provider merely to discuss a patient's care with that patient? In its July 6, 2001, Guidance the OCR sought to clarify many of the questions surrounding its inclusion of oral communications in the final rule.

First, the OCR clarifies that it will adopt a reasonable enforcement posture in applying the Standards to oral communications. n55 While providers must "reasonably safeguard" PHI during oral communications, the OCR states that it does not expect covered entities "to guarantee the privacy of PHI from any and all potential risks. . . . The Privacy Rule is not intended to prohibit providers from talking to each other and to their patients Providers' primary consideration is the appropriate treatment of their patients." n56 "Overheard communications are unavoidable." n57

n55 *See* Guidance, *supra* note 30, at 22-23.

n56 *Id.*

n57 *Id.*

Examples of "reasonable safeguards" include speaking quietly when discussing a patient's condition and avoiding patients' names in public hallways. n58 In addition, the OCR explains that: (1) the Privacy Standards do not prevent healthcare staff from orally coordinating services at hospital nursing stations; (2) healthcare professionals may discuss a patient's condition over the phone and may discuss lab test results with a patient or other provider in a joint treatment area; (3) healthcare professionals may discuss a patient's condition during training rounds; and (4) providers may call out patient names in waiting rooms. n59

n58 *Id.* at 23.

n59 *Id.* at 23-24.

Very significantly, the OCR explains that the Privacy Standards will not require structural changes to facilities to protect the confidentiality of oral communications. n60 Providers do not need to soundproof patient rooms, provide

private rooms, encrypt wireless or emergency medical radio communications, or encrypt telephone calls. n61 However, the OCR may expect providers to add curtains, screens, cubicles, dividers, shields, or similar barriers where multiple patient-staff communications routinely occur, depending on the size and resources of the provider. n62

n60 Guidance, *supra* note 30, at 24.

n61 *Id.*

n62 *Id.* at 24-25.

The OCR also clarifies how the individual rights requirements apply to oral communications, explaining that the regulations do not require a provider to allow access to the provider's oral communications, since those communications are not part of the "designated record set" that patients may access and copy. n63 However, if an oral disclosure is made for purposes other than treatment, payment, or healthcare operations, the provider must document that oral disclosure to provide an accounting if requested by the patient. n64

n63 *Id.* at 25.

n64 *Id.*

Finally, the OCR states that it will propose modifications to "increase the confidence of covered entities that they are free to engage in whatever communications are required for quick, effective, high quality healthcare, including routine oral communications with family members, treatment discussions with staff involved in coordination of patient care, and using patient names to locate them in waiting areas." n65 The OCR did not specify what changes to expect.

n65 Guidance, *supra* note 30, at 5.

C. What Uses and Disclosures of Protected Health Information Are Required and Permitted by the Privacy Standards?

The Privacy Standards comprehensively regulate the internal use and external disclosure of PHI, creating complicated rules for when patient consent or authorization is required for use and disclosure. n66 The Privacy Standards divide use and disclosure into five categories, based on whether and what type of patient permission is required to use or disclose the information. These include: (1) required disclosures; (2) uses and disclosures for which patient "authorization" is required; (3) uses and disclosures for which patient "consent" is required for treatment, payment, and healthcare operations; (4) uses and disclosures for which the patient must be given an opportunity to object or agree; and (5) uses and disclosures for which no consent, authorization, or opportunity to object is required. n67 In general, the Privacy Standards make the use and disclosure of PHI relatively easy for healthcare purposes, but erect substantial barriers to the use and disclosure of PHI for purposes other than healthcare.

n66 See Standards for Privacy of Individually Identifiable Health Information, 64 Fed. Reg. 82, 462 (Dec. 28, 2000) (to be codified at 45 C.F.R. pts. 160 and 164).

n67 45 C.F.R. §§ 164.502-.512 (2001).

1. Required Disclosures

The Privacy Standards *require* only two types of disclosures: disclosure to the Secretary of DHHS to investigate compliance with the Privacy Standards, and disclosure to an individual of his own PHI. n68

n68 *Id.* § 164.502(a)(2) (2001). *See id.* §§ 164.524, .528.

2. Uses and Disclosures for Which Patient "Authorization" Is Required

The Privacy Standards require "authorization" for use or disclosure of information in two situations: when the use or disclosure is not explicitly required or permitted by the Privacy Standards, and for most uses and disclosures of "psychotherapy notes." n69

n69 *Id.* § 164.508(a).

First, patient authorization is the "back stop" of the Privacy Standards. If the regulations do not explicitly require or permit a certain use or disclosure of PHI, then a Covered Entity must obtain patient authorization. n70 For example, an organization may not sell or rent patient information without obtaining the patient's authorization, because no provision of the Privacy Standards explicitly allows Covered Entities to use or disclose PHI for these purposes without authorization. In addition, organizations generally may not use PHI in fundraising and marketing without patient authorization, unless those activities meet specific regulatory requirements and the organization provides its patients or members with the opportunity to "opt-out" of future solicitations. n71

n70 *Id.* § 164.508.

n71 *Id.* § 164.514(e)-(f).

Second, a provider generally must obtain patient authorization to use or disclose psychotherapy notes (mental health counseling records), except in very limited circumstances. n72 Psychotherapy notes are the only type of patient information that enjoy a higher level of protection under the rules. The possibility of more rigorous protection of information concerning AIDS, HIV, and other communicable diseases, genetic testing, or controlled substance or alcohol abuse are left to the province of state law or other federal laws and regulations.

n72 *Id.* § 164.508(a).

The patient authorization requirements are designed to make it difficult to obtain patient authorization and thus difficult to use or disclose information for the purposes for which authorization must be obtained. First, providers and health plans generally may *not* condition treatment, payment, or enrollment on the individual's authorization to use or disclose information. n73 A valid authorization also requires a detailed explanation of the proposed use or disclosure, a set expiration date or event, and a variety of items that vary according to whether the individual or the Covered Entity requests the use or disclosure, or whether it is created for research purposes. n74 In short, the rigors of collecting a valid patient authorization will deter many of these uses and disclosures.

n73 45 C.F.R. § 164.508(b)(4).

n74 *Id.* § 164.508(c).

3. Uses and Disclosures for Which Patient "Consent" Is Required: Treatment, Payment, and Healthcare Operations

Under the Privacy Standards, direct treatment providers n75 may use or disclose a patient's PHI to treat that patient, to obtain payment for that treatment, or to carry out "health care operations," n76 but only if they first obtain patient "consent" n77 that complies with specific regulatory requirements. n78 Indirect treatment providers, which provide healthcare to the patient based on the orders of another provider and typically report the diagnosis or results to the other provider (such as a clinical laboratory or radiologist), do not require consent. n79

n75 *See id.* § 164.501 (providing definitions). "Direct treatment" providers are defined as those providers who are not "indirect treatment" providers. "Indirect treatment" providers are those who provide care to a patient based on the orders of another provider and who typically provide the services or report the diagnosis or results to the other provider.

n76 *Id.* "Health care operations" consist of a wide range of day-to-day activities, such as quality assessment and improvement, case management and care coordination, review of the competence or qualifications of healthcare professionals and practitioners, conduct of training programs, accreditation, certification, licensing, credentialing, underwriting and premium rating, obtaining legal services, auditing, business planning, and other administrative activities. Any questions as to whether a particular activity falls within this category should be resolved by consulting the actual definition found in the regulations.

n77 *Id.* § 164.506.

n78 *Id.* § 164.506(c).

n79 45 C.F.R. § 164.506. *See id.* § 164.501 (defining "indirect treatment relationship").

However, direct treatment providers need not obtain consent in four situations: (1) where the information is used or disclosed for emergency treatment, so long as the provider attempts to obtain consent as soon as possible after the resolution of the emergency; n80 (2) where the provider is required by law to treat the individual, attempts to obtain consent, but is unable to do so; n81 (3) where the provider is unable to obtain consent due to substantial communication barriers and concludes that the consent to receive treatment can be inferred from the circumstances; n82 or (4) where the provider created or received the information in the course of treating an inmate. n83 In most of these situations, the provider must document its attempt to obtain consent and the reason why consent was not obtained. n84

n80 *See* Guidance, *supra* note 30, at 10. In evaluating whether an "emergency treatment situation" exists, the provider "must . . . exercise professional judgment to determine whether obtaining a consent would interfere with the timely delivery of necessary health care." A provider must obtain consent before providing care if it can be done "without compromising the patient's care." *Id.* Hospitals thus should consider integrating this consent process with other documentation collected in the emergency department to ensure that consent is obtained at an appropriate time. *See* 45 C.F.R. § 164.506(a)(3)(i)(A).

n81 45 C.F.R. § 164.506(a)(3)(i)(B).

n82 *Id.* § 164.506(a)(3)(i)(C).

n83 *Id.* § 164.506(a)(2)(ii).

n84 *Id.* § 164.506(a)(3)(ii).

Interestingly, health plans and healthcare clearinghouses may use health information for treatment, payment, or healthcare operations *without* patient consent. n85 While the Preamble to the rule does not discuss the reasons for this distinction, it presumably is because health plans and healthcare clearinghouses have less direct contact with the patient and thus will have a more difficult time obtaining consent. Of course, if a health plan or healthcare clearinghouse chooses to seek an individual's consent to use or disclose PHI, it may do so; however, it then is required to comply with the terms and conditions of that consent. n86

n85 *Id.* § 164.506(a)(2-3). See Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,510 (Dec. 28, 2000) (to be codified at 45 C.F.R. pts. 160 and 164).

n86 45 C.F.R. § 164.506(a)(4).

Patient "consent" and "authorization" differ substantially and are not terms that are used interchangeably, as is often the case under state law. Significantly, a Covered Entity is allowed to condition treatment and enrollment on a patient's consent to use or disclose his information for treatment, payment, or healthcare operations. n87 Providers thus will be able to obtain patient consent in Conditions of Admission (COA) forms, although the consent must be visually and organizationally separate and must be separately signed and dated. n88 However, providers may not combine the consent with their notice of privacy practices. n89

n87 *Id.* § 164.506(b).

n88 *Id.*

n89 *Id.* § 164.506(b)(3).

The OCR's Guidance previewed important changes to the consent requirements that DHHS plans to soon make in modifications to the Privacy Standards. n90 First, as presently written, the Privacy Standards prohibit a provider with a direct treatment relationship from using PHI for treatment without a signed patient consent. n91 The Privacy Standards thus do not permit pharmacists to fill prescriptions phoned in by a patient's physician before obtaining the patient's written consent. n92 The OCR states that it "did not intend the rule to interfere with a pharmacist's normal activities" and that it will propose changes to the regulations to allow these practices to continue. n93

n90 See Guidance, *supra* note 30.

n91 45 C.F.R. § 164.506(c). See *id.* § 164.501 (defining "direct treatment relationship").

n92 See Guidance, *supra* note 30, at 9.

n93 *Id.* at 5, 9.

In addition, under the Privacy Standards direct treatment providers cannot use PHI to schedule appointments or procedures without first obtaining a patient's signed consent. n94 The OCR stated that it will change the regulations to allow these practices, although it did not elaborate on what the precise changes will be. n95 The OCR did not address the Privacy Standards' prohibition against using PHI without patient consent to facilitate hospital admissions; however, it did indicate that its proposed modifications will have broader application. n96 The Guidance states that "this

unintended problem potentially exists in any circumstance when a patient's first contact with a direct treatment provider is not in person The Secretary is aware of this problem and will propose modifications to fix it." n97

n94 45 C.F.R. § 164.506.

n95 Guidance, *supra* note 30, at 5, 9.

n96 *Id.* at 5.

n97 *Id.* at 9.

4. Uses and Disclosures for Which Advance Notice and Opportunity to Object Is Required

In two limited circumstances, the regulations allow a Covered Entity to use and disclose information without patient consent or authorization, as long as the organization gives the patient advance notice of the use or disclosure and the opportunity to object, or "opt-out" of the use or disclosure. For both purposes, the organization may inform the patient orally of this use or disclosure and obtain the patient's oral agreement, if required. n98

n98 45 C.F.R. § 164.510 (2001).

First, providers may include a patient's name, location in the facility, condition in general terms (as long as it does not communicate specific medical information), and religious affiliation in facility directories. n99 Providers may disclose this information to anyone who asks for the individual by name, except that religious affiliation may be disclosed only to clergy members. n100 Providers must inform patients in advance of the types of information they will include in a facility directory and must give the patient an opportunity to object to including this information in the directory. n101 As long as the Covered Entity gives the patient an opportunity to object, the Covered Entity need not obtain explicit agreement from the patient. n102

n99 *Id.* § 164.510(a)(1)(i)(A-D).

n100 *Id.* § 164.510(a)(1)(ii).

n101 *Id.* § 164.510(a)(2).

n102 *Id.* § 164.510(b)(2)(ii).

Second, any Covered Entity may disclose PHI to family members and others involved in a person's care, if that information is directly relevant to the patient's care or payment for that care, or the Covered Entity is notifying the family member or friends of the patient's location and condition. n103 Different rules apply when the patient is present and able to consent and when the patient is not present or is incapable of consenting. n104

n103 45 C.F.R. § 164.510(b)(1).

n104 *Id.* § 164.510(b)(2).

5. Uses and Disclosures for Which Patient Consent, Authorization, or Opportunity to Object Is Not Required

Finally, DHHS recognized that access to and exchange of PHI is essential for a variety of public purposes that could be compromised by patients control of their health information. n105 Patient consent, authorization, or opportunity to object thus is not required where the disclosure by the Covered Entity is:

- . Required by law;
- . For certain public health activities;
- . About victims of abuse, neglect or domestic violence;
- . For health oversight activities;
- . For judicial and administrative proceedings;
- . For certain law enforcement purposes;
- . To coroners, medical examiners and funeral directors about deceased persons;
- . For cadaveric organ, eye or tissue donation purposes;
- . For research, when approved by an Institutional Review Board or privacy board or for certain other limited purposes;
- . To avert a serious threat to health or safety;
- . For specialized government functions, such as military and veterans activities, national security and intelligence, protective services for the President, correctional institutional custodial situations, or government programs providing public benefits; and
- . For workers' compensation. n106

n105 Standards for Privacy of Individually Identifiable Health Information, 64 Fed. Reg. 59,918, 59,925 (proposed Nov. 3, 1999) (to be codified at 45 C.F.R. pts. 160-164).

n106 45 C.F.R. § 164.512(a)-(l) (2001).

The Privacy Standards contain many detailed requirements for each of these uses and disclosures. n107 However, a discussion of those requirements is beyond the scope of this Article.

n107 See AHILA, *supra* note 36.

Also, it is important to note that disclosures under this section are not *required*, they are *permitted*. n108 A Covered Entity may be approached by any number of government officials, who may argue that they are entitled to access to PHI from the Covered Entity if they meet the specific requirements of the sections noted above. However, where government officials meet the requirements for these uses or disclosures, the Covered Entity merely is permitted to provide this information to the government officials without violating the Privacy Standards. If state law or a Covered Entity's internal policies and procedures prohibit the organization from releasing the information, it is not required to do

so.

n108 45 C.F.R. § 164.502(a)(1) (2001).

6. Uses and Disclosures for Group Health Plans

Finally, the Privacy Standards contain requirements particular to group health plans, which are designed to limit the information flowing to the plan sponsor (the employer). n109 These restrictions, such as requiring "firewalls" for PHI handled by employees who work for both the employer and the group health plan, will pose substantial challenges for self-administered group health plans.

n109 *Id.* §§ 164.504(f), .530(k) (2001).

7. The Minimum Necessary Standard

When Covered Entities use or disclose PHI, or request PHI from another Covered Entity, they must make reasonable efforts to limit the information to the "minimum necessary to accomplish the intended purpose of the use, disclosure, or request." n110 For routine disclosures of information, an organization may establish a protocol to determine what is minimally necessary for the purpose. n111 For all nonroutine disclosures, however, the organization must make an individual determination about whether each proposed disclosure is the minimum necessary information. n112 For internal uses of information, the organization must determine which persons or classes of persons in its workforce need access to PHI and the categories of information to which they need access, and must make reasonable efforts to limit that access. n113 Internal use does not require an individual "minimum necessary" determination in every circumstance.

n110 *Id.* §§ 164.502(b), .514(d). *But see id.* § 164.502(b) (describing exceptions to the minimum necessary standard, including disclosures: (a) to a healthcare provider for treatment; (b) to the individual of her own information; (c) pursuant to an authorization requested by the individual; (d) to the Secretary of DHHS to investigate compliance; (e) as required by law; and (f) as required for compliance with the Privacy Standards).

n111 45 C.F.R. § 164.514(d).

n112 *Id.*

n113 *Id.*

In its Guidance, the OCR went to considerable lengths to diffuse much of the anxiety surrounding this rule. First, the Guidance emphasizes that only "reasonable" efforts are required and that Covered Entities only will be required to implement best practices common in the industry. n114 Thus, "covered entities need not limit information uses and disclosures to those that are absolutely needed to serve the purpose. Rather, this is a reasonableness standard that calls for an approach consistent with the best practices and guidelines already used by many providers today to limit the unnecessary sharing of medical information." n115 Clearly, however, the OCR *will* require that a healthcare organization put thought into its information-sharing procedures:

The minimum necessary standard is intended to make covered entities evaluate their practices and enhance protections as needed to prevent unnecessary or inappropriate access to PHI. It is intended to reflect and be consistent with, not override, professional judgment and standards. Therefore, we expect

that covered entities will utilize the input of prudent professionals involved in health care activities when developing policies and procedures that appropriately will limit access to personal health information without sacrificing the quality of health care. n116

n114 Guidance, *supra* note 30, at 17.

n115 *Id.*

n116 *Id.*

The OCR also emphasizes that the minimum necessary standard will not prevent the use of the entire medical record in many circumstances. n117 The Guidance does make clear, however, that a Covered Entity must have policies and procedures specifying the persons or classes of persons in the workforce who need access to the entire medical record. n118 Covered Entities also may disclose an entire record to outside parties when the entire medical record is necessary. n119 Additionally, routine disclosures can be handled through policies and procedures, while non-routine requests must be examined individually, utilizing criteria to assist in determining when to produce the entire medical record. n120

n117 *Id.* at 19.

n118 *Id.* at 17, 19.

n119 Guidance, *supra* note 30, at 19.

n120 *Id.*

Significantly, the OCR clarifies that Covered Entities will not be required to redesign facilities (such as soundproofing rooms or erecting walls to create private rooms), restructure existing workflow systems, or upgrade computer systems to comply with the minimum necessary requirements. n121 The regulations also will not prohibit Covered Entities from maintaining patient medical charts at bedside, require them to shred empty prescription vials, totally isolate X-ray light boards, or abolish sign-in sheets. n122 Rather, organizations will be required to take "reasonable" measures to limit unauthorized access to PHI:

Covered entities may need to make certain adjustments to their facilities to minimize access [to PHI], such as isolating and locking file cabinets or records rooms, or providing additional security, such as passwords, on computers maintaining personal information.

Covered entities should also take into account their ability to configure their record systems to allow access to only certain fields, and the practicality of organizing systems to allow this capacity. For example, it may not be reasonable for a small, solo practitioner who has largely a paper-based records system to limit access of employees with certain functions to only limited fields in a patient record, while other employees have access to the complete record. Alternatively, a hospital with an electronic patient record system may reasonably implement such controls, and therefore, may choose to limit access in this manner to comply with the rule. n123

n121 *Id.* at 19-20.

n122 *Id.* at 20.

n123 *Id.*

Most importantly, perhaps, the OCR recognizes that the minimum necessary standard remains ambiguous and will issue proposed modifications "to increase covered entities' confidence that these [common] practices are not prohibited." n124

n124 *Id.*

D. Individual Rights

The Privacy Standards also create a number of individual patient rights, some of which are relatively new, and some of which reflect present requirements in most states. Individuals have the right to complain to DHHS about violations of the Privacy Standards. n125 It is likely that patients will be focused on enforcement of their rights, as described in this section. Covered Entities thus should pay careful attention to these individual rights.

n125 45 C.F.R. § 164.520 (2001).

1. Right to Access and Copy Information

Patients will have the right to access and copy their own PHI maintained in "designated record sets." n126 A designated record set includes medical records and billing records maintained by a provider; enrollment, payment, claims adjudication, and case or medical management records systems maintained by a health plan; or records that are used by any Covered Entity to make decisions about an individual. n127 Thus, individuals are not entitled to information contained in peer review or quality assurance files.

n126 *Id.* § 164.524.

n127 *Id.* § 164.501.

A few types of information are exempt from inspection and copying, including psychotherapy notes, information compiled in anticipation of legal proceedings, and information that may not be disclosed directly to individuals under the Clinical Laboratory Improvements Amendments (where lab results must be reported to providers). n128 Moreover, the regulations provide other limited circumstances in which an organization may deny access to an individual, such as where provision of that information would pose a danger to the patient or to others. n129 A Covered Entity usually must respond to an individual's request for access within thirty days, and must provide a process for the individual to challenge most denials of access. n130

n128 *Id.* § 164.524.

n129 *Id.*

n130 *Id.*

2. Right to Amend Information

Individuals also will have the right to amend erroneous or incomplete PHI, unless the information was not created by the Covered Entity, is not in a "designated record set," is accurate and complete, or would not be available for inspection under the previous section. n131 An organization must respond within sixty days by granting or denying the request, and must follow the procedures set forth in the regulations. n132 If the Covered Entity denies the request, an individual may file a statement of disagreement (and the Covered Entity a rebuttal statement), all of which must be included in the patient's record. n133 If the Covered Entity grants the request to amend, it must make the correction in all affected records, inform its business associates and others regarding the correction, and inform the individual. n134 Covered Entities should follow the medical practice model for amending medical records, in order to retain the integrity of the original entry but append the correction. n135

n131 45 C.F.R. § 164.526 (2001).

n132 *Id.*

n133 *Id.*

n134 *Id.*

n135 AHILA, *supra* note 36, at 2-73.

Amendment of health information may carry serious risk management implications, particularly for medical malpractice actions. Covered Entities thus should involve risk management personnel or legal counsel in the consideration of most amendment requests.

3. Right to Obtain Accounting of Certain Disclosures

Individuals also will have the right to obtain an "accounting" of certain disclosures of their PHI made within six years before the request, starting from the compliance date (April 14, 2003, for most Covered Entities). n136 This accounting must include disclosures made both by the Covered Entity and its business associates. n137 The organization must respond within sixty days of the request, and must include the date, recipient's name and address, description of the information disclosed, and the purpose of the disclosure. n138

n136 45 C.F.R. § 164.528 (2001).

n137 *Id.*

n138 *Id.*

Disclosures exempt from the accounting requirement include those: (1) to carry out treatment, payment, or healthcare operations; (2) to individuals or their personal representatives; (3) for the facility's directory; (4) to family members and others involved in the individual's care; (5) for national security or intelligence purposes; and (6) to correctional institutions and other law enforcement agencies under the custodial exception. n139 Most day-to-day disclosures of PHI by healthcare organizations thus will not be included in the accounting.

n139 *Id.*

4. Right to Request Restriction of Use or Disclosure

Individuals have the right to request restrictions on how Covered Entities will use or disclose their PHI for treatment, payment or healthcare operations, and how their information will be disclosed to family members or others involved in their care. n140 A Covered Entity is not required to agree to such a restriction; however, if the Covered Entity agrees, it must comply with that agreement unless the information is required for an emergency, n141 or is requested for law enforcement, n142 judicial and administrative proceedings, n143 or research. n144

n140 *Id.* § 164.522(a).

n141 *Id.* § 164.522(a)(1)(iii).

n142 45 C.F.R. § 164.512(f) (2001).

n143 *Id.* § 164.512(e).

n144 *Id.* § 164.512(l).

5. Right to Receive Confidential Communications

A healthcare provider must accommodate reasonable requests by individuals to receive communications of PHI by alternative means or at alternative locations. n145 For instance, a patient may request that her doctor not send sensitive medical information to her home, so that a family member cannot become aware of that information. A health plan, on the other hand, is not required to accommodate such a request unless the individual states that routine forms of communication could endanger the individual. n146

n145 *Id.* § 164.522(b).

n146 *Id.*

6. Right to Receive Notice of Privacy Practices

An individual also has the right to receive notice of a Covered Entity's privacy practices that describes its uses and disclosures of PHI, the individual's rights under the Privacy Standards, and the organization's legal duties regarding PHI. n147 The notice also must inform individuals of their right to complain to the Covered Entity or the DHHS Secretary if they believe their privacy rights have been violated, and must contain the name and number of a person at the Covered Entity to contact for more information. n148 If the Covered Entity wants to undertake various optional activities, such as the use of PHI for fundraising or marketing, the notice also must contain an explanation of those activities. n149

n147 45 C.F.R. § 164.520 (2001).

n148 *Id.*

n149 *Id.*

The required notice must be in plain language and contain specific elements prescribed by the regulations. n150 This notice must be drafted carefully: An organization may use or disclose information only in compliance with its notice, even if the notice is more restrictive than the regulations. n151 Moreover, if an organization wants to change the privacy practices described by its notice, it must first publish a revised notice. n152 Finally, if an organization does not reserve the right to change its practices in its privacy notice, any change in practices would apply only to PHI received *after* publication of the new notice. n153 This result, however, would be unworkable.

n150 *Id.* For a good discussion of the required elements of the notice, see AHLA, *supra* note 36, at 2-64 to 2-68.

n151 45 C.F.R. § 164.520 (2001).

n152 *Id.*

n153 *Id.*

Finally, the rule specifies that a provider must provide its notice to patients upon request, at first service, and on its Web site (if it maintains one). n154 A health plan, on the other hand, must provide a copy to each of its members by the compliance date, at enrollment, any time it materially revises its notice, and every three years. n155

n154 *Id.*

n155 *Id.*

7. Right to Complain of Privacy Violations

Finally, an individual has the right to complain if her privacy rights have been violated. Covered Entities must have an internal complaint process. n156 In addition, an individual may complain to the DHHS Secretary through the Office of Civil Rights (OCR). n157 A Covered Entity may not require individuals to waive this right as a condition for providing treatment, payment, enrollment, or determining eligibility, n158 and cannot retaliate against any individual who lodges a complaint with the Secretary. n159

n156 45 C.F.R. § 164.530(d) (2001).

n157 *Id.* § 160.306.

n158 *Id.* § 164.530(h).

n159 *Id.* § 164.530(g).

E. Business Associates

1. Who is a business associate?

Simply put, a business associate is a person or **company** who performs an activity or service for a Covered Entity that involves the use or disclosure of individually identifiable health information or any other function regulated by the Privacy Standards. n160 Examples of business associates are firms that conduct claims processing or administration; data analysis; processing or administration; utilization review; quality assurance; billing; benefit management; practice management; repricing; or legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services. n161

n160 *Id.* § 160.103.

n161 *Id.*

Members of the organization's workforce are not business associates. n162 In addition, Covered Entities participating in "organized health care arrangements" (such as clinically integrated care settings) are not business associates of each other simply because they provide services to the arrangement. n163 The Preamble to the Privacy Standards clarifies that healthcare providers and healthcare plans are *not* business associates of each other, because healthcare plans do not perform an activity on behalf of the provider. n164

n162 45 C.F.R. § 164.160.103 (2001).

n163 *Id.*

n164 *See* Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,476 (Dec. 28, 2000) (to be codified at 45 C.F.R. pts. 160 and 164) (neither health plan nor provider "is providing functions or activities on behalf of the other"). However, if a hospital provides billing or other services for physicians with staff privileges, the hospital and physician may be business associates for that purpose.

In identifying which organizations or individuals are "business associates," keep in mind that a Covered Entity may have a business associate relationship with an organization or individual for some purposes but not others. For instance, a medical staff member is not a business associate of the hospital simply because the physician holds privileges at that hospital and provides services to the hospital patients; however, the hospital may be a business associate of the medical staff member if the hospital provides a service (such as billing) to the medical staff member. n165

n165 *See id.* at 82,476.

2. Disclosures to Business Associates--the Business Associate Contract Requirement

Covered Entities may disclose PHI to business associates only when the use or disclosure is permitted by the Privacy Standards. n166 However, in order to disclose PHI to its business associates, Covered Entities must have written contracts or agreements with them (business associate contracts) to ensure that each associate protects the PHI. n167 Covered Entities do not require contracts with their business associates in a few circumstances: (1) where an organization discloses information to a healthcare provider concerning treatment; (2) by a group health plan to a plan sponsor under certain circumstances; and (3) to a government agency determining eligibility for a health plan, if it is not the same agency that is administering the plan. n168

n166 45 C.F.R. § 164.502(e) (2001).

n167 *Id.*

n168 *Id.*

A business associate contract must contain provisions that establish the permitted and required uses and disclosures for PHI. n169 Business associate contracts also must provide, among other things, that the business associate may not use or disclose the information other than as permitted by the contract or as required by law, must use appropriate safeguards to prevent the use or disclosure of the information, must ensure its agents and subcontractors comply with the same restrictions, must report any violations to the Covered Entity, must make PHI and an accounting available to individuals, and must make its practices and records available for inspection by the Secretary of DHHS. n170 Significantly, at the termination of the contract, the business associate must return or destroy all protected health information, if feasible. n171 In short, the Privacy Standards contain numerous requirements for drafting business associate contracts, some of which business associates may resist as invasive.

n169 45 C.F.R. § 164.504(e) (2001).

n170 *Id.*

n171 *Id.*

3. Liability for Business Associate Violations

A Covered Entity may be held liable for its business associate's violation of the Privacy Standards, but only if the Covered Entity knows of a pattern of activity that constituted a material breach of the business associate's contractual obligations, and the Covered Entity fails to take reasonable steps to cure the violation, terminate the contract, or report the breach to the Secretary of DHHS. n172

n172 *Id.*

F. Enforcement

Given the expense of complying with the Privacy Standards, a Covered Entity may be tempted to delay or avoid compliance. What will motivate a provider, health plan, or clearinghouse to comply with the Privacy Standards? First, stringent patient privacy protection is good business and may help an organization avoid common law suits in state courts for violation of privacy rights. Even absent HIPAA, providers and health plans should be moving toward better security and confidentiality of the health information patients entrust to them. People are becoming more savvy about privacy issues, partly due to their increased sensitivity to Internet privacy and the notices of privacy practices many individuals receive from the financial institutional with whom they do business. Individuals already are asking their healthcare providers and plans how *they* are **protecting** individual health information.

Equally as important, however, HIPAA violations can result in both civil and criminal penalties. n173 While DHHS intends to issue a separate regulation on enforcement in the future, the statute and the existing regulations provide some guidance to the enforcement mechanism.

n173 Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, § 1177(b), 110 Stat. 1936, 2029.

The Secretary of DHHS designated its OCR to implement and enforce the Privacy Standards. While DHHS has not

yet issued regulations governing enforcement, the OCR regulations governing complaints may provide guidance. The OCR tends to be more cooperative in enforcing the laws under its jurisdiction than do the Centers for Medicare and Medicaid Services or the Office of Inspector General. Covered Entities thus can expect a focus on education and technical assistance, and a resort to imposition of penalties only when problems cannot be resolved informally or when a healthcare organization has not made good faith efforts to comply with the Privacy Standards.

In fact, the Privacy Standards themselves state that the Secretary will seek the cooperation of a Covered Entity in complying with the Privacy Standards, and may provide technical assistance to help organizations comply voluntarily with the Standards. n174 In exchange, Covered Entities must cooperate with complaint investigations and compliance reviews. n175 Moreover, Covered Entities may not "intimidate, threaten, coerce, discriminate against, or take other retaliatory action against" an individual for exercising her rights under the Privacy Standards or against any person who files a complaint with the Secretary of DHHS, who participates in an investigation, or who opposes any unlawful practice. n176

n174 45 C.F.R. § 160.304 (2001).

n175 *Id.* § 160.310(b).

n176 *Id.* § 164.530(g).

The OCR can discover and investigate violations of the Privacy Standards in two ways. First, any person (not just a patient) who believes an organization is not complying with the Privacy Standards may file a written complaint with the Secretary of DHHS within 180 days of when the person knew or should have known of the violation. n177 The Secretary then may investigate the complaint by reviewing an organization's policies, procedures, or practices and the circumstances regarding the alleged violation. n178

n177 *Id.* § 160.306.

n178 *Id.*

Second, the OCR can conduct a compliance review. The regulations require an organization to keep records and produce compliance reports as required by the Secretary, although the content and timing of such compliance reports have not yet been established. n179 An organization must cooperate with periodic compliance reviews, and must permit access by the Secretary during normal business hours to its facilities, books, records, accounts, and other sources of information. n180 If access to information is controlled by another entity that refuses to produce the information, an organization must certify its efforts to obtain the information. n181 DHHS may conduct compliance reviews at its discretion; n182 it generally has access during normal working hours with notice, unless it has reason to believe that information may be destroyed.

n179 45 C.F.R. § 160.310 (2001).

n180 *Id.*

n181 *Id.*

n182 *Id.* § 160.308.

If a complaint investigation or compliance review reveals a violation, the Secretary will inform the organization, and the individual making the complaint, and attempt to resolve the matter informally. n183 The Privacy Standards are unclear whether such "informal" resolutions are in the nature of a financial settlement or whether the Secretary will take a more benign approach, particularly in the initial years of enforcement. If the dispute cannot be resolved informally, the Secretary may issue written findings documenting noncompliance and may initiate civil or criminal action. n184

n183 *Id.* § 160.312.

n184 *Id.*

HIPAA provides civil penalties of \$ 100 per violation up to \$ 25,000 per year for all violations of an "identical" requirement or prohibition. n185 While this may add up quickly, the statute thankfully contains substantial defenses to the imposition of civil penalties. First, DHHS cannot impose a civil penalty if the act or omission is criminally punishable (which is scant comfort to those prosecuted). n186 More importantly, DHHS cannot impose a civil penalty if the person can prove to DHHS' satisfaction that she did not know and could not have reasonably known that she violated the Privacy Standards, n187 or if the failure was, due to reasonable cause, was not a result of willful neglect, or if the failure to comply is corrected within thirty days of the date the organization knew or should have known of the violation. n188 Moreover, the Secretary may extend this thirty-day time period to provide technical assistance and may waive penalties that would be disproportionate to the violation. n189

n185 Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, § 1176(a)(1), 110 Stat. 1936, 2028.

n186 *Id.* § 1176(b)(1).

n187 *Id.* § 1176(b)(2).

n188 *Id.* § 1176(b)(3)(A).

n189 *Id.* § 1176(b)(3)(B).

HIPAA also provides for referral for criminal charges against a person who improperly and knowingly obtains or discloses individually identifiable health information. n190 Penalties are graduated into three levels of severity: (1) for "basic" offenses, a maximum fine of \$ 50,000 and up to one year in prison; (2) for offenses committed under false pretenses, a maximum fine of \$ 100,000 and up to five years in prison; and (3) for offenses committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, a maximum fine of \$ 250,000 and up to ten years prison. n191

n190 HIPAA § 1177(a).

n191 *Id.* § 1177(b).

Finally, HIPAA does not authorize a private cause of action. Moreover, the provision in the *proposed* regulations that required business partner contracts to make patients third-party beneficiaries is *not* found in the final Privacy Standards. Thus, no *federal* cause of action exists for violation of patient's privacy rights. However, private litigants

may attempt to bring claims for violation of privacy rights, "reliance" claims based on violation of the organization's notice of privacy practices, or claims under state consumer protection statutes.

III. Tackling Compliance

The Privacy Standards are extremely complicated and detailed regulations. Where should an organization's compliance efforts begin? The following steps should be appropriate for a large variety of organizations.

A. Set up a HIPAA Compliance Task Force Within the Organization

As shown above, the Privacy Regulations will impact almost every aspect of a healthcare organization's operations. An organization's HIPAA compliance task force thus should have cross-departmental representation (if the organization is a large one), including personnel from compliance, information technology, health information management, billing, admissions, medical and clinical departments, risk management, human resources, research, and legal departments. In addition, a health system should include each of its components in its compliance efforts, including its hospitals, clinics, physician practices, nursing facilities, home health agencies, assisted living, health plans, and any employee benefit plans. The organization should *not* treat HIPAA compliance as just a technology issue.

B. Hire or Designate a Privacy Official

Organizations must designate a "privacy official" responsible for the development and implementation of the privacy policies and procedures. n192 Not every organization will need a new full-time employee for this purpose; small providers may wish to delegate these responsibilities to an existing employee.

n192 45 C.F.R. § 164.530(a) (2001).

While the privacy official's only required duty under the Privacy Standards is to develop the organization's policies and procedures to protect health information, organizations should consider giving her additional duties. These might include chairing the organization's HIPAA task force, conducting employee education about HIPAA, undertaking privacy audits and other compliance monitoring, and functioning as a patient and government liaison. Cross-departmental authority and direct reporting to high-level administration are essential for the privacy official's successful implementation of the organization's HIPAA compliance. Many organizations, such as the American Health Information Management Association, have produced sample job descriptions for the privacy official. n193

n193 See, e.g., American Health Information Management Association, at www.ahima.org.

C. Educate Key Players About the Privacy Standards

Organizations should begin with the individuals on the HIPAA compliance task force, but expand to educate key management and clinical personnel. Also, the organization should educate its Board members, who have a fiduciary responsibility to ensure that the organization is HIPAA-compliant by the enforcement date. In addition, high-level support from management and Board members will increase the likelihood of obtaining a sufficient budget for HIPAA compliance.

D. Set a Budget for the Initial Compliance Activities

Budgets will vary widely from institution to institution, depending on the size of the organization, the present policies concerning protection of health information, and the number of information systems on which PHI is stored.

E. Assess how the Organization Uses and Discloses Protected Health Information

Track the existing flow of PHI inside and outside the organization. Determine who accesses PHI, what particular PHI they may access and when, and whether access to PHI is necessary to their job performance. Evaluate how and when PHI is disclosed to independent contractors inside the organization and to people and businesses outside the organization, and whether PHI is necessary to their function for the organization. In addition, evaluate the organization's current restrictions on access to and disclosure of PHI, including how existing policies and procedures protect health information at the department and parent organization level. Finally, be sure to examine each database in the organization to determine where PHI is archived; a good start may be the systems inventory prepared for Y2K.

Organizations may conduct these assessments in a number of different way. Many larger organizations utilize vendor software designed by consultants to create a database of uses and disclosures. This option generally tends to be expensive, and some software requires up-front work by the healthcare organization to customize the questions to fit the organization. A cheaper alternative is to design a questionnaire to determine the various uses and disclosures, which generally should be followed by in-depth interviews by a member of the HIPAA task force. To ensure that the assessment is actually gathering the information required, healthcare organizations should consider doing a test run to determine the best way to gather this information. n194

n194 See Gordon J. Apple and Mary D. Brandt, *Ready, Set, Assess! An Action Plan for Conducting a HIPAA Privacy Risk Assessment*, at www.ahima.org/journal.

F. Based on the Assessment, Develop a "Gap Analysis"

Once an organization has a handle on how it internally uses and externally discloses PHI, it must then compare its present uses and disclosures against the requirements of the Privacy Standards.

Again, vendors and consultants have developed tools to conduct the gap analysis. If a healthcare organization decides to use a vendor tool, it should determine how the gap analysis tool was assembled and the credentials of the people who created the tool. Because an individual or consultant with comprehensive knowledge of the Privacy Standards should complete the gap analysis, the vendor must be able to demonstrate the expertise of its employees or contractors responsible for the tool.

If a healthcare organization chooses to do its gap analysis inhouse, a number of good tools exist to assist with this process. For instance, the nonprofit Academic Medical Centers (AMC) has produced an excellent guide called "Guidelines for Academic Medical Centers on Security and Privacy: Practical Strategies for Addressing the Health Insurance Portability and Accountability Act." n195 This document is useful to non-academic hospitals as well, because it tracks each privacy and security requirement. While this document is too detailed to use in the initial assessment and information gathering process, it should prove very useful in performing the gap analysis.

n195 Academic Medical Centers, *Guidelines for Academic Medical Centers on Security and Privacy: Practical Strategies for Addressing the Health Insurance Portability and Accountability Act*, (Nov. 30, 2001), at www.aamc.org/members/gir/gasp.

G. Evaluate Whether State Laws Continue to Apply

The Privacy Standards generally preempt all "contrary" state laws--those with respect to which compliance would be contrary to the Privacy Standards. n196 However, there are exceptions allowing even contrary state laws to apply if: (1) the state law relates to the privacy of health information and is "more stringent" (i.e., it is more favorable in some way to the patient); (2) the state law provides for the reporting of disease or injury, child abuse, birth, or death, or for public health surveillance, investigation or intervention; (3) the state law requires a health plan to report or to provide access to information for the purpose of management audits, financial audits, program monitoring and evaluation, or the licensure or certification of facilities or individuals; or (4) the Secretary of DHHS determines that the state law is

necessary to prevent fraud and abuse; to ensure state regulation of insurance and health plans; to serve a compelling public need related to public health, safety or welfare; or that the State law relates to controlled substances. n197

n196 45 C.F.R. § 160.203 (2001).

n197 *Id.*

Because an organization's policies and procedures obviously also must conform to state law requirements, this state law preemption analysis should be conducted before an organization develops its policies and procedures. Many state hospital associations or other professional associations across the country are conducting this preemption analysis for their members. Healthcare organizations should check the availability of such resources before conducting (or paying an attorney to conduct) the preemption analysis.

H. Develop Policies and Procedures

The Privacy Standards require Covered Entities to have an extensive set of policies and procedures to protect the privacy of health information. n198 These policies and procedures should take into account the size and type of activities at the organization. n199 DHHS will expect to see more comprehensive privacy policies at larger healthcare institutions or health plans. The Privacy Standards also require organizations to maintain written or electronic copies of their policies and procedures and of any written communication (such as consents and authorizations) required by the Standards. n200 An organization must maintain that documentation for six years. n201

n198 *Id.* § 164.530(i).

n199 *Id.*

n200 45 C.F.R. § 164.530(j) (2001).

n201 *Id.*

Once the organization has conducted its "gap analysis" and determined what state laws will continue to apply post-HIPAA, it should begin drafting the required policies and procedures, and amending existing policies and procedures. Organizations should draft these policies and procedures well in advance of the April 14, 2003, compliance date. After that date, the organization will be required to provide patients and members its notice of privacy practices, reflecting those policies and procedures. An organization will not be able to change its policies and procedures until it also revises its notice of privacy practices and makes the notice available to its patients and members. n202 For health plans, that also means sending out the notice to its members if its policies and procedures materially change. If an organization develops its policies and procedures well in advance of the compliance deadline, it can try them on for size *before* drafting the notice of privacy practices.

n202 *Id.* § 164.530(i).

I. Draft Notice of Privacy Practices

Once the organization has adopted the policies and procedures that will bring it into compliance with the Privacy Standards, the organization should draft its notice of privacy practices. Many organizations, such as the American

Hospital Association, have made sample notices available on their Web Sites. n203 However, an organization's notice must reflect its own policies and procedures, as well as any state law that continues to limit an organization's use and disclosure of PHI.

n203 See American Hospital Association, at www.aha.org.

J. Conduct Workforce Training

Organizations must train all members of the workforce on their privacy policies and procedures "as necessary and appropriate for the members of the workforce to carry out their function." n204 This training must take place by the compliance date and every time an organization's privacy practices materially change. n205 In addition, an organization must have and apply appropriate sanctions against its workforce members who fail to comply with its policies. n206

n204 45 C.F.R. § 164.530(b) (2001).

n205 *Id.*

n206 *Id.* § 164.530(e).

After an organization has developed its privacy policies and procedures, it should conduct training of its entire workforce, as appropriate to the different types of positions within the organization. For instance, clinical personnel at a hospital obviously will require more substantial privacy training than will the janitorial staff. An organization should conduct this training for its present workforce, and then should incorporate ongoing training efforts into its new employee orientation.

K. Designate an Individual or Office to Accept Complaints

Organizations must provide a process for individuals to complain about their privacy policies and violations of privacy rights. n207 Each organization must designate a person or office responsible for receiving complaints under the Privacy Standards and providing further information about the matters discussed in the privacy notice. n208 Organizations should have vigorous internal complaint policies to address the concerns of their patients and members. If a problem is addressed directly with the healthcare organization, the individual often will not exercise his right to complain n209 to the Secretary of DHHS.

n207 *Id.* § 164.530(d).

n208 *Id.* § 164.530(a).

n209 *Id.* § 164.530(h) (an organization may not require individuals to waive their right to complain as a condition of treatment, payment, or enrollment).

L. Identify Business Associates and Educate Them About the Privacy Standards

As a first step toward complying with the HIPAA Privacy Standards' requirements concerning business associates, the organization should identify which individuals and businesses fall within that definition. Organizations must include businesses with which they do not have written contracts, such as suppliers that present invoices for their services or products.

To make the contracting process smoother, healthcare organizations should consider educating their business associates about the Privacy Standards and the requirements related to business associates. That way, business associates will understand why an organization is proposing a contract with such detailed provisions, including some that seem overly invasive.

M. Negotiate Business Associate Contracts

If an organization enters into new contracts with persons or organizations that fall within the definition of a business associate, it may be premature to insert the required business associate contract provisions. Instead, consider a provision allowing an organization to negotiate an amendment in order to comply with the HIPAA Privacy Standards. As the compliance date nears, negotiate amendments to those contracts to insert the required contractual provisions, or use an addendum to the contract. For sample business associate contract provisions, see the American Health Lawyers Special Member Briefing. n210

n210 AHILA, *supra* note 36.

N. Integrate HIPAA into the Compliance Program

Finally, an organization should integrate HIPAA compliance into its regular compliance program, following the Office of Inspector General's (OIG) Compliance Program Guidance. n211 This will assist an organization in avoiding or minimizing its privacy violations and assist in reducing any fines for criminal violations that occur. Moreover, many of these OIG guidelines reflect good risk management principles that an organization should adopt, regardless of whether it is required to have a compliance program.

n211 OIG Compliance Program, at www.dhhs.gov/progorg/oig/oigreg/cpghosp.pdf.

The OIG recommends that organizations follow the criteria set forth in the federal Sentencing Guidelines for organizations convicted of federal criminal offenses, to demonstrate that the organization exercised due diligence in attempting to prevent and detect criminal conduct. n212 A comprehensive compliance program should include the following seven elements, some of which can be modified to include the HIPAA Privacy Standards:

(1) Develop and distribute written standards of conduct, as well as written policies and procedures, that promote the hospital's commitment to compliance. To incorporate HIPAA Privacy into this compliance element, a healthcare organization should include in its code of conduct the requirement that an employee follow the organization's policies concerning confidentiality and privacy of health information. The organization also should incorporate these obligations in its human resource policies, and require compliance as an element in evaluating managers and employees. The Privacy Standards themselves, of course, require healthcare organizations to adopt policies and procedures to address compliance. n213

(2) Designate a chief compliance officer and other appropriate bodies, such as a corporate compliance committee, charged with the responsibility of operating and monitoring the compliance program, and reporting directly to the CEO and the governing body. The chief compliance officer, who may also be the HIPAA Privacy Official, should incorporate HIPAA Privacy compliance into the laws he is responsible for monitoring. For organizations that have a separate HIPAA Privacy Official who does not report to compliance, the HIPAA Privacy Official should report any privacy violations directly to the CEO and the governing body, or have cross-reporting responsibilities to the chief compliance officer.

(3) Develop and implement a regular, effective education and training program for all affected

employees. As discussed above, the HIPAA Privacy Standards also require healthcare organizations to conduct extensive employee education and training. n214

(4) Maintain a process, such as a hotline, to receive complaints, and adopt procedures to protect the anonymity of individuals who complain and to protect whistleblowers from retaliation. Healthcare organizations should allow employees, patients, and others to report anonymously violations of privacy policies to its general compliance hot line. Under the Privacy Standards, healthcare organizations must not retaliate against whistleblowers or employees who cooperate in compliance investigations. n215

(5) Develop a system to respond to allegations of improper or illegal activities and to instigate appropriate disciplinary action against employees who have violated internal compliance policies, applicable statutes, regulations or federal healthcare program requirements. The HIPAA Privacy Standards require organizations to impose sanctions against employees who violate privacy policies. n216

(6) Use audits or other evaluation techniques to monitor compliance and assist in the reduction of identified problem areas. While the HIPAA Privacy Standards themselves do not require audit or evaluation of internal compliance, such audits are essential from a risk management perspective.

(7) Investigate and remediate identified systemic problems and develop policies addressing the non-employment or retention of sanctioned individuals. As a follow-up activity to an organization's audit or evaluation of compliance with its privacy policies, it must act if it determines that systemic problems exist. However, healthcare organizations will not be required to have policies to address the "non-employment or retention" of individuals that violate privacy policies. Under the Privacy Standards, organizations are required to have policies concerning sanctions that will be imposed against violators, which may (but are not required to) include suspension or termination of employment. The OIG compliance guidelines' reference to "sanctioned individuals," refers to individuals who have been barred from participating in Medicare or other government payor programs. Termination is not required under the Privacy Standards.

n212 *Id.* at 8989.

n213 45 C.F.R. § 164.530(i) (2001).

n214 *Id.* § 164.530(b).

n215 *Id.* § 164.530(g).

n216 *Id.* § 164.530(e)(1).

While healthcare organizations should incorporate HIPAA into their compliance program, this "incorporation" generally will occur after the organization develops its HIPAA Privacy policies and procedures. The HIPAA compliance task force, discussed above, need not operate as part of the general compliance program.

IV. Conclusion

The HIPAA Privacy Standards clearly will have substantial impact on healthcare organizations' internal operations, their relationships with patients, and their interaction with people and businesses outside their organizations. However,

it appears the DHHS Office of Civil Rights is prepared to be reasonable in its enforcement of the regulations: The OCR's Guidance on July 6, 2001 works hard to alleviate the healthcare industry's anxiety about the difficult compliance challenges ahead.

The OCR's Guidance also makes clear that privacy protection will, to some extent, be a moving target. The OCR promises that it will propose modifications to the Privacy Standards, presumably by mid-2002. While OCR telegraphed some of the changes it will propose, its explanation of those potential changes was not detailed enough in many respects to create the predictability the healthcare industry craves for its compliance efforts.

Moreover, keep an eye open for legislation affecting health information privacy. Representative Greenwood, for instance, has introduced the Medical Information Protection and Research Enhancement Act of 2001, n217 which would supplant the Privacy Standards and replace them with less prescriptive requirements to protect health information privacy. In addition, Representative Craig and others have introduced legislation to coordinate the implementation dates of the HIPAA Standard Transactions, security regulations, and national identifiers (except individual identifiers), excluding the Privacy Standards. n218 Finally, the American Hospital Association and others are lobbying Congress to provide financial assistance for the healthcare industry in complying with HIPAA mandates.

n217 H.R. 1215, 107th Cong. (2001).

n218 S. 836, 107th Cong. (2001).

In short, the battle over privacy continues to rage. The compliance challenges continue to mount.

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LENGTH: 17876 words**TITLE:** ARTICLES: A Cure for the Blues: Resolving Nonprofit Blue Cross Conversions**AUTHOR:** Joel Ferber *

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TEXT:

ABSTRACT: This Article analyzes the issues involved in converting nonprofit Blue Cross organizations to for-profit status. These issues have arisen in the context of litigation regarding the "reorganization" of Blue Cross and Blue Shield of Missouri ("BCBSMo"). BCBSMo had reorganized by creating and transferring a majority of its business to a new for-profit subsidiary. Missouri consumer groups and state regulators characterized the "reorganization" as a conversion requiring BCBSMo to transfer its assets to a foundation dedicated to charitable health purposes. BCBSMo, however, denied that it had any obligation to leave behind its assets in the nonprofit sector. The BCBSMo litigation raises issues common to most conversions of nonprofit healthcare organizations, particularly conversions of nonprofit Blue Cross plans. This Article provides a road map for state regulators and the public to follow in ensuring that the public interest is fully protected in such conversions.

I. Background: History of Nonprofit Conversions

Blue Cross organizations are not unique in attempting to convert to for-profit status as a response to changing economic circumstances. Many other nonprofit health insurers and hospitals, originally formed for charitable purposes, have converted to for-profit status. n1 It is well established that when nonprofit health services corporations convert to for-profit status, they must leave the assets they accumulated as nonprofit organizations in the nonprofit sector. n2 Typically, converting corporations have met their charitable trust obligations by transferring their assets to charitable foundations dedicated to health purposes. n3 For instance, as of September 1, 1997, at least eighty-one new health foundations had been created as a direct result of nonprofit to for-profit conversions. n4 As a result of such transfers, the California Wellness Foundation has been endowed with assets of \$ 1.2 billion, the Kansas Health Foundation has assets of \$ 332.8 million, and the Nashville Memorial Health Systems Foundation has assets of \$ 100 million. n5

n1 For example, 58 nonprofit hospitals converted to investor-owned hospitals in 1995, up from 34 conversions in 1994. Robert Kuttner, *Columbia/HCA and the Resurgence of the For-Profit Hospital Business*, 335 NEW ENG. J. MED. 362 (1996).

n2 See, e.g., Howard S. Levy, *The Conversion of Nonprofit Health Maintenance Organizations to For-Profit Status*, 16 N. KY. L. REV. 361 (1989); Theresa McMahon, *Fair Value? The Conversion of Nonprofit HMOs*, 30 U.S.F. L. REV. 355 (1996).

n3 Anne Lowrey Bailey, *Charities Win, Lose in Health Shuffle*, CHRONICLE OF PHILANTHROPY, June 14, 1994, at 1; Rhonda L. Rundle, *Big Charities Born as Health Plans Go for Profit*, WALL ST. J., Apr. 4, 1995, at B1.

n4 Stephen L. Isaacs et al., *Health Care Conversion Foundations: 1997 Status Report* (Oct. 1997) <http://www.gih.org/pubs/conversion_1097/title.htm>.

n5 Bailey, *supra* note 3, at 2.

The legal basis for such charitable foundations is the common law doctrine of "charitable trusts." Under this doctrine, the assets of charitable corporations are impressed with a charitable trust, that is, they may only be used for charitable or public purposes. These trusts mandate that the assets can be used only for the purposes of the corporation at the time the assets were given. Courts will interfere with the discretion of those governing a public charity when the board departs from the dominant purpose of the charity. n6

n6 Taylor v. Baldwin, 247 S.W.2d 741, 750 (Mo. 1952).

The charitable entity's articles of incorporation define the intent of the charitable trust, and when those original purposes become frustrated or impossible, courts may invoke the doctrine of *cy pres* and identify another, similar purpose for the assets of the trust. The *cy pres* doctrine holds that when a charitable trust becomes impossible, inexpedient, or impracticable to fulfill, a court may substitute another charitable object it believes approaches the original purpose as closely as possible. n7 Courts have applied this doctrine to nonprofit corporations, taking the position that the assets of a charitable corporation are imposed with a charitable trust limiting the purposes for which they can be used to the purposes of the corporation as defined initially. n8

n7 Levings v. Danforth, 512 S.W.2d 207, 211 (Mo. Ct. App. 1974). "[A] court of equity has the power (*and indeed the duty*) to apply the *cy pres* doctrine and determine 'as nearly as may be' the general purpose and intent of the settlor and adopt a plan or scheme to carry such general intent into fruition and thus prevent a failure of the charitable trust." *Id.* (*quoting* Restatement (Second) of Trusts, § 399 (1959)) (emphasis added).

n8 See, e.g., Pacific Home v. Los Angeles County, 264 P.2d 539, 543 (Cal. 1953) (applying charitable trust principles and holding that when a nonprofit **nursing home** dissolved as a corporate entity, its assets were required to be distributed according to charitable purpose limited by the articles of incorporation); Queen of Angels Hosp. v. Younger, 66 Cal. App.3d 359, 368 (1977) (nonprofit hospital's diversion of assets for the exclusive use of outpatient clinics would constitute an abandonment of the corporation's primary purpose, which was to operate a hospital); Attorney General v. Hahnemann Hosp., 494 N.E.2d 1011, 1018 (Mass. 1986) (sale of a nonprofit hospital to a for-profit corporation constituted an abandonment of the hospital's principal activity, resulting in violation of charitable trust principles); Mercy Hosp. of Williston v. Stillwell, 358 N.W.2d 506, 510-11 (N.D. 1984) (the merger of two medical care facilities did not terminate a charitable trust of which one of the corporations was beneficiary since the purpose for which the trust was created was not impaired by the merger); Nacol v. State of Tex., 792 S.W.2d 810, 811 (Tex. Ct. App. 1990) (rejecting appellants' argument that nonprofit corporation conducting multiple sclerosis research was not a charitable trust and finding that corporate assets "are deemed impressed with a charitable trust by virtue of an expressed declaration to the corporation's purpose").

State attorneys general are responsible for **protecting** charitable trusts. They have the authority to bring a *cy pres* proceeding to ensure that any conversion is consistent with the charitable trust doctrine. n9 The attorneys general, as guardians of the public trust, have jurisdiction to approve or deny a transaction and should play an active role in ensuring that all such healthcare conversions are in the public interest.

n9 *See, e.g.,* Voelker v. Saint Louis Mercantile Library Ass'n, 359 S.W.2d 689, 694 (Mo. 1962); Levings v. Danforth, 512 S.W.2d 207, 208 (Mo. Ct. App. 1974).

Attorneys general in many states have successfully used their common law authority to take an aggressive stance in monitoring the conversions of nonprofit hospitals. For instance, the Attorney General of Massachusetts intervened to supervise the sale of the majority of assets held by MetroWest Health to Columbia/HCA. n10 The Attorney General not only held a public hearing but retained an accounting firm to establish fair market value of MetroWest Health and extracted from Columbia/HCA a number of commitments. These commitments included: (1) maintaining the same levels of free care; (2) adhering to the Attorney General's community benefit guidelines; (3) using an independent healthcare analyst to monitor and report the levels of care and community health access; and (4) maintaining emergency room and acute medical/surgical care in two communities served by the hospital for three years with sixty days public notice of any proposed service changes following a three year period. n11

n10 *See* Press Release from the Office of the Mass. Attorney General, *Harshbarger to Hold Hearing on Sale of Metro West Medical Center* (June 23, 1995) (on file with the author).

n11 ANIL ADYANTHAYA, OVERVIEW OF THE COLUMBIA-METROWEST AGREEMENT AS IT RELATES TO FREE CARE, COMMUNITY BENEFITS AND THE FUTURE OF THE METROWEST HOSPITALS, 6-10 (Dec. 17, 1996) (on file with the author).

Other state attorneys general have played a similarly aggressive role in regulating nonprofit healthcare conversions. For example, the California Attorney General routinely reviews and modifies terms of these sales, and makes all of the financial details of the sales public. n12 In Michigan, the Attorney General sued based on his general supervisory power over charitable trusts to block Columbia's proposed acquisition of fifty percent of Michigan Capital Medical Center. n13 The Ohio Attorney General has required independent valuations of assets, assured the creation of charitable foundations dedicated to healthcare purposes, and extracted agreements that converting nonprofits maintain pre-transaction levels of care of the poor. n14

n12 Julie Silas et al., *Blue Cross Conversions: Consumer Efforts to Protect the Public's Interests*, 74 BULL. N.Y. ACAD. MED. 256, 274-77 (1997).

n13 Kuttner, *supra* note 1, at 447-48.

n14 Craig R. Mayton, *The View From Ohio: For-profit Health Care Enterprises Are Not Inherently Evil, Says Ohio's Assistant Attorney General*, HEALTH AFF. (Mar.-Apr. 1997).

Unfortunately, state attorneys general do not always monitor healthcare conversions aggressively. In Tennessee, when Nashville Memorial Hospital was sold in 1994 to Healthtrust (later acquired by Columbia), the details of the sale were kept secret. Several hospital trustees learned of the sale only after the deal was struck. n15 The Tennessee Attorney General did not challenge key terms of the deal and did not disclose those terms until after the transaction had been completed. n16 Similarly, the Colorado Attorney General stood by when HealthONE, a six-hospital system in Denver, agreed to a joint venture with Columbia/HCA. The Attorney General took no action while \$ 350 million of HealthONE's \$ 550 million in assets went to pay HealthONE's debt and no money went to a foundation. n17

n15 Kuttner, *supra* note 1, at 447.

n16 *Id.*

n17 *Id.*

The variability in states' treatment of nonprofit healthcare conversions reflects the complexity of the conversion issue, the continuing evolution of the law and policy governing such conversions, and the varying degree of public involvement in conversions across the country.

II. Conversions of Blue Cross Organizations

A. History

Like hospitals and health maintenance organizations ("HMOs"), Blue Cross organizations across the country have responded to changes in the healthcare marketplace by attempting to restructure their operations to compete with for-profit health insurers. n18 Blue Cross and Blue Shield plans ("Blue plans") were formed to combat the difficulty in obtaining healthcare during the Great Depression. n19 At that time, "health insurance was virtually nonexistent, and the inability of many Americans to pay for medical care placed a financial strain on the voluntary hospital system." n20 The Blue plans addressed the crisis by providing "affordable coverage to all individuals, regardless of health status." n21 The Blue "plans were organized on a not-for-profit basis and were dedicated to fulfilling a community service role." n22

n18 Cathy Tokarski, *Mergers, Conversions: Blues' Survival Strategies*, AM. MED. NEWS, May 20, 1996, at 13.

n19 See SYLVIA A. LAW, BLUE CROSS: WHAT WENT WRONG? 6-9 (1976).

n20 U.S. GENERAL ACCOUNTING OFFICE, BLUE CROSS AND BLUE SHIELD, EXPERIENCES OF WEAK PLANS UNDERSCORE THE ROLE OF EFFECTIVE STATE OVERSIGHT, GAO/HEHS-94-71 (1994), available in Westlaw, 1994 WL 833178 (F.D.C.H.).

n21 *Id.*

n22 *Id.*

Until recently, Blue Cross had maintained its charitable obligation. The National Blue Cross and Blue Shield Association ("BCBSA") has strongly defended its legacy of community obligation and charitable purpose. When Congress considered eliminating Blue Cross' federal tax exemption as proposed by the Tax Reform Act of 1986, the president of the BCBSA argued in support of Blue Cross' tax exempt status, stating:

There has always been an important difference between the Blue Cross and Blue Shield Plans and the commercial insurers, however. That difference is one of purpose and philosophy underscored by day-to-day operating practices. The Plans have a strong obligation to their communities, as well as to their subscribers, and discharge those community obligations in ways that do not add to the "bottom line." Commercial insurers do not share these community obligations and, quite understandably, operate to maximize the return to their shareholders.

The philosophical differences between the plans and the commercial insurers lead to very real differences in behavior

In short the Plans . . . maintain a pattern of behavior that is far more community-oriented than their competition. n23

n23 U.S. Senate Comm. on Fin., 99th Cong. 2d Sess., 36-38 (Feb. 4, 1986) (Statement of Bernard R. Tresnowski, President, Blue Cross and Blue Shield Ass'n, Chicago, IL), *reprinted in* BERNARD D. REAMS, JR. & MARGARET H. McDERMOTT, *TAX REFORM 1986: A LEGISLATIVE HISTORY OF THE TAX REFORM ACT OF 1986* (1987) (emphasis added).

Similarly, in a letter to Congress, the BCBSA noted the following:

For over fifty years, all Blue Cross and Blue Shield Plans have been exempt from federal taxation. *This exemption is warranted because the Plans serve the public interest* by assuring that millions of Americans have access to comprehensive and affordable coverage. n24

n24 Otto Shill, *Revocation of Blue Cross & Blue Shield's Tax-Exempt Status an Unhealthy Change? An Analysis of the Effect of the Tax Reform Act of 1986 on the Taxation of Blue Cross & Blue Shield and Health Insurance Activities*, 6 B.U.J. TAX L. 147, 173 (1988) (emphasis added).

Members of Congress have also acknowledged and promoted Blue Cross' special status. During consideration of the Tax Reform Act, Senator Packwood testified that Blue Cross "organizations would be allowed a special deduction in recognition of their community service activities." n25

n25 S. CONF. REP. No. 13898-01, 99th Cong., 2d Sess. (1986) (statement of Sen. Packwood).

In June 1994, however, the BCBSA changed its long-standing rule requiring all Blue Cross and Blue Shield licensees to be nonprofit corporations and established new standards for licensing the Blue Cross and Blue Shield marks to for-profit **companies**. n26 Pursuant to this change, the number of Blue plans seeking to convert to for-profit status has increased, sparking a state-by-state effort by consumer groups, attorneys general, and state insurance commissioners to protect the charitable assets of the Blue plans.

n26 Milt Freudenheim, *Blue Cross Lets Plans Sell Stock*, N.Y. TIMES, June 30, 1994, at D1.

B. Blue Cross Conversions

Across the country, Blue plans are converting to for-profit status through various methods and processes. Converting Blue plans sometimes acknowledge their charitable obligations when they convert and agree to leave their assets behind in the nonprofit sector, while other Blue plans resist fulfilling their charitable obligations.

1. Acknowledgment of Charitable Obligations and State "Conversion" Legislation

In some states, Blue plans explicitly convert to for-profit status, agreeing to transfer assets to nonprofit foundations while negotiating the amount of the assets with the relevant state authorities. For example, New York and Colorado Blue plans are converting while voluntarily agreeing to leave behind the value of their assets in the nonprofit sector. n27 In Colorado, Blue Cross is converting pursuant to a statutorily-prescribed process.

n27 CONSUMERS UNION & COMMUNITY CATALYST, *CONVERSION AND PRESERVATION OF CHARITABLE ASSETS OF BLUE CROSS AND BLUE SHIELD PLANS: HOW STATES HAVE PROTECTED OR FAILED TO PROTECT THE PUBLIC'S INTERESTS* 1, 10 (May 19, 1998) [hereinafter CONSUMERS UNION & COMMUNITY CATALYST].

In fact, many states have enacted legislation establishing a clear and explicit process for regulating conversions of nonprofit health plans and hospitals. n28 Such legislation generally makes it more difficult for converting health

organizations to evade their charitable trust obligations. n29 For instance, the California statute n30 requires: (1) the establishment of a section 501(c)(3) charitable foundation upon conversion; n31 (2) that the regulator consider the effects of a conversion on community health and submit a community benefits plan; n32 and (3) that a regulator monitor the foundation and its activities after the conversion transaction. n33 Colorado's legislation requires that: (1) the newly created foundation be designated either a section 501(c)(3) or 501(c)(4) foundation; n34 (2) the foundation be independent from the for-profit corporation; n35 and (3) the foundation's charitable mission and grant-making abilities be limited to "promoting or serving the healthcare needs of the citizens of Colorado." n36

n28 Natalie Seto et al., *Protecting Health, Preserving Assets: Laws Governing Conversions, Mergers, and Acquisitions Among Health Care Entities*, CLEARINGHOUSE REV., Mar.-Apr. 1998, at 618. As of September 15, 1997, 19 states had passed a total of 21 new laws governing nonprofit conversions, mergers, and acquisitions. *Id.*

n29 In Georgia, however, Blue Cross relied on state legislation to avoid its charitable obligations. The Georgia legislature passed a bill in 1995 that allowed Blue Cross and Blue Shield of Georgia to convert to a for-profit entity without transferring any of its assets to another charitable organization. The Insurance Commissioner and two attorneys general failed to take any action, allowing millions of dollars of public assets to go unprotected. *See Nicole Starr, Georgia Consumer Groups Still Singing the Blues: The Conversion and Settlement of Georgia Blue Under New Georgia Statute*, ___J. HEALTH L.___ (1999).

n30 CAL. HEALTH & SAFETY CODE §§ 1399.70-.76 (West 1998) (brief overview of the conversion requirements and associated costs). CAL. CORP. CODE §§ 5914-5919 (Deering 1997) (overview of the for-profit conversion process and associated costs).

n31 CAL. HEALTH & SAFETY CODE § 1399.72(2).

n32 *Id.* § 1399.71(b).

n33 *Id.* § 1399.72(7).

n34 COLO. REV. STAT. § 10-16-324(4)(e)(I)(G) (1997).

n35 *Id.* § 10-16-324(4)(e)(I)(E).

n36 *Id.* § 10-16-324(e)(I)(F). For a further discussion of various states' legislative responses to conversions, see generally Seto, *supra* note 28.

2. Resistance to Meeting Charitable Obligations

In contrast to the above mentioned examples, other Blue plans have resisted meeting their charitable obligations and have contested that their proposed reorganizations were "conversions." The most well known of these examples is the case of Blue Cross of California ("BC-Cal"). Despite its initial resistance to transferring any of its assets to a charitable foundation, BC-Cal and state regulators reached a settlement that required BC-Cal to transfer \$ 3 billion in assets to a charitable foundation dedicated to healthcare purposes. n37 The State and Blue Cross reached this agreement even though California regulators had initially approved the **company's** reorganization, without requiring BC-Cal to leave any assets in the nonprofit sector.

n37 James Sterngold, *A Deal by Wellpoint Creates a Health Provider and Two Charities*, N.Y. TIMES, May 21, 1996, at D4.

In some states, Blue plans' resistance to complying with their charitable obligations has resulted in litigation between the Blue plans and state regulators and/or consumer advocates. In Georgia, eight consumer organizations filed

a class action lawsuit against the Blue plan and the state in response to legislation declaring that Blue Cross was *not* a charitable and benevolent organization, thereby depriving Georgia citizens of millions of dollars. On July 8, 1998, Blue Cross agreed in a settlement to transfer between \$ 60 million and \$ 80 million to a new charitable foundation. n38

n38 Consumers Union & Community Catalyst, *FYI: Big News in Georgia* (July 16, 1998) (on file with the author). *See also* Starr, *supra* note 29.

Litigation also ensued in Ohio when Blue Cross and Blue Shield Mutual of Ohio ("BCBS-Ohio") attempted to "restructure" by selling a substantial portion of its assets to Columbia/HCA, a national for-profit hospital chain. The Ohio Attorney General subsequently filed a complaint against BCBS-Ohio, whereupon the Ohio Commissioner of Insurance rejected the transaction. After negotiating a consent decree, BCBS-Ohio acknowledged that even as a mutual **company**, it is a charitable organization and therefore must preserve its assets for charitable purposes. n39 Likewise, Blue Cross and Blue Shield of New Jersey ("BCBSNJ") attempted to deny that it was, or ever had been, a charitable organization, contradicting its own articles of incorporation and New Jersey law. n40 In April 1997, the trial court issued a declaratory judgment that BCBSNJ was by statutory definition, "a charitable and benevolent institution." n41 The appellate court affirmed the lower court's decision and the New Jersey Supreme Court denied the Petition for Certification. n42

n39 *See* Consent Decree and Final Judgment Entry, *State of Ohio v. Blue Cross and Blue Shield Mutual of Ohio* (Ct. C.P., Cuyahoga County) (Dec. 17, 1997) (No. 311632).

n40 Silas, *supra* note 12.

n41 Order Granting Partial Summary Judgment, Denying Motion to Dismiss and Dismissing Certain Counts Without Prejudice, In the Matter of the Application by Blue Cross and Blue Shield of New Jersey, Inc. of Conversion to a Domestic Mutual Insurer Pursuant to N.J.S.A. § 17:48E-45 et seq. (N.J. Super. Ct. App.) (Apr. 14, 1997) (No. ESX-L-1591-97).

n42 CONSUMERS UNION & COMMUNITY CATALYST, *supra* note 27.

Missouri is another state in which a dispute regarding a Blue Cross plan's conversion to a for-profit business is being litigated. The next two sections describe the Missouri Blue Cross controversy, the resulting litigation, and issues that must be resolved in reaching an equitable resolution of Blue Cross conversions.

III. The Missouri Blue Cross Conversion: A Case Study

A. Background

Like many other nonprofit Blue plans, BCBSMo reorganized its business to compete in the new healthcare environment. Consumer groups and state regulators argued that this "restructuring" was a conversion to for-profit status, triggering charitable trust obligations. They argued that BCBSMo was trying to have it both ways: convert to a for-profit operation and still keep all of its charitable assets. n43

n43 Brief of Amici Curiae The League of Women Voters of Missouri et al., *Blue Cross and Blue Shield of Missouri v. Angoff*, No. 53798, at 5 (Mo. Ct. App.).

In April 1994, BCBSMo sought expedited approval from the Missouri Department of Insurance ("DOI") to "reorganize." It proposed to transfer its managed care business to a newly created for-profit subsidiary, RightCHOICE, in exchange for shares of RightCHOICE stock. Within fourteen days, the DOI approved the transaction. BCBSMo sold

twenty percent of the RightCHOICE stock at a public offering and retained the remaining eighty percent. n44 BCBSMo eventually transferred most of its business to the new for-profit subsidiary. RightCHOICE became the dominant operation of BCBSMo while the original nonprofit became a mere shell. n45

n44 CONSUMERS UNION & COMMUNITY CATALYST, *supra* note 27.

n45 Order and Judgment Denying Plaintiff's Motion for Summary Judgment and Granting Defendant Attorney General's Motion for Partial Summary Judgment, *Blue Cross and Blue Shield of Mo. v. Angoff*, No. CV196-619CC, at 17-18 (Cir. Ct. Cole County, Mo.) (Dec. 30, 1996) [hereinafter Order and Judgment on Motions for Summary Judgment]. *See also* Amici Curiae The League of Women Voters' et al., Memorandum in Opposition to Blue Cross and Blue Shield of Missouri's Motion for Summary Judgment, *Blue Cross and Blue Shield of Mo. v. Angoff*, No. CV196-619CC, at 28-29 (Cir. Ct. Cole County, Mo.).

Consumer groups became concerned about the reorganization when RightCHOICE proposed to acquire HealthLink, a for-profit HMO. Consumer groups alleged that the Blue Cross "reorganization" was actually a "conversion" to for-profit status, which required Blue Cross to transfer its nonprofit assets to a nonprofit foundation dedicated to charitable health purposes. The groups held public forums and educated the media about the Blue Cross restructuring. n46 Approximately fifty consumer groups signed a "statement of concern" stating that Blue Cross had converted to for-profit status and therefore should transfer its assets to a nonprofit foundation. The Missouri legislature held hearings to address the controversy in late 1995 and into the 1996 legislative session. The Missouri Senate considered legislation to help regulate the conversions of both Missouri Blue Cross plans. n47 While no legislation was enacted, the hearings increased the visibility of and helped focus media attention on the conversion controversy.

n46 *See* Melinda Roth, *Double Cross*, RIVERFRONT TIMES, Oct. 25-31, 1995, at 24; *Blue Cross' Moral Obligation*, ST. LOUIS POST-DISPATCH, May 20, 1996, at 12B; *Wrong Choice on Right Choice*, ST. LOUIS POST-DISPATCH, June 25, 1996; Julius A. Karash, *Groups Petition on Blue Cross Assets*, KANSAS CITY STAR, May 17, 1996, at B2.

n47 Blue Cross and Blue Shield of Kansas City ("BCBSKC") supported legislation that would let it convert while setting aside only a fraction of its assets to charitable health purposes. *See* S.B. 851, 87th Gen. Ass., 2d Sess. (Mo. 1996). On the other hand, consumer groups supported legislation that would require the fair market value of all of the assets to be set aside for charitable health purposes as a result of the Missouri Blue Cross "conversion" and in the event of a conversion by BCBSKC. *See* S.B. 977, 87th Gen. Ass., 2d Sess. (Mo. 1996). Neither piece of legislation was enacted, leaving Missouri's existing nonprofit law and common law doctrines as the governing authority for resolving the conversion controversies.

Reversing its previous position, the DOI demanded that Blue Cross transfer all of its assets to a nonprofit foundation as a result of the conversion. As a basis for the reversal, the DOI alleged that Blue Cross misrepresented the scope of the reorganization by transferring all of its fee-for-service Medicare supplement business to the new for-profit subsidiary, while informing the State that only the managed care business would be transferred to RightCHOICE. The DOI also pointed to several significant changes to Blue Cross' articles of incorporation -- changes of which it was not apprised -- including the elimination of the obligation to operate voluntary nonprofit health services plans. n48

n48 Answer and Counterclaims of Defendants Jay Angoff and the Missouri Department of Insurance to Plaintiff's First Amended Petition, *Blue Cross and Blue Shield of Mo. v. Angoff*, No. CV196-619CC (June 13, 1996); *Blue Cross and Blue Shield of Mo. v. Angoff*, Nos. WD 53798, WD 53799, WD 53800, WD 53851 (Mo. Ct. App. Aug. 4, 1998), *available in* Westlaw, 1998 WL 435697 (appeal from the Circuit Court of Cole County).

On May 13, 1996, BCBSMo filed a lawsuit to prevent the DOI and the Attorney General from enforcing its charitable obligations. Three days later, eighteen consumer and religious groups filed an administrative petition against the DOI. They demanded that the DOI enforce the public benefit obligations of BCBSMo and establish a public process for reviewing and overseeing healthcare conversions. BCBSMo obtained a temporary restraining order preventing the

DOI from responding to the administrative petition or taking any other action against BCBSMo.

Several consumer groups filed a motion to intervene in the litigation. The court denied the motion, finding that the existing parties (the DOI and Attorney General) could adequately represent the public's interests. However, the court did invite consumer groups to file amici curiae briefs.

B. The Trial Court Decision

BCBSMo moved for summary judgment against the DOI. On September 9, 1996, the court found that the DOI could not reconsider its approval of the reorganization. Additionally, it found that the DOI lacked standing to enforce Blue Cross' public benefit obligations. n49 The court found that the 1994 reorganization was authorized under Missouri's nonprofit corporation laws and the DOI was not authorized to revoke or revisit the Director's original approval of the reorganization. Further, it held that BCBSMo did not owe, and the Director was not authorized to demand, a payment or charitable asset settlement as a result of the reorganization. n50 The court, therefore, enjoined the DOI from commencing a valuation of Blue Cross' assets for the purpose of demanding a charitable asset settlement or commencing any administrative proceedings regarding the reorganization. n51

n49 See Memorandum and Order, *Blue Cross and Blue Shield of Mo. v. Angoff*, No. CV196-619CC (Cir. Ct. Cole County, Mo.) (Sept. 9, 1996).

n50 *Id.*

n51 *Id.*

In its September 9, 1996 order, the trial court did not address the Attorney General's counterclaim against BCBSMo. On December 30, 1996, however, the court ruled against Blue Cross and in favor of the State on the one remaining counterclaim. The decision was practically a 180 degree turn from the court's earlier decision in favor of Blue Cross. n52 The court held that since the restructuring, Blue Cross had exceeded or abused its statutory authority as a nonprofit health services corporation in violation of Missouri statutes. In determining the authority conferred by law on Blue Cross, the judge looked both to Chapter 355 (governing nonprofit corporations) and to Chapter 354 (regulating nonprofit health services corporations) of the Missouri Revised Statutes. n53

n52 The final order entered by the court on December 30 modified the previous September order. The court noted that to the extent that the December order contradicted the September order, the December order superseded the previous order. The court in fact deleted certain findings from the September 9 order regarding whether Blue Cross had any "charitable trust" or "public benefit" obligations. Order and Judgment on Motions for Summary Judgment, *supra* note 45.

n53 See *id.*

Under these statutory schemes, a nonprofit health services corporation may not be created for or engaged in business or activity for profit. The court was careful to point out that this prohibition does not mean that health services corporations or other nonprofit organizations can never have a for-profit subsidiary. n54 Instead, the court held that the creation or operation of a for-profit subsidiary must be seen in relation to the health services corporation's purpose as a nonprofit organization. The court asked: does the for-profit activity of the subsidiary serve and further the nonprofit purpose of the health services corporation or is the for-profit activity the bottom-line purpose of the "nonprofit" organization? n55

n54 *Id.* at 15.

n55 *Id.*

The court applied that analysis to the creation and operation of Blue Cross' for-profit subsidiary, RightCHOICE, and concluded that these activities had severely compromised, rather than furthered, the ability of Blue Cross to conduct its nonprofit health plan business. n56 The court noted that Blue Cross transferred between eighty and ninety percent of its business to RightCHOICE. n57 Given that Blue Cross' earned premiums and net income had been increasing in the years immediately preceding the transfer, the permanent loss of so much business was not reasonably necessary for its continued survival in a competitive health insurance market. n58

n56 *Id.* at 25.

n57 *Id.* at 18.

n58 *Id.* at 19-21.

Nor did that loss confer long-term financial flexibility and benefits on Blue Cross. The court pointed to two key facts in this regard. First, before the reorganization, Blue Cross was free to use its more profitable nonprofit plans to subsidize its less profitable ones. Now, the RightCHOICE board of directors would have to decide, in light of its duty to its own stockholders, to declare a dividend or buy back some of its stock from Blue Cross in order to further Blue Cross' nonprofit activities. n59 Second, the court pointed out that Blue Cross gave RightCHOICE the exclusive right to use the Blue Cross trademark for managed care business in eighty-five counties, thus crippling its own ability to market managed care products on a nonprofit basis in a substantial part of the state. Concluding that the operation of RightCHOICE and its for-profit activities had become the bottom-line purpose of Blue Cross, the court held that Blue Cross had exceeded or abused the authority conferred upon it by Missouri law. n60

n59 *Id.* at 22.

n60 *Id.* at 29.

The trial court did not, however, determine the remedy for Blue Cross' violation of Missouri nonprofit law. It postponed that issue pending appeal of its finding on liability. n61

n61 The court also did not reach the question of whether Blue Cross was a mutual benefit corporation or a public benefit corporation. A mutual benefit corporation holds itself out as benefitting and representing a group of individuals or entities usually referred to as members. REVISED MODEL NONPROFIT CORPORATION ACT xxviii (1988). Upon dissolution of a mutual benefit corporation, unless the corporation's articles or bylaws specify the distribution of assets, the corporation transfers its assets to its members, or if there are no members, to those persons whom the corporation holds itself out as benefitting or serving. MO. ANN. STAT. § 355.691(7) (Vernon 1997).

In contrast, a public benefit corporation is a corporation that is organized for a public or charitable purpose and holds itself out as benefitting society. REVISED MODEL NONPROFIT CORPORATION ACT xxiv. Upon dissolution of a public benefit corporation, that corporation must distribute its assets to another public benefit corporation, the United States, a state or a person which is recognized as exempt under § 501(c)(3) of the Internal Revenue Code, or any successor section. MO. REV. STAT. § 355.881(4) (1997). The court indicated that it would consider this question, along with whether there are reasonable alternatives to dissolution of Blue Cross, and whether such dissolution is in the public interest. Order and Judgment on Motions for Summary Judgment, *supra* note 45.

However, the court gave an indication of how it would resolve the issue in separate litigation involving BCBSKC.

On September 11, 1998, the same trial judge who had ruled against BCBSMo held that BCBSKC is a public benefit corporation and as such, was prevented from engaging in "any merger activity or other conduct inconsistent with its status as a public benefit corporation under Missouri law." Order and Judgment, Blue Cross and Blue Shield of Kansas City, Inc. v. Nixon, No. CV197-330CC (Cir. Ct. Cole County, Mo.) (Sept. 14, 1998). The court found that BCBSKC was organized for and dedicated to the public throughout its existence. *Id.* The court also noted that BCBSKC took advantage of tax considerations and its status in the community based on its pledge to serve a public benefit mission. *Id.* Jackson v. Nixon, *appeal docketed*, No. CV 197-330CC (Mo. Ct. App.) (Oct. 4, 1998).

C. The Appellate Court Decision

Blue Cross appealed the trial court's decision to the Missouri Court of Appeals, Western District. On August 4, 1998, the Court of Appeals affirmed the decision that Blue Cross had exceeded or abused its authority under Missouri's nonprofit law. n62 The court concluded that "the purpose of the reorganization was not to further or support Blue Cross' nonprofit activities." n63 The court recognized that before the reorganization, Blue Cross was the largest provider of managed care healthcare benefits in Missouri with premium revenues of between \$ 597 million and \$ 842 million, net income gains of between \$ 17.3 million and \$ 25.5 million, and net underwriting gains of between \$ 4.8 million and \$ 19.1 million. n64 Yet, after the reorganization, Blue Cross reported premium revenues of only 1/10 of those revenues. n65

n62 Blue Cross and Blue Shield of Mo. v. Angoff, Nos. WD 53798, WD 53799, WD 53800, WD 53851 (Mo. Ct. App. Aug. 4, 1998), available in Westlaw, 1998 WL 435697 (appeal from the Circuit Court of Cole County).

n63 *Id.* at 28.

n64 *Id.*

n65 *Id.*

Meanwhile, RightCHOICE became the largest provider of managed healthcare benefits in Missouri. n66 RightCHOICE was earning literally millions of dollars each year, yet none of the money was used for nonprofit purposes. n67 Instead, all of the money was reinvested into RightCHOICE to foster its for-profit purposes. n68 Like the trial court, the Court of Appeals rejected Blue Cross' argument that the reorganization was necessary for the **company's** survival, noting that Blue Cross was highly profitable in the four years preceding the reorganization. n69

n66 *Id.*

n67 *Id.*

n68 *Id.* at 29.

n69 *Id.* at 33.

The Court of Appeals noted that the record demonstrated Blue Cross' intent to abandon its nonprofit purposes, citing meeting minutes in which legal counsel discussed the "intricacies of *how one proceeds from a not for profit company, [Blue Cross], to a for profit company, in which the parent owns approximately 80%.*" n70 The court also pointed to the three amendments to BCBSMo's articles of incorporation where it "effectively eliminated" all of its nonprofit purposes. n71 The post-reorganization of RightCHOICE drastically reduced Blue Cross' most valuable health

plans. n72

n70 *Id.* at 29.

n71 *Id.* at 30.

n72 The court of appeals also rejected several procedural arguments raised by Blue Cross. For example, the court rejected the argument that the Attorney General could be estopped by the DOI's prior approval of Blue Cross' 1994 reorganization, noting Blue Cross' failure to demonstrate affirmative misconduct by the DOI and the rarity of circumstances in which estoppel against the government is granted. *Id.* at 18.

During the pendency of the appeal, the parties reached a proposed settlement which they presented to the trial court for its approval. The trial court appointed a Special Master who, as of this writing, was holding hearings to review the proposed settlement. Meanwhile, the Missouri Supreme Court, on Blue Cross' motion, has accepted transfer. n73 The Attorney General, with Blue Cross' consent, has requested a stay of the Supreme Court proceedings, pending the trial court's review of the proposed settlement. n74

n73 *See* Blue Cross and Blue Shield of Mo. v. Angoff, No. 81172 (Mo.) (Nov. 24, 1998) (Supreme Court of Missouri Order).

n74 Response of Plaintiff-Appellant Blue Cross and Blue Shield of Missouri to Motion for Stay of Proceedings of the Attorney General, Blue Cross and Blue Shield of Mo. v. Angoff, No. 81172 (Mo.) (Dec. 7, 1998).

IV. Key Issues in Blue Cross Conversions

This section discusses the key issues that have arisen in the Missouri litigation, and which are critical to resolving almost any Blue Cross conversion. Other states must address these issues, even when Blue Plans voluntarily and explicitly convert to for-profit status and agree to transfer their assets to charitable foundations. n75

n75 For example, the Colorado and New York Blue Cross plans have not chosen the California/Missouri approach of transferring business to newly created for-profit subsidiaries and maintaining that they are still nonprofit entities. Instead, they are following a process under which the nonprofit Blue Cross plan will convert entirely to a for-profit **company**, without maintaining a nonprofit shell. In these instances, the issues are not whether a conversion has occurred, or whether the Blue Plan has violated state law by converting, but rather, how the conversion can occur in a way that best protects the public interest while meeting the state's legal requirements.

As indicated earlier, these issues will sometimes arise in accordance with a statutorily mandated process for regulating Blue Cross conversions. For example, the Colorado statute explicitly provides a detailed set of procedures for converting health insurers to follow, standards for evaluating the proposed conversion, public notice and hearing requirements, and judicial review of regulatory actions. COLO. REV. STAT. § 10-16-324. *See supra* text accompanying notes 34-36.

A. Valuation

The valuation of the charitable assets is probably the most important issue in any nonprofit healthcare conversion. The value of the original nonprofit corporation must include the full "fair market value" n76 of the original nonprofit corporation's assets so that all of the assets impressed with a charitable trust continue to benefit the public in accordance with the *cy pres* doctrine. n77

n76 Fair market value is a legal term of art in most states. Typically, it is the price that the assets bring in a fair sale in an open and competitive market in which buyer and seller are each prudent and knowledgeable, and the price is not affected by undue stimulus. Silas, *supra* note 12, at 276.

n77 *See supra* notes 7-9 and accompanying text.

The assets of converting nonprofits are often undervalued, causing the community to lose charitable assets. There are numerous examples of cases in which investor-owned **companies** have reaped windfall profits when nonprofits misjudge the value of what they had to sell. For example, in 1984, Greater Delaware Valley Health Care in Concordville, Pennsylvania was sold for \$ 100,000. n78 Two years later, the new owners sold it for \$ 20 million. n79 Similarly, the Group Health Plan of Greater St. Louis was sold for \$ 4 million in 1985 and valued at \$ 40 million a year later. n80 These undervaluations raise questions about improper private benefit from the sale of charitable assets. There is a risk that much of the value of the charitable assets will end up in the pockets of individuals associated with the original nonprofit organization. n81

n78 Bailey, *supra* note 3.

n79 *Id.*

n80 *Id.*

n81 Mary Gabay & Sidney M. Wolfe, *Who Controls the Local Hospital? The Current Hospital Merger and Acquisition Craze and the Disturbing Trend of Not-For-Profit Hospital Conversions to For-profit Status* 18 (June 1996).

A number of factors have been cited as the cause of these undervaluations, including: insufficient oversight by state regulators, faulty valuation methodologies, and the fact that insiders who acquire the not-for profits are often the same people who oversee the sale. n82 Gross undervaluations of a corporation's assets have occurred when corporate insiders convinced regulators that the corporation's assets should not be valued as an ongoing healthcare business whose assets are offered to the highest bidder. n83 For this reason, many state regulators have chosen to employ independent "valuation" experts to advise them on whether the public is receiving fair value of the assets in a conversion transaction. n84

n82 *See, e.g.,* Judith Bell et al., *The Preservation of Charitable Health Care Assets*, HEALTH AFF. (Mar.-Apr. 1997); McMahon, *supra* note 2, at 372-73; Bailey, *supra* note 3.

n83 Bell, *supra* note 82. The value of a nonprofit's assets depends on the valuation method that the regulator relies on and the independence of those completing the valuation. *See* James J. Fishman, *Checkpoints on the Conversion Highway: Some Trouble Spots in the Conversion of Nonprofit Health Care Organizations to For-Profit Status*, 23 J. CORP. L. 701, 718 (1998). *See also* Judith E. Bell et al., *The Public Interest in Conversions of Nonprofit Health Charities* (1997), for a more detailed discussion of the various valuation methodologies.

n84 *See, e.g.,* Mayton, *supra* note 14; James R. Schwartz, *The California Model: Openness is the Key in Health Care Conversions*, HEALTH AFF. (Mar.-Apr. 1997); Richard C. Allen, *The Massachusetts Experience: Health Care in Massachusetts Has Been Predominantly Nonprofit -- Until Now*, HEALTH AFF. (Mar.-Apr. 1997).

1. Receipt of Assets

The charitable foundation receiving the assets of a converting nonprofit should receive the full "fair market value" of the converted assets. In Missouri, consumer groups insisted that the final settlement be based on the entire amount of Blue Cross' assets. n85 In California, the state regulator used expert assistance to ensure that the full value of BC-Cal

was transferred to the new charitable foundations. n86

n85 Memorandum of Amici Curiae The League of Women Voters et al., on the Proposed Settlement, Blue Cross and Blue Shield of Mo. v. Angoff, No. CV196-0619CC, at 15 (Cir. Ct. Cole County, Mo.) (Dec. 23, 1998) [hereinafter Memorandum of Amici Curiae].

n86 Test. of Margo Hunter, Tr. at 23, Blue Cross and Blue Shield of Mo. v. Angoff, No. CV196-619CC (Dec. 4, 1998).

In order to meet their charitable obligations, converting nonprofits sometimes transfer stock in the new for-profit **companies** to conversion foundations. n87 However, a converting Blue plan may have "value" in addition to the stock it holds in the new for-profit. For example, the Blue plan may hold real estate or engage in other nonprofit insurance business that will be converted to the new for-profit under a final conversion agreement. In Missouri, the trial judge directed the Special Master to inquire whether Blue Cross had any other nonprofit assets, in addition to the RightCHOICE stock and the proposed \$ 175,000 cash payment. n88 The California Department of Corporations Commissioner examined the value of the "residual assets" that had not already been transferred to the new for-profit subsidiary but would be converted in the final agreement between the State and BC-Cal. n89

n87 For example, when Health Net, a nonprofit California HMO proposed to convert to for-profit, the conversion foundation received 80% equity interest in the new for-profit. Bell, *supra* note 82. Also in California, a conversion foundation received 80% of the equity securities of WellPoint, the new for-profit Blue Cross plan. Gary S. Mendoza & Nancy M. Kane, *Seeing Red in the Rules of the New Blue Cross*, N.Y. TIMES, July 7, 1996, § 3, at 5.

n88 Order of Reference, Blue Cross and Blue Shield of Mo. v. Angoff, No. CV196-0619CC, at 4 (Cir. Ct. Cole County, Mo.) (Nov. 6, 1998) [hereinafter Order of Reference]. In the proposed Missouri settlement, the foundation would receive *only* the stock that Blue Cross holds in RightCHOICE and a nominal cash payment. Because Blue Cross conducted more nonprofit business than its 80% investment in RightCHOICE, consumer groups argued that the final settlement should take into account the total value of Blue Cross, not just the RightCHOICE stock owned by Blue Cross. For instance, the nonprofit Blue Cross still provided nonprofit fee-for-service healthcare coverage (unlike the managed care business that is already operated exclusively through RightCHOICE) and owned real estate that would be transferred to the new for-profit under the proposed settlement. See Memorandum in Support of Approval of Settlement, Blue Cross and Blue Shield of Mo. v. Angoff, No. CV196-0619CC (Cir. Ct. Cole County, Mo.) (Nov. 6, 1998) [hereinafter Memorandum in Support of Approval of Settlement]. As indicated above, the court agreed that the Special Master should explore whether there is other "value" that would not be transferred to the new foundation under the proposed settlement. Order of Reference, *supra* at 4. BCBSMo has argued that the stock which the new foundation will receive in fact equals or exceeds the full value of the converting nonprofit, a claim that the court can independently assess with expert assistance. See Memorandum in Support of Approval of Settlement, *supra* at 49-55.

n89 Test. of Gary Mendoza, Tr. at 65-66, Blue Cross and Blue Shield of Mo. v. Angoff, No. CV196-619CC (Dec. 4, 1998) [hereinafter Mendoza Testimony].

In addition, these conversions allow Blue Cross to transfer the *exclusive* right of the Blue Cross trademark to the for-profit, which means that the value of the mark will be *converted* to the for-profit business. Consumer advocates have argued that the final valuation should include a separate determination of the value of the Blue Cross trademark, which will add substantial value to the new for-profit Blue Cross. n90 Because the public loses these nonprofit assets as part of the "conversion," it should be compensated. n91 While some state regulators may settle for less than full value to resolve litigation over conversions, there is no reasonable justification for allowing less than all of the assets to be transferred to the new foundation.

n90 Test. of Rachel Farr Fitch, Tr. at 116, Blue Cross and Blue Shield of Mo. v. Angoff, No. CV196-619CC (Dec. 4, 1998); Test. of Peter DeSimone, Tr. at 118, Blue Cross and Blue Shield of Mo. v. Angoff, No. CV196-619CC (Dec. 4, 1998).

n91 Judith Bell et al., *supra* note 83, at 2.

2. Public Compensation for "Lost" Assets

In cases in which a Blue Cross plan contests the issue of its charitable trust obligations, state regulators and/or courts must address whether the public has lost important community assets during the time in which the conversion has been contested. If BCBSMo had willingly transferred its assets to a charitable foundation upon its conversion to for-profit status in 1994, the public would have received the value of Blue Cross' assets at the time of the initial reorganization -- rather than after years of protracted litigation.

The value of BCBSMo at the time it converted was substantially higher than the market price at the time that the court was evaluating the proposed settlement -- after several years of litigation.ⁿ⁹² Consequently, consumer groups argued that the public would lose valuable nonprofit dollars if the final settlement is based on the market value of Blue Cross shares in RightCHOICE at the time of settlement. Whether the public should be compensated for such lost value is certainly a significant issue for state regulators and/or courts to review. In Missouri, the Special Master has indicated that he is interested in assessing the value of Blue Cross' assets when it first reorganized its business rather than the value of its business during the conversion litigation -- Blue Cross' point of reference for measuring its value.ⁿ⁹³

ⁿ⁹² Memorandum in Support of Approval of Settlement, *supra* note 88, at Exhibit A. In the third quarter of 1994 when Blue Cross conducted the initial public offering of RightCHOICE stock, the market price of the outstanding common shares was \$ 14 3/8 per share. As of close of the business day November 25, 1998, the 15 million shares that would be transferred to the new foundation were only worth \$ 9.44 per share. Thus, the value of the nonprofit assets substantially diminished during the course of the litigation.

ⁿ⁹³ Statement of Special Master Russell, Tr. at 235, *Blue Cross and Blue Shield of Mo. v. Angoff*, No. CV196-619CC (Dec. 4, 1998); Memorandum of Amici Curiae, *supra* note 85.

Another issue that arises when a Blue Cross plan contests its charitable obligation is whether the public should be reimbursed for the appreciation in value that the foundation would have realized had it received the assets at the time of the initial reorganization rather than after several years of litigation. If the foundation had received the assets of the original conversion, it could have divested some of the stock and accrued interest on the funds generated from the sale of stock. Compensating the public for its delayed access to these funds could serve as a deterrent for other converting organizations that might attempt to contest their charitable obligations. Without this relief, Blue Cross plans have an incentive to continue to resist meeting their charitable obligations. They will not pay any penalty for assets lost to the foundation as a result of an initial failure to comply with charitable trust obligations.

In the context of litigation, the issue of "lost value" should be considered part of any settlement discussions or court-imposed remedy. Of course, this problem should not occur in states that have enacted specific legislation to regulate these transactions. Such legislation will generally require the conversion to take place according to specific procedures. These procedures should ensure that the foundation will receive the stock without the delay that results when a Blue Cross plan attempts to evade its charitable obligations.

3. Public Reimbursement for Private Inurement

Because the converted assets are derived from the nonprofit sector, the directors of converting Blue plans should receive no personal benefit from the conversion. Consumer groups have asked whether the public will be compensated for the significant and improper private inurement to Blue Cross officers that often occurs as a result of conversions.

Federal and state laws generally prohibit "private inurement" within the nonprofit framework.ⁿ⁹⁴ Section 501(c)(3) of the federal tax code provides that "no part" of the organization's net earnings can "inure to the benefit of any private shareholder or individual."ⁿ⁹⁵ This means no individual is permitted to gain financially from the operation or conversion of a nonprofit.ⁿ⁹⁶ The intent of these provisions is to distinguish between the characteristics of the nonprofit health organization (public-service oriented) from the for-profit model (profit oriented).ⁿ⁹⁷

n94 *When your Community Hospital Goes Up For Sale: A Guide to Understanding the Sale and Conversion of Not-For-Profit Hospitals to For-Profit Corporations and What You Can Do About It* 5 (1996) [hereinafter *Community Hospital Goes Up For Sale*].

n95 26 U.S.C. § 501(c)(3) (1998).

n96 *Community Hospital Goes Up For Sale*, *supra* note 94.

n97 *Id.*

Private inurement generally results when a portion of the exempt organization's net earnings is distributed to insurers or individuals such as directors, officers, and key employees, who exert some level of control over the organization. Private inurement has been an important issue in hospital conversion transactions. Many nonprofit hospital sales result in lucrative employment contracts for hospital management and/or trustees. This result raises the specter of private inurement and whether there are conflicts of interest for those involved in negotiating the sale. n98

n98 *Id.*

Similar concerns arise in Blue Cross conversions in which officers receive bonuses and stock options in conjunction with the conversion. For example, in the proposed BCBS-Ohio merger with Columbia/HCA, each Blue Cross board member who approved the deal would have received \$ 1 million-dollar retirement packages had the deal been approved. n99 In Missouri, Blue Cross executive Roy Heimberger received over a quarter of a million dollars as a bonus for conducting the public offering of RightCHOICE. n100 While this figure may appear insubstantial compared to the total amount of the proposed settlement, a quarter of a million dollars can be very significant for a potential grantee of a new conversion foundation.

n99 Silas, *supra* note 12.

n100 *Blue Cross and Blue Shield of Mo. v. Angoff* 2891, *appeal docketed*, No. 53798 (Mo. Ct. App. 1998).

State regulators and courts should certainly consider making repayment of any improper windfalls resulting from the conversions part of the final "conversion" agreement. In the BCBSMo transaction, the Special Master specifically asked the parties to provide information to the court regarding all stock options that were issued in connection with the RightCHOICE initial public offering, n101 thus indicating an awareness of the potential for improper private inurement relating to the conversion.

n101 *See* Order of Reference, *supra* note 88, at 5.

4. Potential Devaluation of Stock

When the resulting for-profit corporation meets its charitable obligation by transferring stock, a major issue in ascertaining the proper valuation is whether the stock that will fund the new foundation accurately reflects the value of the for-profit. If the stock is "devalued," then the public will not receive the full fair market value of the converted assets.

In Blue Cross conversions, the stock of a for-profit **company** may not reflect the full fair market value because of restrictions on the stock that are imposed by the BCBSA, which prevent the stock from being freely traded on the market. For example, the BCBSA rules prohibit any individual from obtaining more than five percent of the stock of a

for-profit Blues plan and prohibit conversion foundations from having the full voting rights that are normally associated with ownership. n102 In the absence of such restrictions, the equity interest of the foundation likely would command a higher price, given the possibility of a purchaser willing to pay a "control premium" for the majority interest in the for-profit entity. n103 The inability of a buyer to acquire the controlling interest in a Blue Cross plan because of the BCBSA's rules makes the stock less valuable than it would be without such restrictions.

n102 The impact of these valuation issues on conversions in California and New York conversions is addressed in James J. Barbra, *The Special Advisory Review Panel, Review of Empire's Conversion to a For-Profit Company* (May 1997) and in Mendoza & Kane, *supra* note 87.

According to the BCBSA, the conditions that attach to approval by BCBSA of a proposed for-profit conversion can be summarized as follows: (1) The Plan will have to remain in full compliance with all BCBSA rules except for the Foundation's initial ownership. This includes Charter provisions which in BCBSA's judgment adequately preclude other parties from obtaining more than 5% control and other protections against unwanted takeover efforts; (2) The Foundation will initially hold no more than 80% of the Plan's stock and will sell down its shares so that within five years, it is under the licensure minimums; (3) The Foundation will not have any involvement in the nominating process for Plan directors and its voting power over the Plan shall be consigned to a voting trust that, in BCBSA's judgment, provides adequate assurance that the Foundation will not influence or control the Plan; (4) The Foundation's Board will be impartially and independently selected and be free from any concentration of special interest, including the state or local government; and (5) The Foundation will be the only holder of 5% or more of the Plan's stock. *Blue Cross and Blue Shield Association ("BCBSA") Responses to Questions Submitted by Blue Cross and Blue Shield of Missouri ("BCBSMo")* (Dec. 15, 1998) [hereinafter *BCBSA Responses*].

n103 Bell, *supra* note 82; Mendoza & Kane, *supra* note 87.

In California, the BCBSA's rules "may have significantly undermined the conversion's total value to the foundation -- that is the public. In essence the rules made it impossible for the foundation to capture a valuable asset: the premium associated with ownership of a controlling interest in a particular **company**." n104 In New York, a Special Advisory Review Panel similarly questioned the ability of the foundation to receive a true market value through the sale of stock in light of the Blue Cross restrictions, the limitation on voting rights, and the lack of constraints on future stock sales by the **company**. The panel found that there was "no protection for the foundation against serious dilution of the value of their stock (whether on a per share basis, or as a whole)." n105 The panel recommended establishing the valuation "through *independent appraisals* and a negotiation between the **company**, the regulators, the court, and the foundation." n106

n104 Mendoza & Kane, *supra* note 87; Barbra, *supra* note 102.

n105 Barbra, *supra* note 102.

n106 *Id.* (emphasis added).

The trial court in Missouri also expressed concern that "the proposed settlement agreement places so many restrictions on the stock that there is a concern whether the fair market value of the shares will ever be realized" and inquired as to the value of an eighty percent interest in RightCHOICE "on the open market, without restrictions." n107 Perhaps for these reasons, the Colorado conversion statute provides that:

The [insurance] Commissioner shall determine the fair market value of the corporation at the time of conversion, determined as if it had voting stock outstanding and one hundred percent of its stock were freely transferable and available for purchase *without restrictions*. Consideration shall be given to market

value, investment or earnings value, net asset value, and a control premium, if any. If a qualifying entity or entities receive, at the time of conversion, one hundred percent of the shares of the then-outstanding stock of the corporation, the qualifying entity or entities shall be regarded as having acquired the fair market value of the corporation, *unless the commissioner finds that such outstanding stock does not represent the fair market value of the corporation.* n108

n107 Order of Reference, *supra* note 88, at 4.

n108 COLO. REV. STAT. § 10-16-324(4)(e)(B) (emphasis added).

State regulators can obtain expert assistance in ascertaining the impact of various restrictions on the value that will be transferred to the new foundation. If the value of the stock is too greatly diminished, funding the new foundations exclusively by a transfer of stock may not be in the best interests of the public. Regardless of the outcome of any such valuation, the public should be clearly apprised of the extent to which the value to be transferred to a conversion foundation deviates from the actual value of the **company**, as determined by valuation experts.

B. Form of the Transfer

The valuation issues discussed above could also have a direct impact on the method of transferring the for-profit's assets to the new foundation. In other words, the structure of the final agreement (i.e., the form in which assets are transferred) should be one which best captures the full fair market value of the nonprofit assets. If an independent appraisal determines that the stock is devalued significantly, state regulators and/or courts should consider alternative methods of funding the new foundation. For instance, the new foundation could receive the value entirely in cash or through the issuance of a note or other debt instrument.

Among the advantages of funding the foundation with cash or other alternatives to stock are that the foundation would not have to gamble on the future condition of the stock market. At the same time, however, cash alternatives to stock can preclude the foundation from realizing the potential increases in the value of the stock at a future point in time. This may be far superior to the amount of funds that can be realized if the stock is converted to cash at the time of conversion. Indeed, the California foundation's stock has greatly appreciated in value since the time of the original conversion agreement. n109

n109 Mendoza Testimony, *supra* note 89, at 48, 57; Memorandum in Support of Approval of Settlement, *supra* note 88, at 58-59.

Perhaps the best way to capture the full value of the nonprofit's assets is to provide the new foundation with a combination of sufficient start-up cash and stock in the new for-profit. n110 In order to fully compensate the public for the conversion of nonprofit assets in California, cash was provided to the new "conversion" foundations, *over and above* the stock in the for-profit subsidiary. n111 In Missouri, the proposed settlement of the litigation opted to fund the new foundation with all of the RightCHOICE stock owned by Blue Cross and \$ 175,000 cash to aid in the start-up costs of the foundation. These issues must be carefully reviewed in consultation with independent experts on valuation and nonprofit conversions.

n110 This method was used in California in 1991 when Health Net, a nonprofit California HMO, proposed to convert to for-profit status. The new nonprofit foundation received \$ 300 million in cash and 80% equity interest in Health Net's converted for-profit business. The combination equaled the market value of the nonprofit Health Net. Bell, *supra* note 82.

n111 Silas, *supra* note 12, at 267.

C. Voting Trusts

Another area of concern in setting up Blue Cross "conversion foundations" is the placement of the new foundation's shares in a "voting trust." The rules of the BCBSA require the establishment of a voting trust in order to comply with the requirement that no individual investor control more than five percent of the shares in a for-profit Blue Cross plan. n112

n112 BCBSA Responses, *supra* note 102.

In a voting trust agreement, the foundation formally transfers legal title of its shares in the for-profit to a trustee who will vote the shares in accordance with the agreement. n113 Thus, the foundation loses the right to freely vote the stock that it owns. The trustee will also have substantial limitations on his/her ability to vote the shares in the new for-profit **company**. The voting trust is a way to ensure that the new foundation does not control the activities of the new for-profit Blue Cross plan in spite of its ownership of a substantial majority of the shares in the new for-profit **company**.

n113 ROBERT CHARLES CLARK, CORPORATE LAW 777 (1986).

Historically, voting trusts have been viewed with great suspicion, an attitude that has been partially reversed by state statutes that specifically recognize and validate voting trusts. However, voting trusts are still control mechanisms that are subject to abuse by corporate officers and directors. n114 In the context of Blue Cross and Blue Shield conversions, the voting trust agreement significantly compromises the new foundation's rights as the primary shareholder of the for-profit corporation's stock. n115

n114 ROBERT HAMILTON, CASES AND MATERIALS ON CORPORATIONS: INCLUDING PARTNERSHIPS AND LIMITED LIABILITY COMPANIES 461 (6th ed. 1998). Justice Douglas described voting trusts as "little more than a vehicle for corporate kidnapping," a reflection of the early attitudes toward voting trusts. JAMES ALLEN ED., DEMOCRACY AND FINANCE 43 (1940).

n115 For example, in a similar conversion in California, the nonprofit foundation held approximately 80% of the equity securities of WellPoint, the for-profit subsidiary. However, the voting trust agreement required that the foundation could not vote more than 49% of the for-profit **company's** stock. *See* Mendoza & Kane, *supra* note 87.

As pointed out by Gary Mendoza, the California Corporations Commissioner, and Nancy Kane, an expert retained by the California Commissioner, the effect of the BCBSA rules -- which restrict the foundation's voting rights -- is "to assure managers of the for-profit plan . . . that they *would not have to be fully accountable to their largest shareholder*, the charitable foundation representing the public interest." n116 If not accountable (i.e., the shareholders do not have authority to vote on any issues related to the financial health of the **company**), there is a risk that the managers of the **company** will act in ways that do not maximize the value to the shareholders. The trial court in the BCBSM litigation similarly pointed out:

The parties propose that the Right Choice stock be placed into a voting trust. Voting rights are to [sic] exercised by a Trustee to be named (and apparently controlled) by Right Choice. . . . *The voting trust appears to eliminate any effective control by the Foundation*. Section 4.06 [of the proposed settlement agreement] would prohibit the Trustee from following instructions of the Foundation. Section 5.03 makes it clear that the Foundation would have no control over Right Choice's Board of Directors, in spite of the fact that the Foundation would own 80% of the stock. Sections 5.04 and 5.05 appears [sic] to

freeze the Foundation out of any meaningful role in the sale of the stock . . . Is Blue Cross, who has strayed from its nonprofit purposes, allowing the for-profit management of Right Choice to indirectly but effectively control the nonprofit assets of Blue Cross? n117

n116 *See id.* As indicated above, the lack of full voting rights may also devalue the stock controlled by the new foundation.

n117 Order of Reference, *supra* note 88, at 2-3 (emphasis added).

State regulators must ensure that the new foundation's charitable assets are not severely compromised under the terms of the voting trust. A voting trust agreement should include protections to enable the new foundation to retain some measure of control over its "investment" in the new for-profit's stock and receive the true value of the nonprofit assets.

While the new foundation has no interest in controlling the day-to-day operations of the new for-profit entity, it should have *some* protections against improper investments and mismanagement by the new for-profit's board and management. For instance, the foundation could be allowed to exercise full voting rights in circumstances in which decisions of the for-profit's board would have a material and detrimental financial impact on the new for-profit. Additionally, the trustee could be permitted to exercise full voting rights under certain stated financial conditions (e.g., the **company** loses money and/or no dividends are paid out for three consecutive years). n118 After all, the new foundation's own assets are directly related to the success of the new for-profit until the new foundation's divestiture of the for-profit's stock. Further, the agreement could prohibit the trustee from selling, transferring or assigning the shares in the trust without the direction of the foundation. Finally, the foundation should still retain ownership in the shares held in trust, including the right to receive dividends or other distributions. As discussed above, the voting trust restrictions are also a reason that state regulators may prefer not to fund a foundation entirely with stock.

n118 In the proposed Missouri settlement, the Foundation has limited authority to vote on matters of the new for-profit RightCHOICE. However, the proposed voting trust agreement does require the trustee to vote with a majority of *independent* board members, thus limiting the authority of the officers and directors of RightCHOICE to influence the trustee's voting decisions. Proposed Settlement Agreement, Blue Cross and Blue Shield of Mo. v. Angoff, at Exhibit L, 5 (Sept. 20, 1998) [hereinafter Proposed Settlement].

D. Divestiture of Assets

When Blue Cross plans convert to for-profit status and the foundation receives shares in the for-profit, the new foundation's stock will likely be subject to a predetermined divestiture plan. In addition, when the new foundation is funded through the sale of its shares of stock in the for-profit **company**, it must have the ability to divest itself of its shares without undue restrictions.

A final "conversion" agreement protects the new foundation as it divests its shares by affording the foundation appropriate "registration rights" -- rights concerning how and when the stock is registered for sale on the stock market. Ideally, the conversion transaction will include a divestiture plan that would protect the foundation and help it retain as much flexibility as possible when it divests stock. n119 The flexibility would allow the new foundation to make advantageous decisions and would prevent the new foundation from being required to divest stock at inopportune times. n120

n119 *See* Letter from Consumers Union and Community Catalyst to Jeremiah Nixon, Attorney General, Jay Angoff, Director, Department of Insurance, and Mel Carnahan, Governor of Missouri, 3-4 (May 11, 1998) (on file with the author).

n120 *Id.*

Two specific rights that would help the foundation divest its stock are "demand registration rights" and "piggyback registration rights." Demand registration rights allow the new foundation to demand the for-profit register the foundation's stock in the for-profit **company**. Too many restrictions on the foundation's ability to exercise a demand could make it difficult for the new foundation to divest its shares in the for-profit. The problem is that such restrictions may require the foundation to sell its stock at times under which market conditions are unfavorable (e.g., if the foundation is allowed only one registration per year). Without such limitations, the foundation can sell its securities at times of its own choosing. Therefore, a final conversion agreement should not unduly restrict the foundation's rights by imposing inflexible "time limitations" and/or caps on the number of demands the new foundation can exercise. n121

n121 *Id.*

The new foundation must also be given sufficient piggyback rights. Piggyback rights afford the foundation an opportunity to participate in any registration the for-profit conducts. This protection enables the new foundation to use its assets for public benefit rather than incur the expense of registering its own shares of stock.

E. Tax Status

An issue that also arises when a new foundation is created is the new foundation's tax status. A foundation that results from a Blue Cross conversion may be a section 501(c)(3) private foundation, a section 501(c)(4) social welfare foundation, or a combination of the two. n122

n122 26 U.S.C. §§ 501(c)(3), 501(c)(4).

Section 501(c)(3) private foundations are charitable organizations that are tax-exempt under section 501(c)(3) of the Internal Revenue Code ("IRC") and classified as private foundations under section 509(a) of the code. Private foundations are funded primarily from one source and receive ongoing funding through investment income rather than charitable contributions. n123 Section 501(c)(3) states that an organization must be "organized and operated exclusively for religious, charitable, scientific, testing of public safety, literary, or educational purposes" n124 A disadvantage to a section 501(c)(3) is that under this tax status, the foundation would be required to pay a tax on its net investment income, a tax that is not required of 501(c)(4)s. n125

n123 Isaacs, *supra* note 4.

n124 26 U.S.C. § 501(c)(3).

n125 26 U.S.C. § 4940 (1998).

However, section 501(c)(3) private foundations are required to comply with a number of beneficial consumer protections that are stronger than the protections required of section 501(c)(4) foundations. For instance, a section 501(c)(3) private foundation is required to make grants in amounts of at least five percent of its total assets each year, thus ensuring that the foundation is engaged in substantial charitable activity. n126 In addition, although private inurement is prohibited in most nonprofit organizations, section 501(c)(3) private foundations are specifically prohibited from engaging in transactions between the foundation and its board, management, entities, and individuals related to the board or management. n127 A section 501(c)(3) private foundation is limited in its ability to lobby or endorse candidates for public office, or fund political campaigns. n128 The assets of a section 501(c)(3) private foundation also

have protections in that the foundation is subject to penalties for investments that jeopardize the charitable purpose of the foundation. n129 Finally, the reporting requirements are more stringent for a section 501(c)(3) private foundation. The foundation is required to file a Form 990-PF that requires detailed reporting about self-dealing transactions, failure to distribute income as required, excess business holdings, investments that jeopardize charitable purposes, taxable expenditures, and political expenditures. n130

n126 Isaacs, *supra* note 4.

n127 26 U.S.C. § 4941 (1998); Nancy M. Kane, *Some Guidelines for Managing Charitable Assets from Conversions*, HEALTH AFF. (Mar.-Apr. 1997).

n128 26 U.S.C. § 4945 (1998).

n129 26 U.S.C. § 4944(a)(1) (1998).

n130 26 U.S.C. § 6033(a)-(c) (1998). *See generally* BRUCE R. HOPKINS, THE LAW OF TAX-EXEMPT ORGANIZATIONS 769-71 (6th ed. 1992 & Supp. 1997).

Section 501(c)(4) foundations are "social welfare" organizations that are tax-exempt under section 501(c)(4) of the IRC. A section 501(c)(4) organization must be engaged exclusively in social welfare activities. n131 501(c)(4)'s are not bound by the consumer protections that are required of 501(c)(3)'s and are not subject to the tax on investment income that applies to 501(c)(3) organizations.

n131 "Social welfare" is a somewhat vaguely defined notion of "consumer good and general welfare." Activities of 501(c)(4) organizations must benefit a broad community, not just a limited group. Kane, *supra* note 127.

One alternative to creating a 501(c)(3) private foundation is to establish a section 501(c)(4) foundation and require that the section 501(c)(3) private foundation protections be incorporated into the articles of incorporation and by-laws of the new foundation. This is the approach proposed in the Missouri and Colorado Blue Cross conversions. n132 This approach would require section 501(c)(3) protections while avoiding a two percent tax on the new foundation's net investment income that section 501(c)(3) private foundations must pay. n133 The avoidance of significant tax liability for the foundation may justify this approach. The potential downside to this methodology is that the state attorney general, rather than the IRS, is charged with enforcing these protections. n134

n132 *See, e.g.*, CARING FOR COLORADO FOUNDATION, ARTICLES OF INCORPORATION 1-2 (The Caring for Colorado Foundation will receive the assets of Blue Cross and Blue Shield of Colorado when it converts to for-profit status.). *See also* Proposed Settlement, *supra* note 118, at Exhibit A, 2.

n133 26 U.S.C. § 4940.

n134 *See, e.g.*, Kane, *supra* note 127.

Another approach is to endow two foundations -- a section 501(c)(3) private foundation and a section 501(c)(4) foundation -- with the 501(c)(4) holding and divesting the stock and using the proceeds to fund the 501(c)(3) which serves the grantmaking function. California regulators applied this approach when BC-Cal converted to for-profit status. The 501(c)(3) had the primary function of grantmaking and investment management, financed by Wellpoint's (the new

for-profit subsidiary's) monetization (the foundation also received more than \$ 1 billion in cash up front). The 501(c)(4) had the primary function of maximizing the value generated from the monetization of WellPoint successor **company** stock and then transferring at least eighty percent of the proceeds to the 501(c)(3). The 501(c)(4) received eighty percent of the stock of the WellPoint successor **company**. n135

n135 *Id.*

Establishing two foundations (a 501(c)(3) and (c)(4)) may be wasteful and expensive because of the duplication of administrative and management expenses. Indeed, the former California Corporations Commissioner testified to this effect in the Missouri litigation. n136 It is far more preferable to spend available resources on fulfilling the purposes of the new foundation rather than on duplicative expenses. Therefore, designating a section 501(c)(4) social welfare foundation with the section 501(c)(3) protections may be the best approach because it avoids the tax liability that 501(c)(3)'s would incur.

n136 Mendoza Testimony, *supra* note 89, at 67-68.

F. Governance of New Foundation

Once the new foundation is created, state regulators must address the selection of the new foundation's board members, including the method of board selection and the degree of independence between the foundation and the converting for-profit.

1. Selection of the Board of Directors

The composition of the board of directors is a critical issue in conversion transactions. Consumer groups have argued that the board should reflect the diversity of the community in ethnicity, race, socioeconomic status, and gender. Additionally, consumer groups have argued that the board should represent the interests of consumers and the community at large, rather than simply healthcare providers. Recent conversion agreements have included provisions to this effect. n137 These provisions are designed to ensure that the foundation will truly represent the diversity of interests in the communities that Blue Cross was originally designed to serve. Consumer groups in Missouri, for example, presented evidence of the great variety of healthcare needs in the rural and urban areas previously served by Blue Cross. A diverse board that is representative of the community can help ensure that the wide ranging health needs of the community are met. n138

n137 For example, the proposed Bylaws of the Caring for Colorado Foundation state that the Directors should be selected so that as a whole they represent the geographic, ethnic, gender, age, socioeconomic and other factors that the board considers to represent the diversity of Colorado society. CARING FOR COLORADO FOUNDATION, BYLAWS art. III, § 3.3. In Missouri, the board of directors should "represent the state's gender, racial, cultural, geographic and ethnic diversity." *See* Proposed Settlement, *supra* note 118, at Exhibit B, art. 4.2.4.

n138 Test. of Edwin Kahn, Tr. at 134-35, Blue Cross and Blue Shield of Mo. v. Angoff, No. CV196-619CC (Dec. 4, 1998) [hereinafter Kahn Testimony]; Test. of Deborah Cowan, Tr. at 162-64, Blue Cross and Blue Shield of Mo. v. Angoff, No. CV196-619CC (Dec. 4, 1998) [hereinafter Cowan Testimony].

The board can be selected several ways. One approach is for an independent nominating group or community advisory committee to recommend potential board members to be initially appointed by the DOI, Attorney General, or the Governor. n139 Such committees may include a stable and diverse mix of public or private nonprofit community members who are primarily concerned with the healthcare needs of the state's low-income and vulnerable populations.

Consumer groups that have a demonstrated record of advocacy for health resources for low income persons can be given significant input regarding the members of the nominating group. The new foundation's articles of incorporation may provide for a *continuing* community advisory committee that is responsible for the nomination of board members in the future (i.e., after the appointment of the initial board). n140 After the initial board selection, the State need not have any role in ongoing board selection, which is the continuing role of the community advisory committee. n141

n139 In the proposed Missouri settlement, the community advisory committee would eventually select board members but the initial board would be chosen by the Governor and the Attorney General subject to qualifications enumerated in the new foundation's articles of incorporation. See Proposed Settlement, *supra* note 118, at Exhibit B, 2, art. 4.2.2.

n140 For a more detailed discussion of the role of consumer advisory committees, see, e.g., Deborah Cowan et al., *Community Advisory Committees: An Important Structural Provision for Conversion Foundations* (on file with author); Julie Silas et al., *Community Advisory Committees: Important Role in Conversion Foundations* (available from Consumers Union (415-431-6747) and Community Catalyst (617-338-6035)).

n141 The selection of the initial board is particularly important because the initial board "sets the tone" for the foundation. If consumer representatives are not there at the outset to help set the tone for the future and the direction of the board and the board staff, then their impact afterward is likely to be minimized. Kahn Testimony, *supra* note 138, at 152-53. In addition, the initial board will make many choices and decisions that will shape the foundation, establish its reputation, and set its direction. Cowan Testimony, *supra* note 138, at 163. For these reasons, Missouri consumer groups advocated for a consumer advisory committee to play an active role in the initial board selection. Memorandum of Amici Curiae, *supra* note 85.

The advantage to using a community advisory committee is the greater likelihood that the board will reflect the real diversity of interests in the community, rather than be the result of a political process in which persons with political or financial influence are selected regardless of whether they have expertise in the healthcare needs of the community. For example, in Colorado, the original plan was to appoint to the board the directors of the three largest foundations in the state, the Chief Justice of the Colorado Supreme Court, the president of the University of Denver, and the dean of the medical school. n142 Subsequently a community advisory committee was established that was far more reflective of the diversity of interests across the state. The advisory committee included representatives from one of the largest health providers in the state, from Legal Aid, from a clinic that serves migrant workers, from **nursing homes**, as well as healthcare consumers. n143

n142 Kahn Testimony, *supra* note 138, at 133.

n143 *Id.* at 134.

Ongoing public input can continue through the community advisory committee once the new foundation is established. The committee can serve as an ongoing operational committee to advise and assist board members with their community outreach activities and obligations, and to ensure community input in all facets of the new foundation. Thus, the committee would assist the new foundation board in identifying community healthcare needs and create an information exchange between the community and the new foundation.

Two potential problems in using this method of board selection are the additional costs associated with establishing such a committee and the steps that it adds to the process of board selection that can further delay the process. Nonetheless, the value of ensuring community input into board selection may well be worth any such additional cost or delay. n144

n144 In the Colorado conversion process, Professor Kane testified that the process by which board members are selected must include

both public input and expedience. *See* Pre-Hearing Test. of Dr. Nancy Morgan Kane, at 10, *Blue Cross and Blue Shield of Mo. v. Angoff*, No. 0-97-024 (discussing her testimony before the Division of Insurance, State of Colorado). Professor Kane also disagreed with the notion of having "interest groups" participate on the board itself. She stated that using political criteria rather than public health criteria to provide services to the under-served would distract the board. The board might get too involved in the grant-making rather than focusing on improving the health of Colorado citizens *Id.* at 9. As indicated above, Colorado ultimately chose to use a community advisory committee to select a Board of Directors.

One alternative to the community advisory committee is the public search process used in California. Three executive search agencies and an independent advisory group of three distinguished persons from the public health arena, BC-Cal, and the California Department of Corporations conducted a public search for board members. The national search led to a list of twenty-four candidates, from which the fourteen board members were chosen by BC-Cal. n145 The final board members included three persons with extensive foundation backgrounds, four with financial management/investment banking experience, three with independent public health experience, two with medical backgrounds, two from community agencies in health or legal services, and three with corporate management experience. n146

n145 Kane, *supra* note 127.

n146 *Id.*

According to Professor Nancy Kane, who assisted the state with the board selection process, California's methodology succeed in getting "new blood" community representation on the board. However, Professor Kane questioned whether such an extensive process could be replicated in other conversions -- depending in part on the ability and willingness of states' attorneys general to insist on such a process and the research that can be obtained from the converting organization. n147

n147 *Id.* at 235.

2. Board Independence

Another issue that arises regarding foundation governance is the degree of independence between the new conversion foundation and the new for-profit Blue Cross plan. State attorneys general must determine whether there are any potential conflicts of interests, including conflicts that arise from the transfer of assets to charitable foundations. Consumer groups argue that staff, executives, and officers of the converting or restructuring corporations should be prohibited from serving on the board or being employed by a foundation created as a result of the conversion or restructuring. n148 The interests of the new foundation are simply inconsistent with those of the new for-profit **company**.

n148 In Missouri, consumer groups argued strenuously against allowing Blue Cross to have any role on the board of the new foundation. Memorandum of Amici Curiae, *supra* note 85. In the New York Blue Cross and Blue Shield conversion to for-profit status, the Special Advisory Review Panel similarly recommended that there be no overlap between the board of the new foundation and either the board of the new for-profit corporation or the board of the existing nonprofit. Barbra, *supra* note 102, at 4.

In some recent hospital transactions, the resulting charitable foundation has been given part ownership of the for-profit hospital, calling into question the independence of the charitable foundation for several reasons. n149 Officers and directors who negotiate the sale and conversion of a nonprofit entity often accept lucrative positions in the for-profit buyer's **company** or in the foundation that has been established with the proceeds of the sale. n150 In such circumstances, the foundation might not choose to fund projects of nonprofit hospitals that compete with the for-profit hospital of which they have become part owner. n151 Or, they might be pressured by the new for-profit into funding

certain services. For example, in Tennessee, the Attorney General consented to sale agreements that required a portion of the nonprofit foundation's earnings to go back to the for-profit purchaser. n152

n149 Gabay & Wolfe, *supra* note 81, at 20.

n150 *Id.* See also *Community Hospital Goes Up For Sale*, *supra* note 94, at 4.

n151 For example, Thomas Frist, Jr., former chairman, president, and CEO of Hospital Corporation of America and now vice chairman of Columbia/HCA stated that he wanted the foundations to fund some money-losing operations at HCA's hospitals. Gabay & Wolfe, *supra* note 81, at 20.

n152 *Converting to For-Profit Health Care: What Advocates Should Know*, 5 STATES OF HEALTH 1 (Nov. 1995).

Several problems may occur in Blue Cross conversion transactions if the new for-profit is allowed to retain influence over the charitable assets. Blue Cross board members (who may want to be represented on the new foundation board) have already had relationships with the management of the for-profit **company** and may be subject to improper influence. The new for-profit Blue Cross could pressure the foundation to award grants that benefit or even purchase insurance from the new for-profit corporation. n153 In addition, Blue Cross could influence the foundation board's decisions regarding the sale and divestiture of stock -- decisions which should be based on maximizing value to the foundation, rather than serving the financial interests of the new for-profit Blue Cross plan.

n153 The proposed Missouri Blue Cross settlement included a provision that would give RightCHOICE preferential bidding status if the new foundation decides to purchase health benefits products. According to the settlement, the new foundation must provide RightCHOICE the final opportunity to provide health benefit products on the same terms as other potential providers before the new foundation would purchase any product from any other provider. Proposed Settlement, *supra* note 118, at Exhibit E, 20. While neither regulators nor consumer groups anticipate that the Foundation will purchase health insurance, the inclusion of such a provision granting preference to RightCHOICE in the foundation's activities is, at a minimum, problematic and inconsistent with the goal of prohibiting conflicts of interest between RightCHOICE and the new conversion foundation.

Consumer groups have argued that when a Blue Cross plan's improper and illegal conduct precipitated the conversion controversy, it is highly inappropriate for Blue Cross to have any influence over the new foundation. A Blue Cross plan's attempt to convert without complying with its charitable trust obligations should preclude it from having any role when it finally transfers its assets to a charitable foundation.

The trial court in Missouri expressed a similar concern. The court questioned whether Blue Cross, which had strayed from its nonprofit purposes, should allow the for-profit management of RightCHOICE to indirectly but effectively control the nonprofit assets of Blue Cross in the proposed settlement. n154 Given the findings that Blue Cross had engaged in illegal activity in reorganizing as a for-profit and the inherent conflicts between for-profit and nonprofit purposes, it would be inappropriate for Blue Cross to play a role in the new charitable foundation formed as a result of the conversion.

n154 Order of Reference, *supra* note 88, at 2-3.

If Blue Cross board members are permitted to be on the new foundation's board, then the final conversion agreement should include time limits on the tenure of the board and provide that the Blue Cross directors will be considered *with all of the other potential candidates* rather than guaranteed positions on the board. n155 Because of the problems identified above, state attorneys general should carefully examine any potential conflicts of interest that might result from any such conversions and ensure the highest degree of independence between the new foundation and the

converting nonprofit.

n155 The preliminary settlement in Missouri would have allowed a minority of the new foundation's directors to be directors of Blue Cross or RightCHOICE. See *Highlights of Conceptual Framework Jointly Proposed By Governor Mel Carnahan, Attorney General Jay Nixon, Department of Insurance Director Jay Angoff and Blue Cross and Blue Shield of Missouri* (Apr. 22, 1998) (provided in Blue Cross Press Packet). This provision was at odds with the position that consumer groups have taken during the course of this controversy, and was subsequently dropped from the proposed settlement.

G. Foundation Purposes

The purpose of the new foundation, which is set forth in the foundation's articles of incorporation, is a critical issue. The purpose statement indicates the mission of the foundation, guides the board of directors in decision-making, and determines how the foundation allocates its funding. The purpose statement may also come into play in the event of a *cy pres* proceeding because courts will look to the purpose statement to determine how the foundation's assets should be used in the event that its original purposes become frustrated. The foundation's purpose should be broad enough to encompass changing healthcare needs, yet not too broad so as to divert the assets for purposes for which the assets were originally unintended.

There have certainly been examples in which charitable healthcare assets were diverted to questionable purposes as a result of a conversion. For example, one foundation resulting from the sale of a nonprofit hospital considered financing a sports training complex, arts center, and a foreign language program. n156 Although these may be worthwhile objectives, they are not the original reasons that society invested in nonprofit hospitals and insurers. n157 This result would almost certainly violate the doctrine of *cy pres*, requiring that charitable assets be used as closely as possible to the original purposes of the nonprofit. n158

n156 Kane, *supra* note 127. In other such conversions, the sale proceeds have gone to such unrelated purposes as flying lessons for high school students and ethnic festivals. See, e.g., Greg Jaffe & Monica Langley, *Generous to a Fault? Fledgling Charities Get Billions From the Sales of Nonprofit Hospitals*, WALL ST.J., Nov. 6, 1996, at A1.

n157 Gerard F. Anderson, *The Role of Investment Bankers in Nonprofit Conversions*, HEALTH AFF. (Mar.-Apr. 1997).

n158 The *cy pres* doctrine holds that when a charitable trust becomes impossible, inexpedient, or impracticable to fulfill, a court may substitute another charitable object that is believed to approach the original purposes as closely as possible. See, e.g., *Levings v. Danforth*, 512 S.W.2d 207 (Mo. Ct. App. 1974). In Ohio, the Attorney General has not only required that the charitable assets be dedicated to healthcare purposes but has more specifically required, in the case of a converting psychiatric hospital (whose assets were accumulated for a more narrow charitable purpose), that the proceeds from the sale had to be dedicated to mental healthcare. Mayton, *supra* note 14.

To prevent such results, consumer groups have generally insisted that the new "conversion" foundations be dedicated to charitable health purposes, with a particular emphasis on underserved populations. This purpose is broad enough to serve the public's needs in an evolving healthcare industry. n159 Within the broad charitable mission, the board members, and not the government, should decide the specific grants for which such charitable assets should be used. Given the substantial nature of the likely endowments resulting from Blue Cross conversions, the new foundations should be in a position to make large grants that could significantly impact the medically underserved. However, the new foundations will not be in a position to provide health insurance coverage for large groups of residents. Although the new foundation may choose to fund pilot programs, requiring the new foundation to provide health insurance coverage would quickly deplete the foundation's assets. n160 If, however, the foundation uses its funds to provide grants and fund pilot programs, its funds can last forever. Additionally, the new foundation should not supplant government's responsibilities to provide and regulate healthcare. n161 While conversion foundations' endowments are significant, they are simply insufficient to replace what government can do to cover its uninsured citizens. n162 The proposed Missouri and Colorado approaches of endowing foundations dedicated to charitable health purposes are most

consistent with the *cy pres* and charitable trust doctrines.

n159 For example, the Caring for Colorado Foundation has the following broad mission statement:

The mission of the corporation is to promote and serve the healthcare needs of the citizens of Colorado. Underlying the corporation's mission and essential to its implementation is adherence to the following Core Values: (a) Corporation programs and grants will support activities that aim to achieve measurable improvements in the health of Colorado citizens, particularly the health of underserved populations, (b) Corporation programs and grants will supplement, and not supplant, the activities of government, (c) Program initiatives will be designed with the flexibility to incorporate ongoing community input and collaboration in their definition and implementation. This flexibility will permit small grants as well as larger, longer-term grants, and will permit the funding of existing as well as new community programs, (d) the corporation will incorporate population based vital statistics and other health indicators relevant to local communities in its strategic decision-making and funding priorities, (e) the corporation will seek opportunities to collaborate with other foundations as well as public and private organizations in the pursuit of program goals.

CARING FOR COLORADO FOUNDATION, ARTICLES OF INCORPORATION 1-2.

n160 For example, in Missouri, approximately 755,000 people were without healthcare coverage in 1995. Missouri Dep't of Health, *Provisional Statistics*, 31 MO. MONTHLY VITAL STAT. 9 (Nov. 1997).

n161 The Missouri settlement explicitly includes a provision indicating that the foundation will not supplant the existing responsibilities of government. Proposed Settlement, *supra* note 118, at Exhibit B, 21.

n162 Cowan Testimony, *supra* note 138, at 167-68; Test. of Patrick Harvey, Tr. at 85-86, Blue Cross and Blue Shield of Mo. v. Angoff, No. CV196-619CC (Dec. 4, 1998); Test. of Garland Land, Tr. at 107, Blue Cross and Blue Shield of Mo. v. Angoff, No. CV196-619CC (Dec. 4, 1998); Test. of Tullia Hamilton, Tr. at 176, Blue Cross and Blue Shield of Mo. v. Angoff, No. CV196-619CC (Dec. 4, 1998).

H. Foundation Representation

Although state attorneys general represent the interests of the public as guardians of charitable assets, at some point, new foundations will need their *own* representation free from political considerations or public pressure. In Missouri, consumer groups recommended that the new foundation, as the contemplated owner of eighty percent of RightCHOICE's equity, should be independently represented during the course of the negotiations. n163

n163 See Letter from Joel D. Ferber & Ann B. Lever, Attorneys for Amicus Curiae Reform Organization of Welfare, to Jeremiah W. Nixon, Attorney General of Missouri, and Jay Angoff, Director, Missouri Department of Insurance (May 11, 1998) (on file with the author).

One approach to ensuring the new foundation is adequately represented is to establish a temporary board to ensure that the concerns of the foundation are fully represented throughout the process without having to delay negotiations until the new foundation is created. n164 Another approach would be to include the funds to hire an impartial investment advisor and/or securities lawyer in the start-up costs of the new foundation. This representative would ensure that the new foundation will make informed financial decisions and would protect the new foundation's future assets. Blue Cross could be required to cover the cost of the new foundation's representative. Bringing in a representative at an early stage could also help with such issues as the effect of limited voting rights on valuation of the assets and the impact of any independent valuation on the form in which the foundation is transferred the nonprofit assets.

n164 In the New York Blue Cross and Blue Shield conversion, the Special Advisory Panel recommended a temporary foundation board to avoid some of the delays that may occur in creating or selecting a foundation. Barbra, *supra* note 102, at 3.

I. Public Involvement

Public involvement is critical to ensuring an equitable resolution of nonprofit healthcare conversions. After all, the public is the beneficiary of the charitable trust with which a nonprofit's assets are endowed. In Missouri, consumer groups have argued that there would be no lawsuit, let alone a settlement, if it had not been for the vigilant advocacy of Missouri consumer groups. n165 Therefore, state attorneys general should seek public input and involvement from consumer-based organizations as proposed conversion agreements are developed. State regulators should make the public aware of all the critical details including the divestiture plan, voting trust agreement, and the valuation of the **company**.

n165 The Attorney General took no position on the Blue Cross "reorganization" until he was sued by Blue Cross.

When the public is involved in conversions, community interests are more likely to be protected and preserved. n166 According to one state's deputy attorney general, government officials act in secrecy in these matters for one of three reasons:

- (1) they do not really know what they are doing and are afraid someone will find out;
- (2) they do not understand the full implication of the fact that the nonprofit's assets belong to the public; or
- (3) something untoward is actually going on. n167

n166 See Bell, *supra* note 82.

n167 Schwartz, *supra* note 84.

For these reasons, public input and disclosure are critical.

In the BCBSMo controversy, consumer groups inserted themselves in the process through various means, including filing amici curiae briefs in the trial and appellate courts, corresponding and meeting regularly with state regulators, and appearing through counsel at hearings before the Special Master. Consumer groups in other states have similarly involved themselves in "conversion" processes to ensure that public and consumer input is part of the process.

V. Conclusion

Conversions of nonprofit health plans are an increasingly important aspect of the changes in our nation's healthcare system. A multitude of issues must be addressed to ensure that the public interest is served when such conversions occur. The resolution of these issues will help determine whether ongoing and future Blue Cross conversions are truly in the public interest.

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TITLE: Articles: What Litigators Need to Know About HIPAA

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TEXT:

ABSTRACT: HIPAA's Privacy Regulations impose a number of new requirements on Covered Entities concerning disclosure of an individual's personal health information. This Article briefly outlines the primary function of HIPAA's general nondisclosure rule and discusses the exceptions under which HIPAA permits disclosure in the course of litigation or government investigations.

Requests for confidential health information, in the context of healthcare-related litigation or government investigations, involve very sensitive issues and can arise in a variety of situations. A medical malpractice case will involve the disclosure of sensitive medical information about the plaintiff. A hospital may be asked to produce medical information relating to dozens or hundreds of patients in connection with an antitrust case. A self-insured employer or health plan may be asked by the Department of Labor (DOL) to produce medical information about individual employees or insureds. So too, a medical billing **company** may be asked to produce medical information in connection with a lawsuit or investigation under the federal False Claims Act.

Handling requests for confidential health information often entails a delicate balancing act between the requesting party's need for the information sought, on one hand, and the privacy rights of the individuals whose medical information is requested, on the other. Making matters more difficult, the disclosure of confidential health information is subject to a labyrinth of overlapping, and sometimes conflicting, federal and state laws. Providers--and their lawyers--who disclose or obtain confidential health information in violation of state laws have been held liable for such violations under a variety of state common-law theories. n1

n1 *See, e.g.,* Jeffrey H. v. Imai, Tadlock & Keeney, 101 Cal. Rptr. 2d 916, 926 (App. 2000) (reversing dismissal of claim against a law firm for invasion of privacy arising out of the "willful and unnecessary disclosure of constitutionally protected [health] information"); Biddle v. Warren Gen. Hosp., 715 N.E.2d 518, 521, 528 (Ohio 1999) (recognizing tort action against a law firm for inducing a client hospital's unauthorized disclosure of nonpublic medical information). *See also* Mann v. Univ. of Cincinnati, 152 F.R.D. 119, 127 (S.D. Ohio 1993) (affirming Rule 37 sanctions against a law firm for improper use of a subpoena to obtain plaintiff's medical records).

In April 2003, regulations (the Privacy Regulations) promulgated by the United States Department of Health and Human Services (HHS) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) n2 took effect. n3 While many states have their own laws governing health information, the existence and scope of those protections vary from state to state. The Privacy Regulations are the culmination of a congressional effort to establish a uniform

federal "floor" of privacy protections for individual medical information, establishing a firm default rule that an individual's health information may not be disclosed unless disclosure is expressly permitted by the Privacy Regulations. n4 Although the Privacy Regulations preempt certain state laws, they do not preempt state laws that are "more stringent" than the Privacy Regulations. Thus, Covered Entities need to be familiar both with the Privacy Regulations and with any applicable state laws.

n2 Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 26, 29, and 42 U.S.C.).

n3 Small health plans (those having annual receipts of \$ 5 million or less) are not required to comply with the Privacy Regulations until April 14, 2004. 45 C.F.R. § 164.534(b)(2) (2003).

n4 *See id.* § 164.502(a).

This Article will generally describe how the Privacy Regulations affect requests for health information in the context of litigation or government investigations, and will outline the circumstances under which the Privacy Regulations permit disclosure. The Privacy Regulations will affect a broad range of clients and have implications not only for healthcare attorneys, but also attorneys specializing in other fields involving clients that create or have access to personal health information, including environmental law, products liability, labor and employment law, and employee benefits. In addition, the Privacy Regulations will affect virtually any employer that offers health insurance regulated by the Employee Retirement Income Security Act (ERISA), regardless of the nature of the employer's underlying business.

This Article is divided into two parts. The first part provides general information concerning HIPAA and exceptions to the general nondisclosure rule that are most applicable to requests for disclosure of confidential health information in the context of litigation or government investigations. The second part of the Article discusses a number of related issues of which those who deal with disclosures of confidential health information in the course of litigation or government investigations should be aware. This section includes a discussion of how overlapping exceptions to HIPAA's general nondisclosure rule are treated, and how the Privacy Regulations interact with existing federal and state laws governing disclosure of protected health information. It also examines the potential consequences for those who do not comply with the Privacy Regulations.

I. HIPAA's General Nondisclosure Rule and its Exceptions

A detailed discussion of the Privacy Regulations is beyond the scope of this Article, but the basic rule provides that a person's individually identifiable health information (IIHI) cannot be disclosed unless the patient has consented in writing to the disclosure, or unless disclosure is otherwise specifically permitted or required by the Privacy Regulations. n5 IIHI is broadly defined to include any oral or written information that:

(1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual and

(i) That identifies the individual; or

(ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual. n6

n5 *Id.*

n6 *Id.* § 160.103.

Technically, the Privacy Regulations apply only to "Covered Entities." These include any "health plan," "health care clearinghouse," or "health care provider who transmits any health information in electronic form." n7 Common types of Covered Entities include physicians, hospitals and hospital systems, **nursing homes**, durable medical equipment **companies**, healthcare billing **companies**, self-insured employers, health maintenance organizations (HMOs), preferred provider organizations (PPOs), and government insurers such as the Centers for Medicare and Medicaid Services (CMS). n8 Because ERISA may treat the provision of health insurance by an employer as a "health plan" legally distinct from the employer (regardless of whether the employer treats it as such), n9 any business that offers its employees health insurance through an ERISA-regulated plan may be (or may sponsor) a Covered Entity, regardless of whether the employer's business involves a healthcare-related field. As an aid, the CMS Web site includes questionnaires to help a **company** determine whether it is a Covered Entity. n10

n7 *Id.* § 160.102(a).

n8 The term "health plan," as defined in the Privacy Regulations, does not include all types of insurers that traditionally deal with health-related issues. While it includes, for example, any employee welfare benefit plan (insured or self-insured) subject to ERISA, it specifically *excludes* the following types of insurers, despite the fact that these insurers are likely to create, receive, or have access to, health-related information: accident insurance; disability income insurance; supplements to liability insurance; liability insurance (including general liability insurance and automobile liability insurance); workers' compensation insurance; automobile medical payment insurance; credit-only insurance; and coverage for on-site medical clinics. *See* 45 C.F.R. § 160.103 (2003); 42 U.S.C. § 300gg-91(c)(1) (2003).

n9 29 U.S.C. § 1129(d)(1) (2003).

n10 Centers for Medicare and Medicaid Services, *Covered Entity Decision Tools*, at cms.hhs.gov/hipaa/hipaa2/support/tools/decisionsupport/default.asp (last visited June 23, 2003).

When faced with a request for IIIHI in the course of litigation or a government investigation, obtaining written consent from the individuals whose IIIHI is requested may not be easy. In a medical malpractice case, obtaining the plaintiff's consent for disclosure of his IIIHI should not be difficult. Yet, when a Covered Entity is asked to disclose IIIHI relating to large numbers of individuals who are not parties to the litigation, as may be the case in antitrust, false claims, or other business-related litigation, obtaining the consent from all of the individuals may be prohibitively burdensome or expensive.

In lieu of obtaining individual consent, a Covered Entity could also elect to redact IIIHI. To sufficiently "de-identify" health information, however, is a cumbersome task. A Covered Entity must ensure that eighteen different types of identifiers, including the patient's name, street address, phone numbers, e-mail addresses, photographs, and medical record numbers, are redacted. n11 As a practical matter, when large numbers of records are involved, the process of de-identification may be as prohibitively burdensome and expensive as obtaining individual consent.

n11 *See* 45 C.F.R. § 164.514(a), (b) (2003).

When individual consent cannot be obtained, and de-identification is not an option, a Covered Entity may not

disclose IIIHI unless one of the enumerated exceptions to HIPAA's general nondisclosure rule applies. When disclosure is sought in connection with litigation or a government investigation, there are three exceptions that are most likely to apply: (1) disclosures in judicial or administrative proceedings; (2) disclosures for health oversight activities; and (3) disclosures for law-enforcement purposes. n12

n12 *See id.* § 164.512(d)-(f).

Even if an exception applies, however, this is not the end of the inquiry. The Privacy Regulations and their exceptions merely set forth the circumstances under which federal law *permits* disclosure. They do not stand in the way of any "more stringent" state laws that prohibit disclosure of IIIHI.

A. Litigation or Administrative Proceedings

The Privacy Regulations impose strict new guidelines on Covered Entities for disclosing IIIHI during the course of litigation or administrative proceedings. HHS, which is responsible for implementing and enforcing HIPAA, stated that the new protections afforded by the Privacy Regulations are necessitated because, "the current system [of discovery] . . . does not provide sufficient protection for protected health information." n13

n13 Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,596.

The Privacy Regulations' limitations on the use or disclosure of health information in litigation or administrative proceedings apply regardless of whether the Covered Entity is a party to the proceedings, and regardless of whether the proceedings take place in a state or federal forum. n14 The regulations and commentary are directed towards proceedings before "courts" and "administrative tribunals." n15 This leaves open the question of whether less-formal alternative dispute resolution procedures, such as arbitration and mediation, are covered by the regulations. It would create a strange problem if the regulations did not apply, as it would make it much more difficult to obtain IIIHI in arbitration or mediation than in more formal legal proceedings. While it seems unlikely HHS would take the position that the litigation exception does not apply to alternative dispute resolution procedures, this issue has not yet been formally addressed.

n14 *See id.*; Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,596 (Dec. 28, 2000) (codified at 45 C.F.R. pts. 160, 164)

n15 *See* 45 C.F.R. § 164.512(e)(1) (2003); Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,529-30.

1. Court Order

The most effective way under HIPAA for a litigant or government agency to obtain IIIHI from a Covered Entity is to obtain a court order compelling disclosure. n16 For purposes of this exception, a subpoena issued by a court is a "court order," but a subpoena issued by an attorney is not. This is because a subpoena issued by a court, unlike one signed only by an attorney, is deemed to reflect a judicial determination that the requested information is necessary and relevant to the proceedings. n17

n16 *See* 45 C.F.R. § 164.512(e)(1)(i) (2003).

n17 See Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,529-30. See *United States v. Sutherland*, 143 F. Supp. 2d 609, 612 n.3 (W.D. Va. 2001).

A Covered Entity presented with a valid court order is "not required to second-guess the scope or purpose of the order." n18 The Covered Entity, however, may produce only the IHHI that is ordered to be produced. n19

n18 Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,530.

n19 See *id.*

2. Attorney-Issued Subpoena, Discovery Request, or Other Lawful Process

A Covered Entity may also produce IHHI in response to an attorney-issued subpoena, discovery request, or other lawful process, but only if the Covered Entity receives "satisfactory assurances" that (1) the requesting party has made reasonable efforts to secure a qualified protective order; or (2) reasonable efforts have been made by the requesting party to notify the individuals whose IHHI is sought of the request. n20 If neither of these conditions is met and no other exception applies, IHHI may not be disclosed in the course of litigation or administrative proceedings. n21

n20 45 C.F.R. § 164.512(e)(1)(ii) (2003).

n21 See *id.*

In this regard, the new requirements reflect just how broadly the "strong federal policy to protect the privacy of patient medical records" extends. n22 For example, a plaintiff who puts his medical condition at issue in a lawsuit, such as by filing a medical malpractice suit, traditionally has been deemed to have waived any right to object to the disclosure of personal medical information. The rationale is that when a party puts his medical condition at issue, that party cannot deprive the opposing party of relevant evidence on that issue.

n22 *Sutherland*, 143 F. Supp. 2d at 612.

While included in the draft version, the final Privacy Regulations omitted an exception for this deemed waiver. Thus, under HIPAA, a party that places her medical condition at issue in the litigation is entitled to the full protections afforded by the Privacy Regulations. HHS expressed its view that elimination of the "at issue" exception was "not intended to disrupt current practice whereby an individual who is a party to a proceeding and has put his or her medical condition at issue will not prevail without consenting to the production of his or her [IHHI]." n23 The fact that opposing parties must jump through the Privacy Regulations' procedural hurdles in cases in which even HHS acknowledges that IHHI is key to the litigation reflects HHS's goal of ensuring that patients have greater control over the use and disclosure of their IHHI.

n23 Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,530.

a. Qualified Protective Order Sought

A Covered Entity may produce IHHI in response to an attorney-issued subpoena, discovery request, or other lawful process if it receives "satisfactory assurances" from the requesting party that it has made "reasonable efforts" to secure a "qualified protective order." n24 A Covered Entity receives "satisfactory assurances" if it receives a written statement

and accompanying documentation demonstrating that (1) the parties to the underlying dispute "have agreed to a qualified protective order and have presented it to the court or administrative tribunal with jurisdiction over the dispute;" or (2) the requesting party has requested a qualified protective order from the court or administrative tribunal with jurisdiction over the dispute. n25

n24 45 C.F.R. § 164.512(e)(1)(ii)(B) (2003).

n25 *Id.* § 164.512(e)(1)(iv).

The term "protective order" is misleading, because an actual protective order need not have been entered for a Covered Entity to be permitted to disclose IIHI. It is sufficient that (1) the parties to the underlying dispute stipulated that they are prohibited from using or disclosing IIHI for any purpose other than the litigation or proceeding for which such information is requested, and that at the conclusion of the litigation, the IIHI will either be destroyed or returned to the Covered Entity from which it was requested; and (2) the parties presented this stipulation to the court or administrative tribunal. n26 While the Privacy Regulations do not require that the stipulation or proposed order actually be entered for the Covered Entity to disclose the IIHI, a Covered Entity may object to disclosure on the ground that the court has not yet entered the stipulation or order.

n26 *Id.* § 164.512(e)(1)(iv), (v).

b. Notice and Opportunity to Object

A Covered Entity may also disclose IIHI in response to an attorney-issued subpoena, discovery request, or other lawful process, if it receives "satisfactory assurances" that the requesting party made reasonable efforts to give notice of the request to the individuals whose IIHI is being requested, to ensure that those individuals have an opportunity to object. n27 "Satisfactory assurances" consist of a written statement and accompanying documentation demonstrating that (1) the requesting party has made a good-faith effort to provide written notice to the persons whose IIHI is being requested, as well as sufficient information about the particular litigation or proceeding for which the IIHI is being requested; and (2) the time to raise objections has lapsed and no objections were filed, or the objections were resolved and disclosure is permitted. n28 A person who wishes to object to disclosure of her IIHI must object to the court or administrative tribunal, not to the Covered Entity from whom disclosure is requested. n29 The Covered Entity is not required to directly respond to objections or explain the available objection procedures, unless another law (such as an applicable state law) requires a response or explanation. n30

n27 45 C.F.R. § 164.512(e)(1)(ii)(A) (2003).

n28 *Id.* § 164.512(e)(1)(iii). The regulation does not set a time limit in which an individual must raise objections.

n29 Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,530 (Dec. 28, 2000) (codified at 45 C.F.R. pts. 160, 164).

n30 *See id.*

As a practical matter, there are two reasons why this exception is unlikely to be of much use when Covered Entities receive requests for the IIHI of numerous individuals. First, the exception presumes that the requesting party knows the specific identities of the persons whose IIHI it is requesting prior to production. Second, the process involved with

providing notice to each individual is likely to be much more arduous than seeking a qualified protective order from the court or tribunal.

c. Scope of Disclosure in Given Satisfactory Assurances

When a Covered Entity makes disclosures after receiving "satisfactory assurances," it must make reasonable efforts to ensure that it discloses only the "minimum necessary" amount of information that is required to comply with the request. n31 For example, if the request calls for a specific patient's medical records relating to a specific date of treatment, the Covered Entity may not produce the patient's entire medical record or allow the requesting party to determine what it needs from the medical record. n32 Instead, the Covered Entity must cull through the file to ensure that it produces only the specific requested information.

n31 *Id.*

n32 *See id.*

If a Covered Entity does not receive either of the "satisfactory assurances" described earlier, then it is not permitted to produce the requested IIIHI. n33 The fact that a Covered Entity receives the required "satisfactory assurances," however, does not preclude it from choosing to interpose other standard discovery objections to a request for IIIHI. If the Covered Entity receives satisfactory assurances, then it is not obligated to second-guess the scope or purpose of the request, "or take any action to resist the request because it believes it is over broad." n34

n33 If, for some reason, the Covered Entity desires to make the requested disclosure notwithstanding the lack of "satisfactory assurance," it may make reasonable efforts to seek a qualified protective order. 45 C.F.R. § 164.512(e)(1)(vi) (2003). It is not, however, required to do so. *See Standards for Privacy of Individually Identifiable Health Information*, 65 Fed. Reg. at 82,530.

n34 *Standards for Privacy of Individually Identifiable Health Information*, 65 Fed. Reg. at 82,530.

B. Government Investigations

Outside the context of litigation, a Covered Entity may be asked to produce IIIHI in response to an agency subpoena or some other formal government process. Whether and under what circumstances a Covered Entity is permitted to disclose IIIHI in response to such a request depends in large part on whether the underlying investigation relates to oversight of the healthcare system.

1. Health Oversight Activities

Relatively few procedural protections exist when a Covered Entity is asked by a "health oversight agency" to produce IIIHI pursuant to the agency's "health oversight activities." n35 A "health oversight agency" is not required to justify its request to the Covered Entity or document its need for IIIHI, and the regulations allow the Covered Entity to rely on representations made by agency representatives that they have requested only the minimum necessary amount of information. n36 So long as disclosure is limited to the relevant requirements of the request or law pursuant to which disclosure is made, a Covered Entity is permitted to produce IIIHI requested by a health oversight agency. n37

n35 *See* 45 C.F.R. § 164.512(d) (2003).

n36 *See Standards for Privacy of Individually Identifiable Health Information*, 65 Fed. Reg. at 82,715.

n37 *See id.*; Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,672.

The term "health oversight activities" is broad enough to encompass the vast majority of situations in which a government agency might request IIIHI. It includes any audit, civil investigation, criminal investigation, administrative investigation, inspection, licensure action, disciplinary action, or other activity related to oversight of: (1) "the health care system;" n38 (2) "government benefit programs for which health information is relevant to beneficiary eligibility;" n39 (3) "entities subject to government regulatory programs for which health information is necessary for determining" whether the entity is complying with the program's requirements; n40 or (4) "entities subject to civil rights laws for which health information is necessary" to determine whether the entity is in compliance with such laws. n41 Due to the breadth of this definition, virtually every Covered Entity is subject to "health care oversight" from one or more government agencies in the ordinary course of its business.

n38 45 C.F.R. § 164.512(d)(1) (2003).

n39 *Id.*

n40 *Id.*

n41 *Id.*

Any agency that engages in "health oversight activities" is, when doing so, considered to be a "health oversight agency." n42 Thus, the universe of health oversight agencies includes not only those whose primary or sole focus is healthcare oversight, such as state medical licensure boards, public health agencies, and CMS, but also agencies such as the Federal Trade Commission, Department of Justice (DOJ), Equal Opportunity Employment Commission (EEOC), DOL, Federal Bureau of Investigation (FBI), and state Attorneys General.

n42 Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,529.

The preamble to the Privacy Regulations suggests that the health oversight exception is primarily aimed at healthcare fraud investigations. In reality, however, it is not so limited. n43 While this exception clearly applies in the context of healthcare fraud investigations, such as a DOJ request for IIIHI in connection with an investigation into hospital overbilling, by its express terms the exception also applies in numerous other contexts unrelated to healthcare fraud. For example, the health-oversight exception applies to an EEOC request for information in connection with an investigation into whether an employer is in compliance with the Americans With Disabilities Act. This certainly is not a subject area traditionally thought to fall within the realm of "healthcare fraud."

n43 A "health care fraud investigation" is one that arises out of and is directly related to (a) "the receipt of health care," (b) "[a] claim for public benefits related to health," or (c) the "qualification for or receipt of public benefits or services when a patient's health is integral to the claim for public benefits or services." 45 C.F.R. § 164.512(d)(2) (2003). *See* Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,529.

2. Law Enforcement

The "health oversight activities" exception encompasses virtually any health oversight agency request for IIIHI from a Covered Entity pursuant to an investigation. The Privacy Regulations, however, may bar the disclosure of IIIHI when the agency investigation is directed towards "law enforcement" activities, instead of "health-oversight activities." "Law enforcement" activities encompass requests for IIIHI for an individual who is the *subject* of an investigation, *other* than

an investigation relating to (i) the receipt of healthcare, (ii) a claim for public benefits related to health, or (iii) the individual's qualification for or receipt of public benefits or services, when health is integral to the claim for benefits or services. n44 The Privacy Regulations provide greater protections for IIIHI in these circumstances than the general health oversight activities exception.

n44 *See* 45 C.F.R. § 164.512(d)(2) (2003); Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,529, 82,673.

In striking a balance between the government's need for information for law-enforcement purposes unrelated to healthcare fraud and an individual's privacy interest in her medical records, the Privacy Regulations distinguish between requests made directly by a government agency, and those made by a court or other supervisory body. When IIIHI is requested pursuant to a court order, court-ordered warrant, court-issued subpoena, summons issued by a judicial officer, or a grand-jury subpoena, the Privacy Regulations permit the Covered Entity to disclose the requested information without any further demonstration of need by the requesting agency. n45 The rationale is that either there already has been some judicial oversight (in cases in which judicial officers issue court orders) or that current secrecy laws (in cases of grand-jury subpoenas) are deemed to provide sufficient protection. n46

n45 *See* 45 C.F.R. § 164.512(f)(1)(ii)(A), (B) (2003).

n46 *See id.*

In some cases, a request for IIIHI in the context of law-enforcement activities may be made through an administrative subpoena, summons, or civil investigative demand. n47 In these circumstances, a Covered Entity may not disclose the requested IIIHI unless: "(1) the information sought is relevant and material to a legitimate law enforcement inquiry; (2) the request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and (3) [d]e-identified information could not reasonably be used." n48

n47 *Id.* § 164.512(f)(1)(ii)(C).

n48 *Id.*

These additional requirements are in place because administrative requests lack the judicial oversight or other secrecy protections that exist in other IIIHI requests for law-enforcement purposes. n49 The Privacy Regulations are silent as to whether the agency or the Covered Entity bears the burden of proving that these three conditions exist. HHS noted that a Covered Entity is permitted to disclose IIIHI in response to an administrative request if the request "indicates on its face that the three-part test has been met, or where a separate document so indicates." n50 This suggests that, as is the case with the healthcare oversight exception, a Covered Entity may rely on the representation of a government official that the standard has been satisfied. n51

n49 *See* Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,683.

n50 *Id.*

n51 *Id.*

The fact that disclosure is permitted under the law-enforcement exception does not preclude a Covered Entity from asserting any lawful defense or other lawful objection it may have to production of the requested information, including those arising under state law. The preamble to the Privacy Regulations makes clear, however, that the law-enforcement exception is not intended to create a basis for appealing to federal court matters concerning a state official's request for IIHI. n52

n52 *Id.* at 82,533.

The Privacy Regulations offer little guidance as to how to resolve disputes between law-enforcement officials and a Covered Entity when the Covered Entity disputes the appropriate basis for the request. More often than not, agencies engaged in inquiries that fall under the law-enforcement exception have a vested interest in not disclosing to the Covered Entity from whom IIHI is being requested "the purpose for which the information is sought," or why "de-identified information could not reasonably be used." n53 Responding to this concern, HHS has simply noted that because it does not have authority to regulate law-enforcement officials, "the rule must rely on covered entities to implement standards that protect individuals' privacy interests, including the three-part test for disclosure pursuant to administrative subpoenas." n54

n53 45 C.F.R. § 164.512(f)(1)(ii)(C) (2003).

n54 Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,683.

3. Relationship Between Health-Oversight and Law-Enforcement Exceptions

When faced with a government-agency request for IIHI, it may often be difficult for the Covered Entity to determine, from the face of the request, whether disclosure is appropriately analyzed under the "health oversight" or "law enforcement" exceptions. This is true because many agencies engage in both "health oversight" and "law enforcement" activities. For example, if the DOL issues an administrative subpoena to a Covered Entity's health plan seeking information about the health plan's enrollees in connection with an investigation of the Covered Entity, disclosure should be analyzed under the "health oversight" exception. Alternatively, when a government agency requests an individual's IIHI pursuant to an investigation *of that individual*, disclosure must be analyzed under the "law enforcement" exception, unless the investigation relates to the receipt of healthcare, a claim for public benefits related to health, or the individual's qualification for or receipt of public benefits or services, when health is integral to the claim for benefits or services. The preamble to the Privacy Regulations suggests that if there is confusion as to whether an agency is exercising "health oversight" or "law enforcement" functions, the requesting agency should specifically identify which exception it contends authorizes disclosure.

C. Other Exceptions

While this Article focuses on the most applicable exceptions in the context of litigation or government investigations, HIPAA contains other exceptions to its nondisclosure rule. Some of these include allowing disclosure of IIHI in circumstances relating to public health activities, which encompasses certain disclosures relating to activities regulated by the Food and Drug Administration; disclosure for the purpose of reporting abuse, neglect, or domestic violence information; disclosures relating to decedents; disclosures in connection with cadaveric organ, eye, or tissue donation; disclosures relating to research; disclosures necessary to avert a serious threat to health or safety; disclosures relating to certain specialized government functions; and disclosures relating to worker's compensation proceedings. n55 These exceptions to the general nondisclosure rule may be applicable in specific types of litigation or government investigations, but are beyond the scope of this Article.

n55 45 C.F.R. § 164.512 (c), (g), (h), (i), (j), (k), (l) (2003).

Notably, the Privacy Regulations expressly allow Covered Entities to continue disclosing IIIHI to government entities if they are "required by law" n56 to do so. "Law," for these purposes includes both court and administrative orders, Medicare conditions of participation with respect to participating healthcare providers, as well as statutes and regulations requiring the disclosure of IIIHI if payment is sought under any "government program providing public benefits." n57 Thus, for example, a Covered Entity that is required to disclose IIIHI under the Social Security Act, the Family and Medical Leave Act, the Environmental Protection Act, the National Labor Relations Act, state law, or any other "law," remains obligated to do so, and may do so without violating HIPAA. This is true so long as the disclosure complies with, and is limited to, the relevant requirements of that law. n58

n56 *Id.* § 164.103.

n57 *Id.*

n58 Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,485; 45 C.F.R. § 164.512(a)(1) (2003).

Nevertheless, this exception applies only to disclosures *required* by law. If a law *permits*, but does not require, disclosure of IIIHI, then disclosure is not allowed unless one of the other specific HIPAA disclosure exceptions applies. n59 Furthermore, the general "required by law" exception does *not* apply to disclosures requested by law-enforcement officials or in the course of judicial or administrative proceedings, for which the more specific requirements set forth herein must be satisfied. n60

n59 45 C.F.R. § 164.512(a)(1) (2003).

n60 *Id.* § 164.512(a)(2).

II. Related Issues

A. *Exceptions Not Mutually Exclusive*

The exceptions to the Privacy Regulations' general nondisclosure rule are not mutually exclusive. It is quite possible that, in specific circumstances, disclosure may be permitted under more than one section of the Privacy Regulations. Consider, for example, a lawsuit brought by a hospital against an HMO alleging that the HMO failed to properly process claims for services rendered to the hospital's patients. Discovery in that litigation certainly entails the exchange of IIIHI about the specific patients whose claims are at issue. This disclosure can be made without the patient's authorization if the requestor meets the litigation exception requirements. One could also argue, however, that the provider is authorized to provide information to the health plan without first obtaining authorization, pursuant to the section of the Privacy Regulations that allows providers to disclose IIIHI as necessary to carry out "payment" or "health care operations." n61 This tactic avoids the additional hurdles imposed by the litigation exception.

n61 *Id.* § 164.506(a).

To give another example, a government agency may allege that the Covered Entity violated the requirements of a healthcare program overseen by the agency. If, in the midst of litigation, the Covered Entity receives an administrative subpoena from the agency seeking IIIHI relating to the issues in the litigation, the Covered Entity may not resist the subpoena on the ground that the requirements of the litigation exception must be satisfied. Rather, if disclosure is

permitted under the more lenient "health oversight activities" exception, disclosure is permissible, notwithstanding the existence of ongoing litigation on the same subject. Furthermore, nothing in HIPAA limits the ability of a health oversight agency to use PHI obtained under the health oversight exception for other purposes, including purposes for which the Covered Entity would or could not have disclosed the PHI. Thus, using the previous example, the requesting agency would be free to use the PHI that it obtained pursuant to its health oversight activities in the litigation with the Covered Entity.

B. Interaction Between the Privacy Regulations and State Law

Perhaps the most difficult issue facing Covered Entities is reconciling obligations imposed by the Privacy Regulations with applicable state privacy laws. HIPAA establishes a federal floor of privacy protections for all PHI, meaning it preempts state laws that provide individuals with less protection. HIPAA does *not*, however, preempt state laws that "relate to the privacy of" PHI if such laws provide protection "more stringent" than HIPAA.

n62 42 U.S.C. § 1320d-7(a)(2)(B) (2003).

n63 See 45 C.F.R. § 160.202 (2003) (defining "more stringent").

A state law "relates to the privacy" of PHI if it has the specific purpose of **protecting** the privacy of health information or affects the privacy of health information "in a direct, clear, and substantial way." n64 These state laws are considered to be "more stringent" than HIPAA with respect to disclosure of PHI if they prohibit or restrict disclosure in circumstances under which HIPAA would permit disclosure, or otherwise provide greater privacy protections for the individual who is the subject of the PHI. n65 While this standard is less than clear, the Fourth Circuit recently rejected a claim challenging the standard as being unconstitutionally vague, noting that "these criteria will doubtless call for covered entities to make some common sense evaluations and comparisons between state and federal laws, but this does not mean [that] they are either vague or constitutionally infirm." n66

n64 *Id.* § 160.202.

n65 *Id.*

n66 South Carolina Med. Ass'n v. Thompson, 327 F.3d 346, 355 (4th Cir. 2003).

The only reported case directly addressing the issue of whether a specific state law is "more stringent" than the Privacy Regulations is *United States of America ex rel. Stewart v. The Louisiana Clinic*, decided in December 2002. n67 In *Stewart*, a health clinic sought a protective order preventing disclosure of medical records on the basis of a Louisiana statute requiring notice to the patient and a hearing before the patient's records can be produced without her consent. n68 The clinic argued that the Louisiana statute imposed "more stringent" requirements than HIPAA, and therefore the party seeking disclosure was required to satisfy the requirements of both the state law and the Privacy Regulations. n69 The court rejected the clinic's argument, noting that the Privacy Regulations define a state law governing disclosure as "more stringent" only to the extent it addresses the "form, substance, or the need for express legal permission from an individual." n70 Noting that the Louisiana statute did not impose additional requirements for obtaining medical records with the patient's consent but, rather, provided a procedure for *negating* the patient's consent, the court held that the state statute was not "more stringent," as defined in the Privacy Regulations. n71

n67 *United States ex rel. Stewart v. The Louisiana Clinic*, No. Civ. A 99-1767, 2002 WL 31819130 (E.D. La. Dec. 12, 2002).

n68 *Id.* at *1, 3.

n69 *Id.* at *3.

n70 *Id.* at *5 (quoting 45 C.F.R. § 160.202).

n71 *See id.*

In fact, most states have laws that provide special protections for various types of health information, many of which are at least as stringent, if not more stringent, than HIPAA. As such, there may be many circumstances in which HIPAA permits disclosure, but state law does not. In these situations, the more-stringent state law controls. Thus, Covered Entities and their attorneys should become familiar with not only the Privacy Regulations, but also with the provisions of any "more stringent" state law that may apply to requests for disclosure of IIHI. n72

n72 Georgetown University's Health Privacy Project has compiled state-by-state information about health privacy laws. *See* www.healthprivacy.org/info-url_nocat2304/info-url_nocat.htm. In addition, various state government are undertaking their own HIPAA preemption analyses. *See, e.g.,* www.illinois.gov/hipaa (Illinois); www.omh.state.ny.us/omhweb/hipaa/preemption_html/MHLARTICLEOTHERS.htm (New York).

Whether a "more stringent" state law is "applicable" to requests by health-oversight or law-enforcement agencies is largely a federalism issue. A Covered Entity that receives an order from a state court or a subpoena from a state grand jury must ensure that disclosure is permitted under the Privacy Regulations as well as any applicable state law. The fact that disclosure is *permitted* under the Privacy Regulations is insignificant if an applicable state law prohibits disclosure of the requested information. n73

n73 *See, e.g., In re Grand Jury Investigation*, 779 N.E.2d 173, 175, 176-77 (N.Y. 2002) (quashing a state grand jury subpoena to hospital for records that the hospital was prohibited from disclosing under state law).

Determining whether and how HIPAA interacts with "more stringent" state laws in the course of litigation may be more difficult. Many states have laws that are more stringent than HIPAA, including those that impose specific notice or procedural requirements on requests for IIHI. In addition, many states have laws that limit or restrict the disclosure of the most sensitive types of health information, including genetic testing records, information related to human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS), mental health records, and information about sexually transmitted diseases.

1. State Court/Agency Proceedings

When a Covered Entity receives a subpoena or an order from a state court or administrative tribunal in connection with litigation of claims arising under state law, the Covered Entity must take steps to ensure that the requested disclosure is permissible both under HIPAA and state law. For example, a provider who receives a state grand-jury subpoena clearly is permitted under HIPAA to disclose the requested information under the "law enforcement" exception. If a state law prohibits disclosure of the requested information, however, that law is "more stringent" than HIPAA, and the provider must comply with its provisions. That is, the provider is not permitted to produce the requested information. n74

n74 *See id.*

2. Federal Administrative Proceedings

With respect to federal administrative or agency subpoenas, it is well-established that state laws cannot stand in the way of requests for disclosure pursuant to federal law. n75 For example, in *Massanari v. Northwest Community Mental Health Center*, the court held that New York's Mental Hygiene Law was preempted to the extent it prohibited disclosure of information requested by a subpoena validly issued by the federal Social Security Administration. n76

n75 *See, e.g. Massanari v. N.W. Cmty. Mental Health Ctr.*, No. 01-MC-50E, 2001 WL 1518137 at *1 (W.D.N.Y. Nov. 7, 2001).

n76 *Id.*

3. Federal Court Proceedings

When a subpoena or discovery request originates in a federal court proceeding, it is less clear whether the Covered Entity must look to state law in addition to the Privacy Regulations. Responding to the question of whether a federal subpoena requires disclosure of IIIHI if a state law prohibits the release of that same information, HHS stated that "to the extent that an *applicable* state law precludes disclosure of protected health information that would otherwise be permitted under the [regulations], state law governs." n77 HHS did not, however, define the term "applicable." If the term simply means "more stringent," then HHS's response suggests that the Privacy Regulations effectively incorporate into the *Federal Rules of Civil Procedure* the provisions of any "more stringent" laws governing the disclosure of IIIHI existing in the states where district courts sit.

n77 Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,677 (Dec. 28, 2000) (codified at 45 C.F.R. pts. 160, 164) (emphasis added).

More likely, the term "applicable" reflects the fact that state laws may apply to cases litigated in federal court, depending on the nature of the case and the nature of the state law. The federal *Erie* doctrine, which is incorporated into the *Federal Rules of Evidence*, provides that state substantive laws apply in federal courts when state law provides the rule of decision. n78 Under this interpretation, "more stringent" state laws apply when a federal subpoena is issued in connection with litigation in which state law provides the rule of decision, but not when federal law provides the rule of decision.

n78 *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 92 (1938); *see Guarantee Trust Co. v. York*, 326 U.S. 99, 112 (1945). *See also* FED. R. EVID. 501.

Further muddying the waters, in cases in which state law provides the rule of decision, a federal court's decision whether to apply a "more stringent" state law largely depends on whether the federal court interprets that law as merely procedural, or whether it embodies substantive rights. For example, many state laws provide specific protections for certain types of medical records, ranging from procedural safeguards prior to disclosure, to wholesale bans on unauthorized disclosure. In some states, such laws are interpreted as providing "procedural" protections, while in others they are deemed to confer "substantive" rights that are not recognized by federal law, such as the right to privacy in medical records or a physician/patient privilege. Whether a state law is deemed to be procedural or substantive in nature is not just an esoteric legal question. Rather, it has practical consequences for Covered Entities seeking to ensure that they do not violate HIPAA. Well-established principles of federalism provide that if a state law is procedural in nature, federal courts are not required to apply it. n79 If a state law governing IIIHI confers substantive rights, however, *Federal Rule of Evidence* 501 obligates federal courts to honor those rights in cases in which state law provides the rule of decision. n80

n79 *Erie R.R. Co.*, 304 U.S. at 92.

n80 FED. R. EVID. 501 ("In civil actions and proceedings, with respect to an element of a claim or defense as to which State law supplies the rule of decision, the privilege of a witness, person, government, State, or political subdivision thereof shall be determined in accordance with State law."). See *United States ex rel. Stewart v. The Louisiana Clinic*, No. Civ. A 99-1767, 2002 WL 31819130, at *2 (E.D. La. Dec. 12, 2002) ("Louisiana privilege law concerning production of nonparty patient records does not apply in this action brought solely under federal statutory law.").

Thus, in a diversity action, a Covered Entity that receives a federal court subpoena for IIIHI must determine whether any applicable state law precludes disclosure. This is assuming it received the "satisfactory assurances" permitting disclosure under HIPAA. To do this, the Covered Entity must determine whether such a state law exists and, if so, whether the law confers procedural or substantive rights. n81 The latter issue is largely a question of state law, but resolution of that issue determines whether the state law is applicable in federal court.

n81 See, e.g., *Laba v. Lockheed Martin IMS Corp.*, No. Civ.A. 97-926, 1998 WL 187800, at *1 (E.D. La. Apr. 20, 1998) (granting motion to quash in diversity action based on litigant's failure to comply with Louisiana state law requirements regarding patient notice and consent prior to subpoenaing medical records).

A recent case from the United States District Court for the Western District of Virginia considered some of these issues. In *United States v. Sutherland*, a third-party hospital moved to quash a subpoena issued by a United States Attorney seeking hospital pharmacy records of patients whose prescriptions allegedly were written by the defendant physician. The hospital argued that the government failed to comply with a Virginia statute requiring a party seeking to subpoena a nonparty's medical records to notify the individual of the request and provide an opportunity to object. n82 In denying the motion to quash, the court characterized the Virginia statute as one imposing "procedural" requirements that are inapplicable to proceedings in which federal law supplies the rule of decision. n83 Even assuming that the state statute also grants patients a substantive right to privacy in medical records, the court held that such a right was not cognizable in proceedings in which federal law supplies the rule of decision because no federal physician/patient privilege exists. n84

n82 *United States v. Sutherland*, 143 F. Supp. 2d 609, 610 (W.D. Va. 2001).

n83 *Id.* at 611.

n84 *Id.* (citing FED. R. EVID. 501).

C. Liability and Sanctions For Unauthorized Disclosure

The penalties for violating HIPAA can be severe. A Covered Entity that violates HIPAA by using or disclosing IIIHI in an unauthorized manner is subject to civil penalties of \$ 100 per violation, up to \$ 25,000 per year "for all violations of an identical requirement or prohibition." n85 In addition, HIPAA states that any person who knowingly and in violation of HIPAA: "(1) uses or causes to be used a unique health identifier;" (2) obtains IIIHI; or (3) discloses IIIHI, n86 is subject to criminal penalties, including a fine of up to \$ 250,000 or ten years imprisonment. n87

n85 42 U.S.C. § 1320d-5(a) (2003).

n86 *Id.* § 1320d-6.

n87 *See id.*

The phrase "any person" in the criminal penalty portion of the statute is significant because, although HHS's authority only directly extends to Covered Entities, as a practical matter many more people and entities must comply with the Privacy Regulations. This is because the Privacy Regulations require Covered Entities to obtain written agreements from any third-party service providers, including attorneys, whose services involve the use or disclosure of the Covered Entity's IIII. n88 These Business Associate Agreements obligate the Business Associate to provide the same level of privacy protections imposed directly on Covered Entities. n89 While the phrase "any person" in HIPAA's criminal penalty provision has not yet been interpreted, it can be argued that a Business Associate who violates its Business Associate Agreement with a Covered Entity violates HIPAA, and thus falls within the scope of the criminal provision.

n88 45 C.F.R. § 164.508(c) (2003).

n89 *See id.* § 164.504(e)(2). Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,503 (Dec. 28, 2000) (codified at 45 C.F.R. pts. 160, 164). Sample Business Associate Agreement provisions can be found on HHS's Web site. *See* Department of Health and Human Services, Office of Civil Rights, *Medical Privacy--National Standards to Protect the Privacy of Personal Health Information*, at www.hhs.gov/ocr/hipaa/contractprov.html (last visited on June 23, 2003). *See also* Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 53,182, 53,264 (Aug. 14, 2002) (codified at 45 C.F.R. pts. 160, 164).

The Privacy Regulations do not provide a private cause of action to individuals whose IIII is used or disclosed in violation of law. Nor, however, do the Privacy Regulations preempt state law causes of action premised on HIPAA violations. For example, some states allow individuals to sue under state common-law theories, such as invasion of privacy or violation of the physician/patient privilege, for unauthorized use or disclosure of IIII. A violation of HIPAA could also conceivably be used as the basis for claims under federal and state laws challenging unfair or deceptive trade practices.

Whether compliance with the Privacy Regulations will come to be considered the standard "duty of care" under state laws remains to be seen. Presumably, liability extends not only to Covered Entities, but also to any Business Associate of a Covered Entity, if the Business Associate discloses IIII in violation of its Business Associate Agreement. In these circumstances, the Business Associate could also be liable to the Covered Entity for breach of the Business Associate Agreement.

Thus, for example, if a law firm improperly discloses IIII that it received from a Covered Entity client, the firm may be liable to the individual whose IIII is unlawfully disclosed, as well as to its client for breach of contract. The firm's ultimate liability would depend on the language in its Business Associate Agreement.

III. Conclusion

Although HIPAA and its Privacy Regulations receive much attention from attorneys who specialize in healthcare work, all attorneys need to be aware of the provisions. Those attorneys who do not consider themselves "healthcare attorneys," but deal with healthcare clients or health-related issues in the course of representing clients in connection with litigation or government investigations, should especially become familiar with the Privacy Regulations. The information in this Article provides a general outline of HIPAA's provisions. Attorneys faced with specific requests for disclosure should consult the Privacy Regulations to determine whether any other applicable provisions or exceptions not discussed in this Article exist. Additional information about HIPAA, guidance from HHS, and copies of the complete Privacy Regulations can be found on HHS's Web site. n90

n90 United States Department of Health and Human Services, Office for Civil Rights, *HIPAA, Medical Privacy--National Standards to Protect the Privacy of Personal Health Information*, at www.hhs.gov/ocr/hipaa (last visited on June 23, 2003).

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LENGTH: 12655 words**TITLE:** Year in Review 2003-2004: Overview**AUTHOR:** Peter M. Leibold *

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TEXT:

ABSTRACT: The year preceding June 30, 2004, was one of the most active periods in the development of health policy and health law in a generation. Against the odds, President Bush delivered on his promise of a prescription drug benefit for Medicare beneficiaries. As with all momentous legislation, the prescription drug benefit was accompanied by legislative changes both large and small, affecting virtually every sector of the healthcare community. In addition to new legislation, the Bush administration continued to release regulations deemed vitally important by those regulated. The Joint Commission on Accreditation of Healthcare Organizations pursued new standards and processes to improve patient safety, and the courts dealt with a myriad of health law issues.

The Year in Review begins with a "Top Ten" list of some of the year's most noteworthy developments. This obviously subjective collection has been culled from a much larger universe of cases and administrative and legislative events that occurred during the past twelve months. It is the author's belief, however, that it fairly represents the range of significant new issues facing American Health Lawyers Association (Health Lawyers) members.

I. The Top Ten**1. Keeping Promises, Providing Prescription Drugs, and Practicing Politics**

On December 8, 2003, the President signed Public Law 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). n1 This historic legislation, supported by a large majority of Republicans and opposed by many Democrats, is the largest expansion of the Medicare program since the program's inception. n2 The bill became law after the House leadership held open the floor vote for an unprecedented three hours, with legislators complaining of dislocated elbows the next day. n3 Administration actuaries believe that the legislation, estimated to cost \$ 495 billion over ten years at the time it was signed, will be far more costly than estimated. n4

n1 Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat 2066. (codified in scattered sections of 21 and 42 U.S.C. (2004)).

n2 Am. Health Law. Ass'n, *Medicare Prescription Drug Benefit Becomes Law*, 8 HEALTH LAW. NEWS 14, 14 (2004).

n3 *Id.* at 15.

n4 *Senators Question Medicare Act Cost Estimates*, 2 HEALTH LAW WEEKLY 14 (Apr. 2, 2004).

Allegations of stifled administration cost estimates, as well as House floor arm-twisting, have spawned divisive congressional investigations. n5 If political import can be measured by post-passage allegations of wrongdoing, this legislation packs a strong political punch.

n5 *Id.*

The MMA adds a new prescription drug benefit for Medicare beneficiaries that will become effective in January 2006. n6 Until the effective date, the Department of Health and Human Services (DHHS) will make a prescription drug discount card available to beneficiaries. n7

n6 MARIA ABRAHAMSEN ET AL., AM. HEALTH LAW ASS'N, THE NEW MEDICARE MODERNIZATION ACT 5 (Eric Zimmerman & Dinetia Newman, eds. 2004).

n7 Am. Health Law. Ass'n, *supra* note 2, at 16.

The new law replaces the Medicare+Choice program with an expanded managed care program called Medicare Advantage. n8 The new program is intended to increase reimbursement to Medicare managed care plans, and the Centers for Medicare & Medicaid Services (CMS) acted quickly on that promise by promulgating a 10.6% increase for such providers within six weeks of the law's enactment. n9

n8 ABRAHAMSEN ET AL., *supra* note 6, at 16.

n9 *Id.*

The MMA also enacts a myriad of reimbursement adjustments (many of them enhancements) and regulatory changes for a diverse set of Medicare providers. n10

n10 *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 401-1016, 117 Stat 2066, 2262-448 (codified in scattered sections of 21, 42 U.S.C. (2004)).

2. Clarifying EMTALA

On September 9, 2003, CMS issued a final rule clarifying hospital obligations under the Emergency Medical Treatment and Labor Act (EMTALA). n11 This act obligates hospitals and physicians to provide those presenting in the emergency department a medical screening examination, as well as necessary stabilizing treatment or appropriate transfer. n12 The final rule was generally well-received by the healthcare community in that it consciously attempted to balance a hospital's and physician's duty to examine and treat patients with the practical realities of operating hospitals and medical staffs. n13

n11 Medicare Program; Clarifying Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals With Emergency Medical Conditions; Final Rule, 68 Fed. Reg. 53,222 (Sept. 9, 2003) (to be codified at 42 C.F.R. pts. 413, 482, 489).

n12 *Id.* at 53,223.

n13 *Id.* at 53,224.

Specifically, the final rule clarifies the actions that hospitals and physicians may take in registering emergency patients, including hospital and physician inquiries into whether an individual has insurance. The rule reemphasizes that such inquiries may not delay the screening or treatment required by EMTALA. n14 The rule permits emergency room physicians to seek information from a patient's regular physician at anytime if the information is relevant and does not inappropriately delay the screening or stabilization. n15 The final rule adopts a "prudent layperson" standard, so that the obligations of EMTALA are triggered when an individual presents at the emergency room and a prudent layperson observer would believe that the individual needs examination or treatment for a medical condition. n16 In the rule, CMS consciously attempts to provide flexibility to hospitals in complying with EMTALA's requirement that hospitals maintain an on-call roster. n17

n14 Thomas R. Barker & Michelle A. Williams, EMTALA Update: The Rules and the Reality, Address at the American Health Lawyers Association, Hospitals and Health Systems Law Institute 3 (Feb. 12, 2004).

n15 *Id.*

n16 *Id.* at 3-4.

n17 *Id.* at 4-6.

The final rule explains the statutory phrase "comes to the emergency department," clarifying a provider's obligations when a patient presents at a dedicated emergency department or at another part of the hospital, including at off-site facilities. n18 CMS also attempted to clarify confusion in the law and the courts regarding when EMTALA's obligations apply to inpatients. The rule states that EMTALA's obligations cease when a patient is admitted for inpatient care. n19 The final rule also addresses when EMTALA obligations apply to hospital-owned ambulances. n20

n18 *Id.* at 6-10, 11.

n19 Baker & Williams, *supra* note 14 at 11.

n20 *Id.* at 12.

While there is still ambiguity in the statute and its regulations, the healthcare community was generally pleased with CMS' balancing of patient/provider interests.

3. The Great Reimportation Debate

States, struggling under the dual pressures of rising Medicaid costs and cash-strapped constituents, looked to the north for less-expensive prescription drugs. n21 Governor Rod Blagojevich commissioned a study finding that Illinois workers and retirees could realize a combined savings of over \$ 90 million annually by allowing prescription drug purchases from Canada. n22

n21 See AGs Urge Adoption of Rx Import Procedure, as CVS Chief Endorses Imports, 9 BNA HEALTH CARE DAILY REP. 87 (May

6, 2004) (noting that nineteen state attorney generals urge Secretary Thompson to adopt a procedure for importation of drugs).

n22 Ceci Connolly, *Illinois Says Import Drugs Could Save State Millions*, WASH. POST, Oct. 27, 2003, at A3.

In the MMA, Congress gave with one hand while taking with the other. A newly created § 804 of the Food, Drug and Cosmetic Act requires the Secretary of DHHS (Secretary) to promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada. n23 The same section, however, states that the provision will not become effective until the Secretary certifies that it will "pose no additional risk to the public's health and safety." n24 Due to the Secretary's reluctance to make such a certification, this provision effectively kills re-importation.

n23 Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1121, 117 Stat 2066, 2464-69 (codified at 21 U.S.C. §§ 331, 384 (2004)).

n24 *Id.*, 117 Stat at 2468 (codified at 21 U.S.C. § 384).

On March 16, 2004, the President appointed Surgeon General Richard Carmona to head up a Drug Importation Task Force to study how to import drugs safely and to determine the impact on medical costs and patient care. n25

n25 *Drug Importation Task Force Members Named*, 2 HEALTH LAW. WEEKLY 12 (Mar. 19, 2004).

Members of Congress are caught between their constituents and the administration. On April 21, 2004, Senator Byron Dorgan, with an impressively bipartisan list of cosponsors, introduced the Pharmaceutical Market Access and Drug Safety Act. n26 The legislation provides statutory safety protections for consumers of imported drugs but does not require the Secretary's certification prior to importation. n27

n26 Pharmaceutical Market Access and Drug Safety Act, S. 2328, 108th Cong. (2004).

n27 *See* 150 Cong. Rec. S4226-01 (daily ed. Apr. 21, 2004) (statements of Sen. Dorgan and Sen. Kennedy).

4. Putting the Finishing Touches on Stark II

On March 26, 2004, CMS issued the second phase of its final regulations interpreting the expanded federal physician self-referral ban, commonly known as Stark II. n28 The regulations enforcing Stark II have been long in coming because of the enormous difficulty in applying the statute to the complex relationships, many of which are legitimate, that characterize the healthcare marketplace today. Health Lawyers' experts gave CMS credit for these regulations, stating that "the regulations reflect the diligent efforts of CMS to listen to providers and to implement the Stark Law in a realistic manner." n29

n28 Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule, 69 Fed. Reg. 16,054 (Mar. 26, 2004) (to be codified at 42 C.F.R. pts. 411, 424).

n29 ROBERT HOMCHICK ET AL., AM. HEALTH LAW. ASS'N, AMERICAN HEALTH LAW ASSOCIATION MEMBERS BRIEFING: STARK II PHASE II FINAL REGULATIONS 4 (2004).

The Phase II rules introduce a number of new exceptions, n30 clarify the definitions of "set in advance" and "indirect compensation arrangement," modify the physician recruitment exception, eliminate many reporting

requirements, and clarify the "one-year term" requirement. n31 For attorneys providing compliance advice on transactions and operations, the promulgation of these rules was certainly one of the most significant developments of the past year.

n30 The exceptions include the provision of information technology (with exceptions), a conditional temporary lapse in Stark compliance, retention payments in medically underserved areas, two anti-kickback safe harbors, and professional courtesy. *See id.* at 5.

n31 *Id.* at 4-5.

5. Upping the Ante on Antitrust Enforcement

Over the past eighteen months, the federal enforcers of antitrust law have retooled and reenergized their enforcement efforts. Between February and October 2003, the Federal Trade Commission (FTC) and the Department of Justice (DOJ) held a series of hearings entitled Health Care and Competition Law and Policy. n32 These hearings, and the continued aggressiveness of the agencies in prosecuting enforcement actions, caused antitrust enforcement to reach the Top Ten developments of the past year.

n32 *See* Fed. Trade Comm'n & Dep't of Justice, *Public Hearings: Federal Trade Commission and Department of Justice Hearings on Health Care and Competition Law and Policy* (Feb. 2003 - Oct. 2003), available at www.ftc.gov/ogc/healthcarehearings/index.htm (last visited Sept. 6, 2004) [hereinafter *Public Hearings*].

The hearings explored many of today's cutting edge issues in healthcare antitrust enforcement, including the definition of a hospital's product and geographic markets, the impact of specialty hospitals, alleged "tying" by networks, the impact of failed enforcement actions against hospital mergers, an examination of the post-merger conduct of those merged entities, monopsony concerns of providers regarding the health insurance market, the definition of product and geographic markets for physicians, group purchasing organizations, and remedies. n33

n33 *See* Fed. Trade Comm'n & Dep't of Justice, *Agenda for Joint FTC/DOJ Hearings on Health Care and Competition Law and Policy* (Feb. 2003 - Oct. 2003), available at www.ftc.gov/ogc/healthcarehearings/completagenda.pdf (last visited Sept. 6, 2004).

The hearings are expected to generate a comprehensive report by FTC/DOJ sometime this year that will provide meaningful guidance to the healthcare community on the enforcement agencies' views on antitrust enforcement.

In 2002, the FTC admitted that its strategy for challenging anticompetitive hospital mergers in the 1980s and 1990s was no longer successful and announced that it would examine the results of mergers to determine whether administrative action should be taken to challenge them retrospectively. n34 On February 10, 2004, the FTC announced that it was initiating such a challenge by filing In the Matter of Evanston Northwestern Healthcare and ENH Medical Group. In its complaint, the FTC claimed that the 2000 merger of Evanston Northwestern Healthcare and Highland Park Hospital had resulted in higher prices and violations of § 7 of the Clayton Act and § 5 of the Federal Trade Commission Act. n35

n34 *See generally* *FTC Stepping Up Activity in Health Care Enforcement, Official Says*, 7 BNA HEALTH CARE DAILY REP. 217 (2002).

n35 *See* In the Matter of Evanston Northwestern Healthcare Corp. & ENH Med. Group, Inc., F.T.C. Dkt. No. 9315 (2004) (complaint), available at www.ftc.gov/os/caselist/0110234/040210emhcomplaint.pdf (last visited Sept. 6, 2004).

6. Physicians and Hospitals Clash Over Specialty Hospitals

An important theme over the last twelve months has been the rising tension between hospitals and physicians in the provision of healthcare. No activity typifies that antagonism more than the passage of a moratorium on the construction of "specialty hospitals" that was included in the MMA. n36

n36 See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 507, 117 Stat 2066, 2295-96 (codified at 42 U.S.C. § 1395nn (2004)).

There are numerous ongoing causes of the conflict between physicians and hospitals, but one significant factor has been an erosion of physicians' income and an increase in their expenses. n37 The combination has caused physicians to seek innovative ways to earn ancillary income, including the ownership of healthcare facilities. The income earned in this manner, however, comes at the expense of the general hospitals where those procedures otherwise would have been performed. n38

n37 Steven Eisenberg, *Specialty Hospitals: The Great Divide*, 6 HOSPS. AND HEALTH SYS. RX 1, 5 (Spring 2004).

n38 *Id.*

After a significant legislative battle between physicians and hospitals, Congress legislated a compromise. The MMA excludes "specialty hospitals" for eighteen months from the "whole hospital" exception under the Physician Self-Referral Law, effectively forbidding physicians from referring patients to "specialty hospitals" in which the physicians have an ownership or financial interest. n39 Although this moratorium is not a permanent ban, it gave general hospitals a short-term victory.

n39 ABRAHAMSEN ET AL., *supra* note 6, at 49.

Following passage of the law, CMS issued a transmittal on March 19, 2004, expanding on the terms and definitions contained in the original legislation. n40 The transmittal defined a "specialty hospital" as one primarily engaged in the treatment of patients receiving surgery or patients with a cardiac or an orthopedic condition. n41 The legislation had grandfathered specialty hospitals that were in operation or "under development" as of November 18, 2003, and the guidance elaborated on the definition of those terms. n42

n40 DEPT OF HEALTH AND HUMAN SERVS. & CTR. FOR MEDICARE AND MEDICAID SERVS., ONE TIME NOTIFICATION, CMS MANUAL SYSTEM, Pub. 100-20, Transmittal No. 62, Change Request 3036 (March 19, 2004), available at www.cms.hhs.gov/manuals/pm_trans/R62OTN.pdf (last visited Sept. 6, 2004).

n41 *Id.*

n42 *Id.*

To demonstrate the ferocity of the debate, Hospital Corporation of America (HCA) announced that it would notify authorities when it identifies planned surgical hospitals that may not qualify under the "grandfather" clause contained in the new law. n43

n43 Michael Romano, *Public Reporting: HCA Naming Suspected Moratorium Violators*, MODERN HEALTHCARE, May 17, 2004, at 12.

7. The Elusive, Evolving ERISA

The courts continue to struggle with suits by healthcare consumers regarding allegations that managed care plans' coverage decisions adversely affect the quality of care received. Following the Supreme Court's decisions in *Pegram v. Herdrich* n44 and *Rush Prudential HMO v. Moran*, n45 courts have struggled with the difference between coverage decisions governed by remedies under the Employee Retirement Income and Security Act (ERISA) and the medical judgment used to make coverage decisions, for which some states (*e.g.*, Texas) have created state causes of action. n46

n44 *Pegram v. Herdrich*, 530 U.S. 211 (2000).

n45 *Rush Prudential HMO, Inc., v. Moran*, 536 U.S. 355 (2002).

n46 See Miguel A. Estrada, *ERISA after Davila and Calad: An Advanced Look at Preemption and Exclusive Remedies*, Address at American Health Lawyers Association and America's Health Insurance Plans Law Conference for Health Plans, Providers, and Insurers 7-9 (May 11, 2004).

This term, the Supreme Court granted certiorari in two cases to clarify the debate over whether a health plan's medical necessity determinations can subject it to negligence causes of action in state court. n47 Those representing Aetna and CIGNA in the consolidated cases argued that state law governs physicians who exercise medical judgment in providing care, while ERISA's federal remedies govern plans that administer the payment of claims for that medical care. n48 Counsel for patients argued that the state legislature in Texas had the discretion to fashion medical malpractice laws to protect its state's citizens from medical negligence. Counsel for patients further argued that Aetna and CIGNA's utilization review shaped the care received by patients and subjected the plans to state remedies fashioned in the 1997 Texas Health Care Liability Act. n49 On June 21, 2004, the Supreme Court decided that the patients' state causes of action were completely preempted by ERISA § 502. n50

n47 *Aetna Health Inc. v. Davila*, 124 U.S. 2488 (2004).

n48 See Estrada, *supra* note 46, at 8-9 (citing Brief for Petitioner Aetna Health, Inc. at 17, *Aetna Health, Inc. v. Davila*, 124 U.S. 2488 (2004) (No. 02-1845)).

n49 Brief for Respondents at 1-4, *Aetna Health, Inc. v. Davila*, 124 U.S. 2488 (2004) (Nos. 02-1845, 03-83).

n50 *Davila*, 124 U.S. at 2490.

8. Abortion and Privacy: The Rules of Discovery

On November 5, 2003, President Bush signed into law the Partial Birth Abortion Act of 2003. n51 The American Civil Liberties Union and other plaintiffs immediately filed lawsuits to enjoin enforcement, arguing that the law is unconstitutional because it does not have an exception to protect the health of the mother. A federal district court in Nebraska issued a temporary restraining order soon after the bill was signed into law. n52 A California federal district court permanently enjoined enforcement of the law as unconstitutional on June 1, 2004. n53

n51 Partial-Birth Abortion Ban Act of 2003, Pub. L. No. 108-105, 117 Stat. 1201.

n52 See Memorandum and Order, *Carhart v. Ashcroft*, 287 F. Supp. 2d 1015, 1016 (D. Neb. 2003) (No. 4:03 CV 3385).

n53 *Planned Parenthood v. Ashcroft*, No. 03-4872, 2004 WL 1192708, at *1 (N.D. Cal. June 1, 2004).

In defending the statute against three challenges in Nebraska, California, and New York, the DOJ subpoenaed the records of women in California, New York, and Chicago who had undergone the dilation and extraction abortion procedure that is banned by the new law. n54 The DOJ argued that it needed the records to demonstrate that the procedure was not medically necessary and, therefore, a health exception was unnecessary. n55 The DOJ asserted that it would take steps to protect the patients' privacy. n56 Those opposing the subpoenas argued that the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and state privacy laws protected the medical records of the women who had undergone the procedures. n57 District courts in different cities came to different conclusions, with the New York court requiring compliance n58 and the Chicago court quashing the subpoenas. n59

n54 *DOJ, Abortion-Rights Groups Battle Access to Records in Partial Birth Case*, 9 BNA HEALTH CARE DAILY REP. 30 (Feb. 17, 2004) [hereinafter *Abortion Rights Groups Battle*]; see also *Nat'l Abortion Fed'n v. Ashcroft*, No. 03 Civ. 8695(RCC), 2004 WL 555701, at *1 (S.D.N.Y. Mar. 19, 2004).

n55 *DOJ, Abortion-Rights Groups Battle Access to Records in Partial Birth Case*, *supra* note 54.

n56 *Id.*

n57 *Id.*

n58 *Nat'l Abortion Fed'n*, 2004 WL 555701, at *7.

n59 *Nat'l Abortion Fed'n v. Ashcroft*, No. 04 C 55, 2004 WL 292079, at *1 (N.D. Ill. Feb. 6, 2004).

On April 27, 2004, Attorney General John Ashcroft withdrew his subpoena for patient records from two New York hospitals. An assistant U.S. Attorney stated that the DOJ withdrew its request for the records because of an important public interest in resolving the issue quickly. n60

n60 Mark Taylor, *U.S. Appears to Drop Pursuit of Abortion Records*, MODERN HEALTHCARE DAILY DOSE (Apr. 27, 2004).

This issue ranks in the Top Ten because of the clash of privacy interests at the core of the debate and the significance of the suits challenging the constitutionality of this new law.

9. To Discount or Not to Discount? That is the Question

Over the last twelve months, advocates for the uninsured have begun to voice displeasure at being one of the only groups to pay full-billed charges for hospital care. n61 In reaction to the rather successful public relations campaign of Consejo de Latinos Unidos and other advocacy groups, the House Committee on Energy and Commerce began an investigation of health systems' charges to the uninsured by requesting detailed information from twenty major hospital systems. n62

n61 Kenneth T. Bowden & Lawrence L. Foust, *Advanced Issues in Payor-Provider Contracting and Negotiations*, Address at American Health Lawyers Association and America's Health Insurance Plans Law Conference for Health Plans, Providers, and Insurers 25 (May 11, 2004).

n62 *Id.* at 26.

The American Hospital Association (AHA) sent a letter on December 16, 2003, to the Secretary, in which the AHA argued that federal law and regulations make it difficult for hospitals to discount charges for the uninsured: "Federal Medicare regulations as written today contain a string of barriers that discourage hospitals from reducing charges or forgiving debt for these patients without potentially running afoul of the law." n63 The AHA believed that the federal Anti-Kickback Statute, bad-debt reimbursement regulations, and a statute that allows exclusion of providers that bill Medicare more than their usual charges impede this form of discounting. n64

n63 *Hospital Group Considers Cutting Costs For Uninsured*, RICHMOND TIMES, Dec. 18, 2003, at C6 (quoting Letter from Richard J. Davidson, President, Am. Hosp. Ass'n, to the Honorable Tommy G. Thompson, Secretary of Health and Human Servs., U.S. Dep't of Health and Human Servs. (Dec. 16, 2003)).

n64 Bowden & Foust, *supra* note 61, at 26.

On February 19, 2004, the Secretary informed AHA that it is his belief that discounts to the uninsured are permissible: "Your letter suggests that HHS regulations require hospitals to bill all patients using the same schedule of charges and suggests that as a result, the uninsured are forced to pay 'full price' for their care. That suggestion is not correct and certainly does not accurately reflect my policy." n65 He enclosed clarifying materials from CMS and the Office of Inspector General for DHHS with his letter. n66

n65 Letter from the Honorable Tommy G. Thompson, Secretary of Health and Human Servs., U.S. Department of Health and Human Servs., to Richard J. Davidson, President, Am. Hosp. Ass'n (Feb. 19, 2004), *available at* www.hhs.gov/news/press/2004pres/20040219.html (last visited Sept. 13, 2004).

n66 *Id.*

After the release of the Secretary's letter, Tenet Healthcare announced that it would implement discount pricing for uninsured patients at all of its hospitals except those in Texas, believing that Texas law prohibits it. n67 This issue will remain of intense interest to providers and consumers over the next twelve months.

n67 Bowden and Foust, *supra* note 61, at 27.

10. Who Controls the Joint Venture?

The last twelve months have been important in the debate over joint ventures between tax-exempt and taxable entities. On November 7, 2003, the Fifth Circuit reversed the district court in *St. David's Health Care System v. United States*, finding that the Internal Revenue Service's (IRS) decision to revoke St. David's tax-exempt status should proceed to trial. n68 The district court had fashioned an extremely flexible approach to determining whether a nonprofit retains sufficient control over a whole hospital joint venture to preserve its nonprofit status. n69

n68 *St. David's Health Care Sys., Inc. v. United States*, 349 F.3d 232, 244 (5th Cir. 2003).

n69 GERALD GRIFFITH, AM. HEALTH LAW. ASS'N, AMERICAN HEALTH LAW ASSOCIATION MEMBERS BRIEFING: THE ST. DAVID'S DECISION: WHERE DO WE GO FROM HERE? (2003).

The appeals court did not find the flexible approach of the district court persuasive and instead found that the

indicia of control suggested by St. David's did not as a matter of law provide the nonprofit sufficient control of the joint venture. The appeals court found significant factual issues that would be appropriately resolved at trial and would be determinative of the control issue. n70 On remand, a jury found that St. David's should retain its exempt status, dealing the government a significant loss on the issue of control in joint ventures. n71

n70 *Id.* at 3-15.

n71 Kevin Hilvert, *St. David's Tax Exemption Upheld . . . Again*, 2 HEALTH LAW WEEKLY 10 (Mar. 12, 2004).

On May 6, 2004, the IRS released Revenue Ruling 2004-51, finding that a tax-exempt university maintains its tax-exempt status when it contributes an insubstantial part of its assets to an ancillary joint venture with a for-profit **company** that specializes in conducting interactive video training programs. n72 The IRS cited St. David's and favorably addressed some of the control issues that it determined were lacking in the *St. David's* case.

n72 Rev. Rul. 2004-51, 2004-22 I.R.B 974 (2004)

II. Practice Group Analyses

A. Antitrust

As observed earlier, the FTC and DOJ have focused their resources on antitrust investigations and enforcement over the last twelve months. In October, the two departments concluded eight months of hearings related to healthcare competition law and policy. n73

n73 *See Public Hearings, supra* note 32.

The FTC continued to focus its enforcement efforts on the pharmaceutical industry and on fee negotiations through allegedly defective messenger models. The full FTC held that agreements between Schering Plough and two generic manufacturers settling a patent infringement suit constituted an unlawful market allocation agreement. n74 The Eleventh Circuit struggled with the legal standard to apply in such cases. In *Valley Drug Company v. Geneva Pharmaceuticals, Inc.*, the court held that the district court should apply the rule of reason to a case in which Abbot Laboratories settled a patent infringement suit against Geneva Pharmaceuticals and AstraZeneca by limiting the entry of new products in exchange for a substantial payment. n75

n74 *In the Matter of Schering-Plough Corp.*, F.T.C. Dkt. No. 9297 (2004) (opinion), available at www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf (last visited Sept. 13, 2004).

n75 *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003).

The FTC entered into a number of consent decrees this past year that disciplined "messengers" for using illegal means to negotiate fees with payors. The FTC requires substantial integration for separate practices to form an entity that can negotiate on behalf of the group. n76

n76 *See In the Matter of Surgical Specialties of Yakima*, F.T.C. Dkt. No. C-4101 (2003) (decision and order), available at www.ftc.gov/os/2003/11/031118do0210242.pdf (last visited Sept. 7, 2004); *In the Matter of Memorial Hermann Health Network Providers*,

F.T.C. Dkt No. C-4104 (2004) (decision and order), *available at* www.ftc.gov/os/caselist/0310001/031125do0310001.pdf (last visited Sept. 7, 2004).

The FTC investigated, but did not challenge, two major mergers that substantially changed the landscape of the pharmacy benefit management and managed care industries. n77

n77 *See* In the Matter of Caremark Rx, Inc./AdvancePCS, F.T.C. File No. 031 0239 (2004) (statement of the Fed. Trade Comm'n), *available at* www.ftc.gov/os/caselist/0310239/040211ftcstatement0310239.pdf (last visited Sept. 7, 2004); Press Release, Dep't of Justice, Department of Justice Antitrust Division Issues Statement on the Closing of Its Investigation of Anthem, Inc.'s Acquisition of WellPoint Health Networks, Inc. (Mar. 9, 2004), *available at* www.usdoj.gov/atr/public/press_releases/2004/202738.htm (last visited Sept. 7, 2004).

In an impressive show of legislative strength, those supporting the National Resident Matching Program (NRMP), after losing on several motions to dismiss in a district court in Washington, D.C., n78 successfully persuaded Congress to pass an exemption from the antitrust laws for the NRMP in an unrelated piece of pension legislation. n79

n78 *Jung v. Ass'n of Am. Med. Colleges*, 300 F. Supp. 2d 119, 174, (D.D.C. 2004).

n79 Pension Funding Equity Act of 2004, Pub. L. No. 108-218, § 207, 118 Stat 596, 611-14 (codified at 15 U.S.C. § 37b (2004)).

B. Fraud and Abuse, Self-Referrals, and False Claims

The practice group leadership focused on developments in false claims case law, the release of the Stark II, Phase II regulations, and a relatively new area of focus--the costs of prescription drugs.

In 2001, the Ninth Circuit held that a district court's treble damages award under the federal False Claims Act (FCA) is subject to analysis under the Eighth Amendment's excessive fines clause. n80 On remand, the district court upheld the award under the Eighth Amendment, and the Ninth Circuit upheld the district court's decision last August. n81 Mackby, a non-physician who controlled a physical therapy clinic, used his father's personal identification number to file false claims with Medicare. The appeals court found that the fine in this instance was not grossly disproportionate to the gravity of the wrongdoing. n82

n80 *United States v. Mackby*, 261 F.3d 821, 830 (9th Cir. 2001).

n81 *United States v. Mackby*, 339 F.3d 1013, 1019 (9th Cir. 2003).

n82 *Id.* at 1017.

In an expansion of relator rights, the Sixth Circuit held that a relator is entitled to share in the proceeds of a governmentally negotiated settlement when the government decides to pursue a settlement rather than intervene in a relator's qui tam suit. n83 The appeals court held that the settlement between the government and defendants constituted an "alternate remedy" to intervention in the qui tam suit under the terms of the FCA, thereby entitling the relator to a portion of the settlement proceeds. n84

n83 *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 342 F.3d 634, 651 (6th Cir. 2003).

n84 *Id.* at 647-48.

Providers should be on notice that disciplinary action of an individual after the individual has given notice of a potential qui tam action will be scrutinized carefully for evidence of retaliation. A district court in Indiana refused to dismiss a physician's retaliation claim against his employer when the employer was on notice that there was a distinct possibility of a qui tam action by the physician. n85

n85 *Chomer v. Logansport Mem'l Hosp.*, No. 1:03-CV-0733 SEB-VSS, 2003 WL 23009014 at *5 (S.D. Ind. Oct. 29, 2003).

On March 26, 2004, CMS released the "Phase II" final rule under the Stark Law. n86 Phase II contains new exceptions and improvements, but may also jeopardize some existing arrangements.

n86 *See supra* notes 28-31 and accompanying text.

A district court in Massachusetts found that plaintiffs in a proposed class action against pharmaceutical manufacturers and pharmacy benefit managers had sufficiently alleged a Racketeer Influenced and Corrupt Organizations (RICO) enterprise to fraudulently inflate average wholesale prices. n87 In a case demonstrating the increased interest and imagination of plaintiffs' counsel in pursuing cases related to pharmaceutical pricing, the district court rejected a motion to dismiss.

n87 *In re Pharm. Indus. Average Wholesale Price Litig.*, 307 F.Supp.2d 196, 207-08 (D. Mass. 2004).

C. Healthcare Liability and Litigation

The practice group leadership discussed important cases involving mandatory arbitration agreements and vicarious liability that will be of interest to long term care providers and hospitals.

Florida courts ruled both ways on the permissibility of mandatory arbitration agreements in resident admission contracts. In *Romano v. Manor Care*, a Florida appeals court found that an agreement to use mandatory arbitration, including limitations on non-economic damages and an exclusion of punitive damages, was substantively unconscionable. n88 In contrast, another Florida appeals court found that a mandatory arbitration agreement in an admissions agreement was not unconscionable because the individual and family members had time to read it and a choice about signing it. n89 Both cases indicate that institutions seeking to use mandatory arbitration agreements must be careful about the manner used to negotiate them with consumers.

n88 *Romano v. Manor Care, Inc.*, 861 So.2d 59, 63-64 (Fla. Dist. Ct. App. 2003).

n89 *Gainesville Health Care Ctr., Inc. v. Weston*, 857 So.2d 278, 288 (Fla. Dist. Ct. App. 2003).

The Georgia Supreme Court made an important ruling related to vicarious liability, holding that a hospital was not liable for the sexual misconduct of an employee. n90 The supreme court reasoned that the employee's sexual misconduct was not in furtherance of his employer's business and fell outside the scope of his employment. n91 A forceful dissent argued that the majority opinion effectively ruled that respondeat superior does not apply to cases of sexual misconduct. n92

n90 *Piedmont Hosp. v. Palladino*, 580 S.E.2d 215, 216 (Ga. 2003).

n91 *Id.* at 218-19.

n92 *Id.* at 219.

A New Hampshire federal district court granted summary judgment to Concord Hospital when the hospital was sued for the alleged negligence of an anesthesiologist and a certified registered nurse anesthetist who were independent contractors. n93 Given that the hospital had not maintained any appearance from which a reasonable person could conclude the medical personnel had the apparent authority to provide services at its behest, the court rejected a vicarious liability theory. n94

n93 *Ural v. Levy*, No. Civ. 01-215-B, 2003 WL 21511122, at *1 (D.N.H. June 30, 2003).

n94 *Id.* at *3.

D. Health Information and Technology

The HIT Practice Group focused less on cases and more on regulatory and policy developments.

Among the biggest developments of the year was the broad array of provisions touching on health information technology included in the MMA. n95 The leadership mentioned the provision to extend the telemedicine demonstration project, n96 to establish the Commission on Systemic Interoperability, n97 to make matching grants for physicians to acquire electronic prescribing hardware and software, n98 and others.

n95 Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified in scattered sections of 21 and 42 U.S.C. (2004)).

n96 *Id.* § 417.

n97 *Id.* § 1012.

n98 *Id.* § 108.

Privacy-related litigation played heavily in the battle over constitutional challenges to the Partial Birth Abortion Ban Act of 2003. n99 Courts in Illinois and New York handled motions to quash third-party subpoenas by the government to determine whether the abortion procedures banned by the Act were ever medically necessary.

n99 *See supra* note 51 and accompanying text.

A federal district court in Chicago held that Illinois' more stringent privacy laws justified the quashing of a DOJ subpoena to Northwestern Memorial Hospital. n100 The court reasoned that the more stringent Illinois privacy laws are not preempted by HIPAA, and therefore, Illinois law controls and the government subpoena must be quashed. n101

n100 *Nat'l. Abortion Fed'n v. Ashcroft*, No. 04 C 55, 2004 WL 292079, at *5 (N.D. Ill. Feb. 6, 2004).

n101 *Id.* at *4.

A New York federal court reached a different conclusion and enforced a similar subpoena against New York and Presbyterian Hospital. n102 The court, finding that the New York law did not apply, distinguished between incorporating more stringent state law and allowing more stringent state law to continue to operate in its sphere of influence. n103

n102 Nat'l. Abortion Fed'n v. Ashcroft, No. 03 Civ. 8695(RCC), 2004 WL 555701, at *1 (S.D.N.Y. Mar. 19, 2004).

n103 *Id.* at *4-5.

In a demonstration of the growing importance of health information technology, President Bush signed an executive order on April 27, 2004, creating a National Health Information Technology Coordinator at the sub-cabinet level. The coordinator will direct a plan to move the nation towards an interoperable and secure health information system that will reduce medical errors and administrative inefficiencies, and improve quality. n104 The president appointed David Brailer, M.D., Ph.D., to the post.

n104 *Bush Sets 10-Year Goal of Medical Records Going Electronic, Announces Health IT Post*, 9 BNA HEALTH CARE DAILY REP. 80 (Apr. 27, 2004).

E. HMOs and Health Plans

The HMOs and Health Plans Practice Group focused its review on a number of significant ERISA preemption cases, the tension that still exists between providers and plans, and the passage of significant state and federal legislation.

Circuit courts struggled with the aftermath of *Pegram v. Herdrich* n105 and the difference between a health plan's coverage decision, governed by federal law, and a health plan's treatment decision, which can be subject to state malpractice actions. In *Land v. CIGNA Healthcare*, the Eleventh Circuit held that a health maintenance organization (HMO)-employed nurse's decision to discharge a patient, against the advice of the patient's physician, was a mixed eligibility and treatment decision and remanded the case back to state court to be tried as a malpractice case under state law. n106 The Supreme Court, however, recently granted certiorari, vacated the judgment, and remanded the case for further consideration. n107

n105 *See Pegram v. Herdrich*, 120 S. Ct. 2143 (2000).

n106 *Land v. CIGNA Healthcare*, 339 F.3d 1286, 1293-94 (11th Cir. 2003).

n107 *CIGNA Healthcare of Fla. v. Land*, 124 S. Ct. 2903 (2004).

The Third Circuit came to a different conclusion last year when Aetna denied as medically unnecessary a specially designed tracheotomy prescribed by a patient's physician. The Third Circuit affirmed the appeals court decision that this type of claim is completely preempted by ERISA. n108 As referenced in the Top Ten, the U.S. Supreme Court recently held that ERISA preempted similar claims presented in a consolidated case, *Aetna Health v. Davila*. n109

n108 *DeFelice v. Aetna United States Healthcare*, 346 F.3d 442, 452 (3d Cir. 2003).

n109 *Aetna Health, Inc. v. Davila*, 124 S. Ct. 2488, 2493 (2004).

The economic tensions between providers and plans continued to be an important development over the last twelve months. Plans won a victory in persuading the Eleventh Circuit to follow an earlier Supreme Court holding by requiring physicians to arbitrate their class action RICO claims. n110 On the other hand, plans also settled with physicians for significant sums in certain class action suits. n111 In addition, a Texas jury awarded \$ 13 million in a suit brought under a 1997 Texas law allowing insureds to sue health plans for damages relating to benefit determinations, which the Court of Appeals of Texas modified, deleting \$ 10 million in exemplary damages. n112

n110 *In re Humana Inc. Managed Care Litig.*, 333 F.3d 1247, 1248 (11th Cir. 2003).

n111 *See* Notice of Proposed Settlement of Class Action Among CIGNA Healthcare and Physicians, *In re Managed Care Litig.*, Master File No. 00-1334-MD-MORENO (S.D. Fla.2003) (No. 1334) *available at* www.cignaphysiciansettlement.com/documents/G250-InitialNoticeApproved.pdf (last visited Sept. 8, 2004).

n112 *CIGNA Healthcare of Tex., Inc. v. Pybas*, 127 S.W.3d 400, 404 (Tex. App. 2004), *vacated and dismissed after settlement*, *CIGNA Healthcare of Tex., Inc. v. Pybas*, No. 05-03-00517-CV, 2004 WL 585008, at *1 (Mar. 25, 2004).

The federal government and the State of California passed significant legislation relating to health plans, insurance, and healthcare coverage. Title II of the MMA established the Medicare Advantage Program, which was designed to reinvigorate the offering of managed care to Medicare beneficiaries. The Medicare Advantage Program increases reimbursement for Medicare managed care plans immediately and authorizes a number of reforms. In 2010, the Medicare Advantage Program will initiate a six-year demonstration project to test competition between private plans and the original Medicare fee-for-service program. n113

n113 ABRAHAMSEN ET AL., *supra* note 6, at 16.

California, in an effort to increase the insured population, enacted legislation mandating private, employer-funded health benefits. n114 Traditionally known as "pay or play," the reforms generally require an employer to provide coverage to employees by a certain date or pay into a state-administered fund. The legislation has caused quite a furor in the business community, with a coalition being formed to urge its repeal. n115

n114 CALIFORNIA HEALTHCARE FOUND., THE HEALTH INSURANCE ACT OF 2003: AN OVERVIEW OF SB 2, *available at* www.chcf.org/documents/insurance/SB2FactSheet2.pdf (last visited Sept. 13, 2004).

n115 *California Coalition Gathers 620,000 Signatures in Effort to Repeal Health Insurance Mandate*, 8 BNA HEALTH CARE DAILY REP. 231 (Dec. 2, 2003).

F. Hospitals and Health Systems

The Hospitals and Health Systems Practice Group analyzed significant cases on vicarious liability, reimbursement, and EMTALA.

As they do every year in medical malpractice actions, state courts wrestled with the vicarious liability doctrine and cases in which independent contractor physicians act with the apparent authority of the hospital. In *Roessler v. Novak*, a Florida appeals court refused to grant summary judgment to a hospital regarding the alleged negligence of an independent contractor radiologist because the court found a genuine issue of material fact about whether the radiologist was the hospital's apparent agent. n116 In contrast, a Kentucky appeals court weighed heavily the fact that a patient

signed an authorization form clearly stating that the emergency room physician was an independent contractor in its decision to grant summary judgment to the hospital. n117

n116 *Roessler v. Novak*, 858 So. 2d 1158, 1160 (Fla. Dist. Ct. App. 2003).

n117 *Branson v. Cmty. United Methodist Hosp., Inc.*, No. 2003-CA-000087-MR, 2004 WL 405932, at *4 (Ky. Ct. App. Mar. 5, 2004).

In a case of first impression and with a theme of "turnaround is fair play," a Massachusetts federal district court held that the government must exhaust administrative remedies before filing a court action to recoup overpayments to a hospital. n118 The government maintained that the relevant statutory section requiring exhaustion, 42 U.S.C. § 405(h), applied only to cases against the government. n119 The University of Massachusetts Memorial Medical Center argued that the language of the statute fails to make that distinction. n120 The court agreed with the latter argument. n121

n118 *United States v. Univ. Mass. Mem'l Med. Ctr.*, 296 F. Supp. 2d 20, 28 (D. Mass. 2003).

n119 *Id.* at 23.

n120 *Id.* at 23.

n121 *Id.* at 24.

Hospitals obviously followed closely the final rule clarifying hospital obligations under EMTALA that was released last September. n122 They also paid particular attention to revised EMTALA interpretive guidelines issued by CMS to its regional offices and state survey agencies on May 13, 2004. n123

n122 *See supra* notes 11-20 and accompanying text.

n123 *CMS Issues Revised EMTALA Interpretive Guidelines*, 2 HEALTH LAW WEEKLY 21 (May 21, 2004).

With respect to EMTALA case law, a Wisconsin appeals court held that a patient who came to a birthing center is not protected under EMTALA's stabilization requirement because the requirement applies only to patients who report to an emergency department. n124 The court also followed the Eleventh Circuit's holding in *Harry v. Marchant* that EMTALA requires stabilization of a patient only when the patient is going to be transferred. n125

n124 *Preston v. Meriter Hosp., Inc.*, 678 N.W.2d 347, 357 (Wis. Ct. App. 2004).

n125 *Harry v. Marchant*, 291 F.3d 767, 775 (11th Cir. 2002).

G. In-House Counsel

The leaders of the In-House Counsel Practice Group cited cases involving disputes over professional rights, vicarious liability, medical malpractice, and organ donation. These cases often establish standards that will impact the day-to-day operations of healthcare providers.

The professional rights cases generally explore the conflict of rights inherent in hospitals taking quality-related

actions against physicians. In *Meyers v. Columbia/HCA Healthcare Corporation*, the Sixth Circuit held that the peer review protections afforded by the Health Care Quality Improvement Act (HCQIA) extend to all persons involved in the review process, including non-physicians. n126 The California Supreme Court held that a state peer review protection statute establishes a qualified privilege rather than an absolute privilege, not **protecting** communications made with malice. n127 A federal district court in Louisiana refused to recognize a federal privilege to protect medical peer review documents in a § 1983 action, finding no support for the federal privilege in federal common law or in the HCQIA. n128

n126 *Meyers v. Columbia/HCA Healthcare Corp.*, 341 F.3d 461, 472 (6th Cir. 2003).

n127 *Hassan v. Mercy Am. River Hosp.*, 74 P.3d 724, 726 (Cal. 2003).

n128 *Rdzanek v. Hosp. Serv. Dist. # 3*, No. Civ.A. 03-2585, 2003 WL 22466232, at *2-4 (E.D. La. Oct. 29, 2003).

Similar to the Hospitals and Health Systems Practice Group, the In-House Counsel Practice Group also explored several vicarious liability cases. The practice group leaders included cases that demonstrate that courts will look behind agreements and objective factors to determine if a hospital actually exercises control over independent contractor physicians. n129

n129 *Compare Shands Teaching Hosp. & Clinic, Inc. v. Juliana*, 863 So. 2d 343, 350 (Fla. Dist. Ct. App. 2003), *review denied* 865 So.2d 481 (Fla. 2003) *with Ural v. Levy*, No. 01-215-B, 2003 WL 21511122, at *3 (D.N.H. 2003).

The Texas Supreme Court issued two medical malpractice decisions of interest to in-house counsel. In *McIntyre v. Ramirez*, the Texas Supreme Court held that a physician is not liable for damages under the state "Good Samaritan Law" where he had no duty to respond and was not expecting remuneration after responding. n130 The supreme court also found that, under Texas law, parents do not have a cause of action for loss of consortium resulting from a non-fatal injury to a child, even if a child can recover for the loss of consortium of a parent. n131

n130 *McIntyre v. Ramirez*, 109 S.W.3d 741, 742-43 (Tex. 2003).

n131 *Roberts v. Williamson*, 111 S.W.3d 113, 114-18 (Tex. 2003).

In a case related to organ donation, in-house counsel will want to advise hospital personnel to be careful and specific in explaining the details of organ donation. A Missouri appeals court reversed a summary judgment in favor of a hospital and a nurse due to a factual dispute over whether the nurse's representations to the family of the decedent were accurate with respect to the invasiveness of organ harvesting. n132

n132 *Schembre v. Mid-Am. Transplant Ass'n*, 135 S.W.3d 527, 533 (Mo. Ct. App. 2004).

H. Labor and Employment

The leadership of the Labor and Employment Practice Group summarized significant labor and employment cases under numerous federal statutes, including the Fair Labor Standards Act, the Age Discrimination in Employment Act (ADEA), the Civil Rights Act of 1964, as amended in 1991 (CRA), and the Family and Medical Leave Act (FMLA).

The D.C. Circuit held that a private, nonprofit hospital's institution of new management over a previously operated

public hospital meant that the nonprofit hospital was a successor employer under the National Labor Relations Act (NLRA). Therefore, the new management was required to bargain with the public hospital's existing union. n133

n133 *Cnty. Hosps. of Cent. Cal. v. NLRB*, 335 F.3d 1079, 1081-84 (D.C. Cir. 2003).

In a significant case affecting older workers, the Supreme Court held that General Dynamics did not violate the ADEA when it promised to provide retiree health benefits for employees over age fifty but not for employees between forty and fifty. n134 Those in the latter category argued that they should fall within the statute's protected class and were being denied benefits because of their age. n135 The Supreme Court explained that older workers are receiving favorable treatment, which is not a violation of the ADEA. n136

n134 *Gen. Dynamics Land Sys., Inc. v. Cline*, 124 S. Ct. 1236, 1239 (2004).

n135 *Id.*

n136 *Id.* at 1248-49.

The Supreme Court addressed both affirmative action under the Constitution and the evidence needed to prove a mixed motive case under the CRA. In two affirmative action cases involving the University of Michigan, the Supreme Court distinguished between an acceptable affirmative action system and one that violates the Constitution. The Court upheld the law school's use of race as a significant factor in an individualized approach to applications, finding that it was "narrowly tailored . . . to further a compelling interest in obtaining the educational benefits that flow from a diverse student body." n137 The Court rejected the school's undergraduate system of automatically granting minority applicants twenty points as not narrowly tailored to achieve diversity. n138

n137 *Grutter v. Bollinger*, 539 U.S. 306, 343 (2003).

n138 *Gratz v. Hamacher*, 539 U.S. 244, 273-75 (2003).

In a significant victory for plaintiffs in employment discrimination cases, the Court held that the CRA permitted plaintiffs to use circumstantial evidence to show that an employer had used a forbidden consideration in making an employment decision, even though the business also had a legitimate business reason for the decision. n139 This ruling will make it easier for plaintiffs to bring mixed motive cases under the CRA.

n139 *Desert Palace, Inc. v. Costa*, 539 U.S. 90, 101-02 (2003).

The Eleventh Circuit upheld a labor department regulation requiring that an employee be incapacitated for three full and consecutive days to have a serious health condition under the FMLA. n140

n140 *Russell v. North Broward Hosp.*, 346 F.3d 1335, 1337 (11th Cir. 2003).

I. Long Term Care

The Long Term Care Practice Group focused on the use of mandatory arbitration clauses in resident contracts, a

criminal conviction for a failure to report elder abuse, and two state laws, one impacting union organization in California and the other influencing the right to remove nutrition and hydration from a woman in Florida.

Tennessee courts provided guidance on how to draft enforceable arbitration clauses in resident contracts. In *Howell v. NHC Health-care-Fort Sanders*, a Tennessee appeals court found an arbitration clause in a residency contract unconscionable because the clause was "buried" on page ten of an eleven-page contract, did not clearly indicate the forfeiture of a jury trial, and was explained by an admissions coordinator to an individual who could not read or write. n141

n141 *Howell v. NHC Healthcare-Fort Sanders, Inc.*, 109 S.W.3d 731, 733, 734-35 (Tenn. Ct. App. 2003).

In another Tennessee decision, the appeals court found that a husband's signature on his mentally competent wife's residency agreement could not bind the patient to arbitrate disputes with the **nursing home**. n142

n142 *Raiteri ex rel. Cox v. NHC Healthcare/Knoxville, Inc.*, No. E2003-00068-COA-R9-CV, 2003 WL 23094413, at *9 (Tenn. Ct. App. Dec. 30, 2003).

In a case reinforcing the need to report cases of elder abuse, a Missouri court upheld a jury verdict against a **nursing home**, its management **company**, and the management **company's** president for failure to report a case of serious elder abuse to a state hotline. n143 The president was sentenced to one year in prison and a \$ 1,000 fine, the maximum punishment for this misdemeanor. n144

n143 *Missouri v. Kaiser*, Nos. ED 82515, ED 82516, ED 82517, 2004 WL 727030, at *1 (Mo. Ct. App. Apr. 6, 2004).

n144 *Id.*

The Ninth Circuit affirmed a district court's ruling that the NLRA preempted a California statute making it unlawful for entities receiving in excess of \$ 10,000 from the state to use any of those funds to advocate for or against unionization of their workplaces. n145

n145 *Chamber of Commerce v. Lockyer*, 364 F.3d 1154, 1159 (9th Cir. 2004).

The practice group also focused on another state statute, Terri's Law, which permitted Florida Governor Bush to reinstate a feeding tube after a court issued an order permitting the tube's removal. n146 Terri Schiavo's husband, Michael Schiavo, challenged the law's constitutionality in a state lawsuit. A Pinellas County Circuit Court found the law unconstitutional, which decision was recently affirmed by the Florida Supreme Court. n147

n146 *Schiavo v. Bush*, No. 03-008212-CI-20, 2004 WL 980028, at *3 (Fla. Cir. Ct. May 5, 2004).

n147 *Bush v. Schiavo*, 2004 Fla. LEXIS 1539 (Fla. Sept. 23, 2004).

J. Medical Staff, Credentialing, and Peer Review

Leaders of this practice group focused on many of the issues that have increased tensions between physicians and hospitals over the last twelve months, including exclusive contracting, economic credentialing, disruptive healthcare

professionals, and due process rights under medical staff bylaws.

The Tennessee Supreme Court held that state law permits a public hospital to enter into an exclusive contract for its imaging department, refusing access to a radiology group that had opened a competing outpatient diagnostic imaging center. n148

n148 *City of Cookeville v. Humphrey*, 126 S.W.3d 897, 900 (Tenn. 2004).

A trial court in Arkansas issued a preliminary injunction against a hospital's enforcement of an economic conflict of interest policy that denied reappointment to the medical staff of any practitioner who directly or indirectly holds an ownership interest in a competing hospital. n149

n149 *Murphy v. Baptist Health*, No. CV2004-2004 (Pulaski County Ct. Mar. 22, 2004).

The Idaho Supreme Court upheld a hospital's decision not to grant privileges to a physician with a long history of disruptive behavior. n150 The hospital denied the physician's application, finding that the disruptive behavior would interfere with hospital operations and patient care. n151

n150 *Miller v. St. Alphonsus Reg'l Med. Ctr., Inc.*, 87 P.3d 934, 936-37 (Idaho 2004).

n151 *Id.* at 944.

The Wisconsin Supreme Court held that a suspended physician does not have a due process right to representation by an out-of-state attorney. n152 The supreme court found that the words "legal counsel," as used in the medical staff bylaws, refer to an attorney licensed in Wisconsin. n153

n152 *Seitzinger v. Cmty. Health Network*, 676 N.W.2d 426, 437 (Wis. 2004).

n153 *Id.* at 429.

K. Physician Organizations

The Physician Organizations Practice Group focused on the myriad of issues that impact the practice of medicine in today's complex, competitive healthcare environment, including recruitment and employment agreements, antitrust, discrimination, and malpractice issues.

A South Carolina appeals court enforced an arbitration provision in a recruitment contract between a cardiovascular practice and a physician, finding that the agreement was an "activity that involves interstate commerce." n154 The court reasoned that the agreement involved a monetary inducement to cross state lines. n155 A Tennessee appeals court found a noncompete provision between a clinic and a physician enforceable because there is consideration in the agreement, the clinic will suffer financially without the agreement, the employee's economic hardship is minimal, and the agreement is in the public interest. n156

n154 *Thornton v. Trident Med. Ctr.*, 592 S.E.2d 50, 55 (S.C. Ct. App. 2003).

n155 *Id.* at 54.

n156 *Murfreesboro Med. Clinic v. Udom*, No. M2003-00313-COA-R9-CV, 2004 WL 193049, at *5 (Tenn. Ct. App. Jan. 30, 2004) (decision without official published opinion).

The practice group summarized two cases (and cited several more) in which the FTC issued complaints against physician practices for the methods used to negotiate rates with health plans. n157 The FTC is concerned about price-fixing agreements between competitors adding to the cost of healthcare.

n157 *See In the Matter of Cal. Pacific Med. Group, Inc.*, F.T.C. Dkt. No. 9306 (2003) (complaint); *In the Matter of North Tex. Specialty Physicians*, F.T.C. Dkt. No. 9312 (2003) (complaint).

In a case of import to employers providing health benefits to their employees, the U.S. Supreme Court held that ERISA, unlike the Social Security Act, does not require special deference for a treating physician's opinion when making a disability determination about an insured. n158

n158 *Black & Decker Disability Plan v. Nord*, 538 U.S. 822, 825 (2003).

In an important labor decision for physicians, the Sixth Circuit held that independent contractor physicians cannot bring employment discrimination suits against the entities with which they have contractual relationships. n159

n159 *Shah v. Deaconess Hosp.*, 355 F.3d 496, 500 (6th Cir. 2004).

Courts issued numerous malpractice decisions of interest to physician counsel. The Colorado Supreme Court allowed a medical malpractice action to go forward against the Kaiser Foundation Health Plan, even though the decedent's enrollment agreement contained a binding arbitration clause. n160 The supreme court found that Kaiser had failed to meet the typeface and wording requirements of a Colorado law regulating arbitration agreements. n161 In Florida, a hospital assumed a physician's malpractice liability when the hospital failed to ensure that the physician had the insurance coverage required by law. n162

n160 *Allen v. Pacheco*, 71 P.3d 375, 376-77 (Colo. 2003).

n161 *Id.* at 381.

n162 *Mercy Hosp. v. Baumgardner*, 870 So.2d 130, 131-32 (Fla. Dist. Ct. App. 2003).

L. Regulation, Accreditation, and Payment

The last twelve months virtually exploded with payment enhancements for providers authorized by the MMA, new regulations emanating from that law, and accreditation developments from the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) as it strategized to improve patient safety.

The MMA contains provisions to establish a transitional Medicare Prescription Drug Card Program, initiate a new Medicare Advantage Program, and enhance provider payments, among a myriad of other provisions. n163 Several of these sections generated complex regulations produced rapidly by DHHS after the passage of the new act.

n163 See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified in scattered sections of 21, 42 U.S.C. (2004)).

On December 15, 2003, only one week after the president signed the MMA into law, DHHS issued a notice of intent to seek applications for the new Medicare Prescription Drug Discount Card. n164 The Drug Discount Card Program was then launched on May 3, 2004, with supporters and proponents debating whether it resulted in savings for seniors. n165

n164 See Medicare Prescription Drug Discount Card, 68 Fed. Reg. 69,928 (Dec. 15, 2003).

n165 *CMS Refutes Report Questioning Potential Savings of Medicare Discount Drug Card*, 2 HEALTH LAW WEEKLY 19 (May 7, 2004).

On January 16, 2004, CMS announced a significant increase in payment rates for Medicare Advantage health plans to take effect March 1. n166 These increases were authorized by § 211 of the MMA, which was designed to increase plan participation by ensuring that participating plans are paid as much as fee-for-service plans. n167 On May 10, CMS announced a 6.6% increase in payment rates for Medicare Advantage Plans in 2005. n168

n166 See *CMS Announces 10.6% Average Increase in Payment Rates for Medicare Managed Care Plans*, 2 HEALTH LAW WEEKLY 4 (Jan. 23, 2004).

n167 ABRAHAMSEN ET AL., *supra* note 6, at 16.

n168 *CMS Announces 6.6% Bump in 2005 Medicare Advantage Payment Rates*, 2 HEALTH LAW WEEKLY 20 (May 14, 2004).

On January 6, 2004, CMS published an interim final rule authorized by the MMA that increased payments to physicians by an average of more than 1.5% for calendar year 2004. n169 This replaced a November 7, 2003, final rule that would have reduced physician payments. n170

n169 See Medicare Program; Changes to Medicare Payment for Drugs and Physicians Fee Schedule Payments for 2004, 69 Fed. Reg. 1084, 1102 (Jan. 7, 2004) (codified at 42 C.F.R. pts. 405, 414).

n170 See *id.* at 1084.

In the area of accreditation, the practice group leaders focused on JCAHO announcements that enhanced its efforts to protect patient safety. JCAHO's Board of Commissioners approved a universal protocol for preventing wrong site, wrong procedure, and wrong person surgery. All JCAHO-accredited organizations must follow this protocol effective July 1, 2004. n171

n171 See *Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery*, at www.jcaho.org/accredited+organizations/patient+safety/universal+protocol/index.htm (last visited Sept. 8, 2004).

On January 1, 2004, JCAHO officially launched its new "Shared Visions-New Pathways Accreditation Process." n172 In December 2003, JCAHO announced that it had completed pilot testing two components of the new process: the Periodic Performance Review and the Priority Focus. n173

n172 See The Joint Comm'n on Accreditation of Health Care Orgs., *The Launch of Shared Visions New Pathways*, 24 JOINT COMMISSION PERSPECTIVES 1 (2004).

n173 *Id.* at 14.

The practice group leadership also reviewed a number of significant reimbursement cases by providers against the government. These cases included *Baystate Medical Center v. Thompson*, in which a federal district court granted the plaintiffs' motion for summary judgment and issued a writ of mandamus to DHHS compelling the agency to reopen and revise certain determinations related to disproportionate share payments. n174

n174 *In re Medicare Reimbursement Litig.*, 309 F. Supp. 2d 89, 100 (D.D.C. 2004).

M. Tax and Finance

As referenced in the Top Ten, joint ventures topped the list of significant issues summarized by the Tax and Finance Practice Group.

St. David's Health Care System has ridden a roller coaster of litigation after the IRS revoked its tax-exempt status following its entrance into a joint venture with a for-profit affiliate of HCA. In the last twelve months, the Fifth Circuit reversed an extremely favorable federal district court summary judgment decision in the nonprofit system's favor. The Fifth Circuit held that material facts existed as to whether St. David's retained control over the partnership, which could only be determined by examining the partnership's actual operation. n175 On remand, however, a jury found that St. David's should retain its exempt status, dealing the government a significant loss on the issue of control in joint ventures. n176

n175 *St. David's Health Care Sys., Inc. v. United States.*, 349 F.3d 232, 244 (5th Cir. 2003).

n176 Kevin Hilvert, *St. David's Tax Exemption Upheld . . . Again*, 2 HEALTH LAW WEEKLY 10 (Mar. 12, 2004).

The IRS also issued guidance on ancillary joint ventures, finding that a university may maintain its tax-exempt status when it contributes an insubstantial part of its assets to an ancillary joint venture with a for-profit **company** that specializes in conducting interactive video training programs. n177

n177 Rev. Rul. 2004-51, 2004-22 I.R.B. 974 (2004); See *supra* note 72 and accompanying text.

In South Dakota, the attorney general sought to impose constructive trust law, rather than state nonprofit corporation law, on the sale of Banner Health System's South Dakota assets. Banner Health System is an Arizona corporation that owns **nursing homes** and other assets in South Dakota. The attorney general sought to ensure that proceeds from the sale of the assets remained in the state. n178 The South Dakota Supreme Court held that an implied charitable trust could apply to the sale of Banner's South Dakota assets based on theories of unjust enrichment, breach of fiduciary duties, and improper amendment of the corporation's articles of incorporation. n179

n178 *Banner Health Sys. v. Long*, 663 N.W.2d 242, 243 (S.D. 2003).

n179 *Id.* at 248.

The IRS and state attorneys general were not the only arms of government scrutinizing the activities of nonprofit healthcare. Representative Bill Thomas of California, Chairman of the House Ways and Means Committee, stated that his committee would examine the tax-exempt status granted to nonprofit hospitals and other charitable entities. According to news reports, the scrutiny was prompted by a letter from the AHA to the Secretary of DHHS questioning whether regulatory barriers prevented hospitals from offering discounts to the uninsured. n180

n180 *See supra* notes 63-67 and accompanying text.

N. Teaching Hospitals and Academic Medical Centers

The Teaching Hospitals and Academic Medical Centers Practice Group summarized numerous cases in several important areas of law, including legal representation, Medicare and Medicaid payment issues, and indigent care issues.

Two courts awarded attorneys' fees to those suing the Secretary of DHHS for misapplication of Medicare law, finding that the government's position was not substantially justified. n181

n181 *See* Conn. State Dep't of Soc. Servs. v. Thompson, 289 F. Supp. 2d 198, 209 (D. Conn. 2003); *see also* Gray Panthers Project Fund v. Thompson, 304 F. Supp. 2d 36, 42 (D.D.C. 2004).

A California appeals court held internal incident reports privileged in a wrongful death suit because they were prepared for attorney review and designed to prevent accidents. n182

n182 *Scripps Health v. Superior Court*, 135 Cal.Rptr.2d 126, 127 (Ct. App. 2003).

In a Medicare reimbursement case of importance to academic medical centers, a federal district court in Ohio found that resident hours do not need to be spent on direct patient care in order to be counted in the calculation of a teaching hospital's indirect medical education cost adjustment under Medicare. n183

n183 *Riverside Methodist Hosp. v. Thompson*, No. C2-02-94, 2003 U.S. Dist. LEXIS 15163 at *35-36 (S.D. Ohio 2003).

The practice group leadership summarized three cases that explored the legal requirement to exhaust administrative remedies in Medicare cases. n184

n184 *See* *Kaiser v. Blue Cross of Cal.*, 347 F.3d 1107, 1109 (9th Cir. 2003) (constitutional and statutory claims inextricably intertwined with Medicare benefit determinations require exhaustion of administrative remedies); *Fanning v. United States*, 346 F.3d 386, 388 (3d Cir. 2003) (recovery of Medicare payments from settlement of product liability claim arose under Medicare Act and required exhaustion); *Bartlett Mem'l Med. Ctr., Inc. v. Thompson*, 347 F.3d 828, 830-31 (10th Cir. 2003) (challenge of validity of DHHS Secretary's action does not require exhaustion of remedies).

The Kansas Supreme Court applied the collateral source rule in a negligence action, refusing to limit the award for medical expenses to the amount actually paid by Medicare in a suit against Via Christi Health System. n185 In a case of enormous interest to hospitals that use consultants to help maximize reimbursement, a Louisiana appeals court held that a hospital could recover from KPMG under a breach of contract theory when KPMG failed to maximize the hospital's disproportionate share reimbursement. n186

n185 *Rose v. Via Christi Health Sys., Inc.*, 78 P.3d 798, 800-02 (Kan. 2003).

n186 *L.S. Huckabay Mem'l Hosp., Inc., v. KPMG Peat Marwick, LLP*, 843 So.2d 1186, 1188 (La. Ct. App. 2003).

III. Conclusion

Over the past twelve months, the federal government made a huge investment in healthcare. The MMA offers a prescription drug benefit for seniors, constructs a new Medicare managed care program, and increases reimbursement to all types of healthcare providers.

Providers were generally fortunate in their treatment by government but testy in their relationships with each other. Not only did healthcare providers (and plans) receive increased reimbursement from Medicare, but DHHS also issued EMTALA regulations sensitive to their needs and at least attempted to honor the providers' comments in issuing the final set of regulations on Stark II.

In spite of this good news, hospitals and physicians saw increased animosity in their relationships, including battles over specialty hospitals and the use of such tools as economic credentialing, exclusive contracting, loyalty oaths, and the strengthening of conflict of interest policies. n187 The practice groups summarized numerous disputes between physicians and hospitals regarding the revocation of privileges.

n187 See Almeta E. Cooper, Alice G. Gosfield, Gail P. Heagen, Brian M. Peters & Marc S. Raspanti, *Why Can't We All Just Get Along*, Address at American Health Lawyers Association Hospitals and Health Systems Law Institute (Feb. 12, 2004).

The animosity between health plans and providers did not abate either. Plans continued to feel the heat from both providers and consumers. Plans settled several class action suits by providers and continued to battle in others. Plans lost a \$ 13 million judgment in Texas, although later reduced, and are awaiting decisions in two significant Supreme Court actions related to consumer lawsuits. Providers also felt pressure from consumer groups that challenged the undiscounted charges being billed to uninsured patients.

Over the last twelve months, the federal government, states, and consumers have struggled with the high cost of prescription drugs. The federal government passed legislation to subsidize the costs for senior citizens beginning in 2006 and to create a drug discount card in the interim. States and localities wanted to import drugs from foreign countries, where drugs are often priced less than in the U.S., but were opposed by the Food and Drug Administration.

Although the economic "pie" for healthcare expanded remarkably in 2003 and 2004, the players in the healthcare arena still jockeyed for position to reap the benefits. The complexity of healthcare derives from the intertwined, yet distinct, roles of so many different entities that work to keep our populace healthy. Hospitals, health plans, and healthcare professionals compete, yet are interdependent, and many rely significantly on federal and state governments for their livelihood. This intricate economic model leads to fascinating developments every year as the mission of healthcare meets the economic necessities of so many different actors.

This effort to boil one year's worth of developments into a digestible whole may serve as a resource for you until Health Lawyers meets again in San Diego in 2005. Practice Group members expended great effort to make this resource available, and they should be commended for their achievement. n188

n188 The following American Health Lawyers Association members read and summarized case law and policy developments used in this Overview and the full text of the Year in Review: Paul W. Ambrosius, Randal Ammons, Douglas K. Anning, Christina M. Bahr, John B. Beard, Katherine Benesch, Travis L. Blais, Carl P. Bowman, Jamie R. Brashear, Beth Christian, Sherry A. Fabina-Abney, Richard A. Feinstein, Megan R. Flaskamper, Margaret W. Galvin, Lisa J. Gilden, Gina Ginn, Rosalia R. Goddard, Karen L. Goldsmith, Todd Gonyer, Kevin D. Gordon, R. Kenneth Gordon, Barry A. Guryan, Patricia Haas, Bernard K. Ham, Lisa A. Hathaway, Morris Hawk, Valerie

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LENGTH: 22859 words**TITLE:** Bankruptcy Opportunities and Pitfalls: Strategies for Restructuring and Unwinding Integrated Delivery Systems**AUTHOR:** Robert A. Klyman *

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TEXT:

ABSTRACT: Many organizations in the healthcare field are facing issues regarding the "dis-integration" of previously assembled integrated delivery systems. In many situations, bankruptcy is the most effective effective means for pursuing this course of action. This article examines and explains the bankruptcy process, its applicability to an IDS, and strategies for dealing with the process.

I. Introduction

The United States healthcare industry finds itself in a "frenzied and chaotic" n1 sea of change, manifested by the rapid consolidation of a previously fragmented industry into large integrated delivery systems ("IDSs"). n2 The causes of this change are complex and multifaceted, but the primary stimulus has been the evolution of managed care systems. n3 The fear of exclusion from these IDSs and "concerns over who will eventually dominate the managed care market have caused a massive upsurge in affiliations among hospitals, doctors, and insurers." n4 Nationally, in fact, hospitals have acquired physician practices to better position themselves for managed care contracting. n5 Between 1989 and 1993, for example, there were more than \$ 87 billion in healthcare mergers, acquisitions, and joint ventures. n6 SMG Marketing Group, Inc., a consulting group in Chicago, contends that 338 integrated health networks existed nationwide as of February 1995, and that "by the year 2000, 90% of United States hospitals will be involved in integrated networks." n7

n1 See Amy Woodhall, *Integrated Delivery Systems: Reforming The Conflicts Among Federal Referral, Tax Exemption, and Antitrust Laws*, 5 HEALTH MATRIX 181, 182 (1995).

n2 Historically, healthcare has been a fragmented industry characterized by legally separate provider entities, and separate payor and provider organizations. Problems associated with industry fragmentation include duplication among providers (see Kevin Lumsdon, *Home and Community-Based Programs Integrate Acute and Long-Term Care: Bridging the Gap*, 67 HOSP. & HEALTH NETWORKS 44 (1993); Gerald R. Peters, *Integrated Delivery Can Ally Physician and Hospital Plans*, HEALTHCARE FIN. MGMT. 21 (Dec. 1991), fragmented episodic care (see RUSSELL C. COILE, JR., THE NEW GOVERNANCE STRATEGIES FOR AN ERA OF HEALTH REFORM 136-37 (1994)), gaps in insurance payments, and conflicting financial incentives among providers and between payors and providers (see Paul M. Ellwood, Jr., M.D., *When MDs Meet DRGs*, HOSPITALS 62 (Dec. 16, 1983)).

n3 See, e.g., Carl H. Hitchner et al., *Integrated Delivery Systems: A Survey of Organizational Models*, 29 WAKE FOREST L. REV.

273 (1994) ("The major catalyst of [the reorganization of the delivery of healthcare] is the emergence of managed care as a dominant market force."). See also Woodhall, *supra* note 1, at 182 ("The prospect of some type of health reform, the increasingly competitive environment, and the aggressive development of new delivery and financing modes have combined to produce a fundamental restructuring within the industry."); Robin R. Gillies, *Conceptualizing and Measuring Integration: Findings From the Health Systems Integration Study*, 38 HOSP. & HEALTH SERV. ADMIN. 467, 468-70 (1993) (Another cause of the rapid consolidation has been the demand by purchasers for performance measures for defined patient populations. "Developing health status outcomes and demonstrating cost-effectiveness for large patient populations requires clinical integration of healthcare services from a patient-centered perspective, physician integration through economic linkages, governance and management, and the functional integration of strategic planning and quality improvement."); Thomas Greaney, *Managed Competition, Integrated Delivery Systems and Antitrust*, 79 CORNELL L. REV. 1507, 1509 (1994) (discussing reasons the healthcare market has shifted to managed competition).

n4 Mark A. Hall, *Managed Competition and Integrated Health Care Delivery Systems*, 29 WAKE FOREST L. REV. 1, 5 (1994).

n5 Woodhall, *supra* note 1, at 229.

n6 Karen A. Jordan, *Managed Competition and Limited Choice of Providers: Countering Negative Perceptions Through a Responsibility to Select Quality Network Physicians*, 27 ARIZ. ST. L.J. 875, 877 n.9 (1996).

n7 Nicole A. Reuschel, *The Centerpiece of Health Care Reform -- Integrated Delivery Systems: Confronting Tax Code Challenges That Threaten Health Care Integration*, 30 SUFFOLK U. L. REV. 825, 826 n.6 (1997) (citing Lisa Lopez, *Integrated Delivery Systems*, 13 BUS. & HEALTH 31, 32 (1995)). See also, e.g., Pamela Gaynor, *Sale of Non-Profits Raises Questions*, PITTSBURGH POST-GAZETTE, Dec. 22, 1995, at B11 ("sales of nonprofit hospitals to for-profit **companies** have been occurring at a breakneck pace"); Julie Y. Park, *PHOS and the 1996 Federal Antitrust Enforcement Guidelines: Ensuring the Formation of Procompetitive Multiprovider Networks*, 91 NW. U. L. REV. 1684, 1690 (1997).

The most general labels for these affiliations are IDSs or "integrated networks." An IDS typically covers a broad range of services and includes, at a minimum, a full array of hospital and physician services in both inpatient and outpatient settings. n8 The essence of an IDS is that an organized medical practice and a hospital organization are legally merged or affiliated and, to some extent, operate as a single enterprise. n9 In the typical horizontal model, a parent holding **company** is the sole owner of two subsidiaries, a hospital organization and a medical practice organization ("MPO"). Alternatively, a hospital may integrate a MPO as its subsidiary. n10 An IDS owns or leases all assets necessary to provide comprehensive healthcare services to its patients. It: (i) contracts with payors to provide healthcare services; (ii) employs and compensates all employees and independent contractors (including physicians) who provide services to patients; and (iii) earns all revenues for services and goods provided to patients. n11

n8 Park, *supra* note 7, at 1686; PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 79-144 (1988).

n9 GERALD PETERS, *HEALTHCARE INTEGRATION: A LEGAL MANUAL FOR CONSTRUCTING INTEGRATED ORGANIZATIONS* 37 (1995).

n10 *Id.* at 338 (also discussing other models).

n11 *Id.*

Managed care has changed the dynamics of healthcare delivery and "forced participants in the healthcare marketplace into new contractual relationships with one another." n12 Traditionally, physicians held the power in the healthcare arena, because they controlled the decision-making process. n13 Managed care has shifted the balance of power toward the hospital administrator because hospitals, to compete for scarcer resources, "began to consolidate through alliances,

mergers and acquisitions to reduce excess capacity, achieve economies of scale and to strengthen their bargaining power with the new managed care organizations." n14 In this competition, moreover, hospitals were compelled to become more cost-conscious and reduce hospital staff. In addition, hospital management became more centralized, thereby further diluting physician influence locally. n15 Physicians, however, still retained both their autonomy over medical diagnosis and treatment, and their historic hostility to threats against professional autonomy. The creation of an IDS, therefore, occurs despite inherent long-standing conflicts of interest among participants, which, if unchecked, may sow the seeds of disintegration and discord.

n12 Park, *supra* note 7, at 1690.

n13 *Id.* at 1686; STARR, *supra* note 8, at 79-144. Previously, physicians were able to preserve their autonomy in the hospitals by the effective use of what one commentator called medicine's "cultural authority, economic power and political influence." John G. Day, *Managed Care and the Medical Profession: Old Issues and Old Tensions*, 3 CONN. INS. L.J. 1, 4-5 (1996).

n14 Day, *supra* note 13, at 20.

n15 *Id.*

Certain IDSs will be unable to withstand the buffeting winds of consolidation and competition. The natural darwinian process of consolidation in any industry, let alone one built on a shaky foundation, produces winners and losers: "Bankruptcies are often concentrated in industries that have experienced prolonged periods of economic upheaval." n16 Retail, n17 airlines, n18 and trucking n19 are examples of industries in which consolidation and heightened competition led to the bankruptcies of numerous market participants. No doubt healthcare, with its rush to form IDSs and their resultant internally-divided psyche, will be one of the next growth industries for bankruptcy practitioners. n20 Compounding these difficulties is the use to which borrowed money has been put by many IDSs. Many physician management **companies** have spent more on acquisitions than on improving physicians' efficiency or capital performance. In lieu of boosting internal long range growth by investing in information systems, medical equipment, or expansion of medical services, the typical large IDS relies on acquisitions to sustain revenue growth. n21

n16 Stewart L. Cohen, *The Business of Retail -- More Changes to Come*, AM. BANKR. INST. J., available in LEXIS, 1995 ABIJNL. LEXIS 100.

n17 *Id.*

n18 See, e.g., Bettina M. Whyte, *Airline Industry Restructuring: From Stuck in the Mud to Flying High*, AM. BANKR. INST. J., available in LEXIS, 1997 ABI JNL. LEXIS 78 (describing consolidation and bankruptcy in airline industry).

n19 See, e.g., Paul Stephen Dempsey, *The Interstate Commerce Commission -- Disintegration of an American Legal Institution*, 34 AM. U. L. REV. 1, 47 (1994) (describing motor carrier industry as having been consolidated by "the strong," resulting in bankruptcies that "slaughtered the weak").

n20 See, e.g., William M. Sage & James M. Jorling, *A World That Won't Stand Still: Enterprise Liability by Private Contract*, 43 DePAUL L. REV. 1007, 1035 (1994) ("As the health care industry integrates and consolidates to improve efficiency, many health care provider and insurance organizations will no doubt fail and declare bankruptcy.").

n21 See Rhonda L. Rundle & Anita Sharpe, *Physician-Management Firms Have Landed in Sick Bay*, WALL ST. J., July 31, 1998, at

B4 (citing as prominent examples of such acquisition models MedPartners, Phycor, and FPA Medical Management; the latter recently filed for bankruptcy, *In re FPA Medical Management, Inc.*, Case Nos. 98-1596 (PJW) to 98-1685 (PJW) (Bankr. Del. 1998)).

When an IDS unwinds, at least one party to the IDS may seek to block the unwinding or hold-out for a better settlement to the detriment of the IDS's enterprise value and return to the IDS's creditors. Moreover, the unwinding of an IDS necessarily leads to the reallocation of assets and liabilities, leaving the separated entities vulnerable to fraudulent transfer and breach of contract attacks by disgruntled creditors. n22 Further, the former partners in the IDS may have contingent liability for the debts of the IDS; any agreement between them may not bind third party creditors. Even when a sale of assets is the best way to realize value and implement the unwinding of the IDS -- and in consolidating industries, survivors are likely to find acquisition opportunities -- a doctor, creditor, or other party in interest may object to and block the sale. The sale price, even if the sale materializes, may be dampened by the risk to the purchaser of successor liability.

n22 The transfer of assets from one entity to another that leaves the transferor financially weak or unstable may give rise to a lawsuit for avoidance of such transfer. *See, e.g.*, CAL. CIV. CODE §§ 3439-3439.12 (West 1998).

The Bankruptcy Code provides an effective corporate tool to implement the unwinding of an IDS over the objections of third parties while preserving the going concern value of the IDS's assets. While this procedure is not always cost-free, in certain circumstances hospitals and doctor groups would be remiss not to consider the significant benefits that derive from consummating corporate transactions through the bankruptcy process. n23 Any costs, moreover, may be substantially mitigated with careful pre-bankruptcy planning.

n23 Some IDSs are already taking advantage of the relief afforded by the Bankruptcy Code, including one of the largest affiliations in the State of Pennsylvania, Allegheny Health, which upon filing for bankruptcy announced an agreement in principle to sell nine hospitals to a third-party buyer for \$ 502 million. Allegheny Health, Education and Research Foundation, Bankr. W.D. Pa. No. 98-25773 to 98-25777, filed July 21, 1998 (cited in *Pennsylvania: Allegheny Health System Seeks Chapter 11 Protection; Proposes Sale of Nine Hospitals*, Health Law Rep. (BNA) No. 7, at 1193 (July 30, 1998)). Allegheny Health had \$ 1.3 billion in debt at the time it commenced bankruptcy proceedings. Much of the debt arose from the acquisition of hospitals and physician practices. *See* Ron Shinkman, *The Buck Stops Here*, MOD. HEALTHCARE 20 (Aug. 3, 1998).

II. Bankruptcy Background

A bankruptcy case for a corporate entity typically occurs under either Chapter 7 or Chapter 11 of the Bankruptcy Code. By filing a petition for relief under Chapter 7, the debtor starts a straight liquidation case, involving the termination of a debtor's business and the appointment of an independent trustee to take control of and liquidate the debtor's non-exempt assets, and distribute the cash proceeds to creditors based upon the priority of their claims.

Alternatively, a debtor can file a petition for relief under Chapter 11, under which the debtor continues in possession and control of its assets and continues to operate its business free from creditors' collection efforts. The debtor is supposed to use the "breathing space" afforded by the bankruptcy filing to correct the problems that led to the filing. The debtor might be expected to cut expenses, terminate unprofitable lines of business, sell assets, or reject above-market leases and contracts. The debtor should also negotiate with its creditors to work out a plan of reorganization. Such plans typically result in a reduction and/or stretch-out of payment of creditors' claims. n24

n24 *See generally* BRUCE S. NATHAN, **PROTECTING** CORPORATE CREDITORS UNDER THE BANKRUPTCY CODE § 1.03 (1997).

Under either chapter, an IDS debtor can be unwound and its assets sold free and clear of claims, interest, and liens. In Chapter 11 cases only, the IDS can reorganize and operate with a "fresh start" unencumbered by most unsecured pre-bankruptcy debts and obligations, including those to doctors/providers. In addition, the debtor can facilitate the unwinding of the IDS by rejecting contracts and leases, or assigning them to third parties, without regard to most anti-assignment provisions contained in such contracts and leases. Moreover, Medicare may be blocked from setting off post-bankruptcy payments to the IDS against pre-bankruptcy obligations. If the bankruptcy case is "prepackaged," a sale of the IDS or its assets can be quickly implemented and the reorganized IDS can emerge from bankruptcy in a matter of weeks or a few short months. For these and other reasons set forth below, bankruptcy provides a fertile ground for corporate transactions involving the disintegration or restructure of an IDS.

A. WHO IS ELIGIBLE TO BE A DEBTOR UNDER THE BANKRUPTCY CODE?

The threshold question in evaluating whether to pursue the disintegration or unwinding of an IDS through bankruptcy is whether the entity contemplating such proceedings is even eligible to be a "debtor" under the Bankruptcy Code. Section 109 of the Bankruptcy Code sets forth which entities are eligible to seek bankruptcy relief.ⁿ²⁵ The eligibility requirements are rarely at issue in a case outside the healthcare field. An individual, corporation or partnership may file for reorganization under Chapter 11.ⁿ²⁶ A debtor need not demonstrate insolvency or an inability to pay debts as a condition to filing.ⁿ²⁷ In fact, most hospitals and doctor practices are eligible for bankruptcy protection.ⁿ²⁸

ⁿ²⁵ 11 U.S.C. § 109 (1998).

ⁿ²⁶ *Id.* § 101(35).

ⁿ²⁷ *See, e.g., In re Stolrow's, Inc.*, 84 B.R. 167 (Bankr. 9th Cir. 1988).

ⁿ²⁸ Even nonprofit hospitals are eligible to become debtors under Chapter 11 of the Bankruptcy Code. *See, e.g.*, 6A NORTON BANKRUPTCY LAW AND PRACTICE 2d § 157:4, n.23 (identifying the following nonprofit hospitals as debtors: Metropolitan Hospital (Philadelphia), Mercy Hospital (Watertown, NY), Choate (Boston)).

However, there exists a split in the case law as to whether health maintenance organizations ("HMOs"), or other similar healthcare providers, constitute a domestic insurance provider and, thus, are not eligible for bankruptcy relief. Section 109 of the Bankruptcy Code provides that, "A person may be a debtor under Chapter 7 [or Chapter 11] of this title only if such person is not . . . (2) a domestic insurance **company**."ⁿ²⁹ While "person" and "corporation" are defined in the Bankruptcy Code, "domestic insurance **company**" is not. The Bankruptcy Code's express exemption of insurance **companies** from the federal bankruptcy laws has spawned litigation in various jurisdictions as to whether an HMO is such an entity, and therefore ineligible to be a debtor under the Bankruptcy Code.

ⁿ²⁹ 11 U.S.C. § 109(b)(2), (d).

In evaluating an HMO's eligibility to be a debtor, courts have employed one of three basic tests.ⁿ³⁰ The first test, the "independent classification test," rests on pure statutory construction.ⁿ³¹ Pursuant to that test, courts determine bankruptcy eligibility by applying traditional rules of statutory construction to section 109(b)(2). Courts using the independent classification test have relied on Congress' failure to specifically exclude HMOs from bankruptcy as

demonstrative of congressional intent to authorize HMOs to become debtors. n32 Moreover, these courts have held that Congress nowhere expanded or clarified the "domestic insurance **company**" exemption -- in contrast to the broader textual exclusion provided for banks and other financial institutions. Some courts have found these two arguments to be conclusive and authorized the filing of an HMO bankruptcy. n33

n30 See Patrick Collins, *HMO Eligibility for Bankruptcy: The Case For Federal Definitions of 109(b)(2) Entities*, 2 AM. BANKR. INST. L. REV. 425, 428-39 (1994) (and cases cited therein). The following opinions upheld the eligibility of an HMO to seek Title 11 relief: *In re Family Health Servs., Inc.*, 101 B.R. 636 (Bankr. C.D. Cal. 1989) (applying each of the three different tests, the court determined that a Louisiana HMO was eligible for Chapter 11 relief); *In re Family Health Servs., Inc.*, 101 B.R. 628 (Bankr. C.D. Cal. 1989) (applying each of the three different tests, the court determined that an Arizona HMO was eligible for Chapter 11 relief); *In re Family Health Servs., Inc.*, 104 B.R. 628 (Bankr. C.D. Cal. 1989) (applying each of the three tests, the court found that an Illinois HMO, which did business in Illinois, Indiana, and Ohio, was eligible for bankruptcy relief); *In re Group Health Partnership, Inc.*, 137 B.R. 593 (Bankr. E.D. Pa. 1992) (applying the state classification test, the court determined that a Pennsylvania HMO was eligible for relief); *Solomon v. St. Joseph's Mercy Hosp. (In re Michigan Master Health Plan, Inc.)*, 90 B.R. 274 (E.D. Mich. 1985) (deferring to the opinion of Michigan's attorney general, the court held that a Michigan HMO was not a domestic insurance **company** and, therefore, was eligible for relief under Chapter 11); *In re Family Health Servs., Inc.*, 101 B.R. 618 (Bankr. C.D. Cal. 1989) (applying the state classification test, the court held that a Texas HMO was not a domestic insurance **company** and, therefore, was eligible for relief under Chapter 11). On the other hand, the following cases denied eligibility: *In re Estate of Medicare HMO*, 998 F.2d 436 (7th Cir. 1993) (applying the state classification test, the court determined that an Illinois HMO was a domestic insurance **company** and, therefore, ineligible for bankruptcy relief); *In re Family Health Servs., Inc.*, 143 B.R. 232 (C.D. Cal. 1990) (applying the state classification test, the court determined that a Wisconsin HMO was a domestic insurance **company** and ineligible for relief and, therefore, reversed the bankruptcy court's contrary finding); *In re Beacon Health, Inc.*, 105 B.R. 178 (Bankr. D.N.H. 1989) (applying the state classification test, the court held that a New Jersey HMO was a domestic insurer and, therefore, ineligible for bankruptcy relief); *Portland Metro Health, Inc. v. Driscoll (In re Portland Metro Health, Inc.)*, 15 B.R. 102 (Bankr. D. Ore. 1981) (applying the state classification test, the court held that an Oregon HMO was a domestic insurer and, therefore, ineligible for relief under Chapter 11).

n31 See *United States v. Ron Pair Enters., Inc.* 489 U.S. 235, 241 (1989) (The starting point of any analysis of the meaning of a provision of the Bankruptcy Code is the language of the provision itself.).

n32 See, e.g., *In re Family Health Servs.*, 104 B.R. at 272.

n33 See, e.g., *id.* (relying on general rule of statutory construction that "enumeration of exclusions from the operation of a statute applies to all cases not specifically excluded"). Cf. *Cash Currency Exch. v. Shine (In re Cash Currency Exch.)*, 762 F.2d 542, 552 (7th Cir. 1985) (holding that Congress did not intend list of excluded entities to be exhaustive). See generally Collins, *supra* note 30, at 429.

The second test, "state classification test," requires a bankruptcy court to evaluate the state law under which the healthcare provider is organized to determine if an HMO is defined as an insurance **company**, or if an HMO is the functional equivalent of an insurance **company** under state law. Under this analysis, the courts reason that, "By providing no definitions to accompany the list of entities to be excluded from bankruptcy, Congress intended the classification of an entity under the law of the state of incorporation of that entity to be controlling on the issue of exclusion." n34 If the answer to either inquiry is yes, then the HMO is not eligible to be a debtor.

n34 Collins, *supra* note 30, at 429-30.

Finally, courts have applied the "alternative relief test," under which a court looks both to the available state procedures and congressional intent to determine whether relief under the federal bankruptcy statutes offers an acceptable alternative to available state insolvency and reorganization procedures. Under this test, courts have found that bankruptcy is a satisfactory alternative to state insolvency proceedings. n35

n35 *See, e.g., id.* at 437-38; *In re Republic Trust & Sav. Co.*, 59 B.R. 606, 614-15 (Bankr. N.D. Okla. 1986).

B. HOW DOES A BANKRUPTCY CASE START?

A voluntary bankruptcy case, under either Chapter 7 or Chapter 11, is commenced by filing a petition with the bankruptcy court under the applicable chapter by a person eligible to be a debtor under such chapter. n36 The filing of the petition automatically constitutes an "order for relief" under the chapter. No allegation of insolvency is required as a prerequisite to the filing of a petition or for an entry of the order for relief. However, the petition must be filed in "good faith" and not in an attempt to unreasonably deter or harass creditors. n37

n36 11 U.S.C. § 301 (1998).

n37 *See, e.g., In re Marsch*, 36 F.3d 825, 828 (9th Cir. 1994) (section 1112(b) permits dismissal of a case "for cause," which includes a "bad faith" filing). Discussions of other concepts used to evaluate the propriety of a bankruptcy filing, such as improper venue, are beyond the scope of this Article.

The Bankruptcy Code provides no guidance with respect to the corporate authority needed for a corporation to file a bankruptcy petition. The issue is a matter of state corporate law. n38 A voluntary petition may be filed on behalf of a partnership by one or more general partners if all partners consent to the filing of the petition. n39 If fewer than all of the general partners file a petition in the name of the partnership, it is treated as an involuntary petition. n40 Limited partners are given no right to file a petition on behalf of the partnership. Although the Bankruptcy Code does not specify how limited liability **companies** ("LLCs") commence a bankruptcy case, most cases dealing with LLCs have analogized them to general partnerships. An individual who is eligible to be a debtor under a specific chapter may commence his or her case by filing a petition.

n38 *See, e.g., Keenihan v. Heritage Press, Inc.*, 19 F.3d 1255, 1258 (8th Cir. 1994).

n39 FED. R. BANKR. P. 1004(a) (1998).

n40 11 U.S.C. § 303(b)(3)(A) (1998).

A bankruptcy case may also be commenced involuntarily. If a debtor has less than twelve creditors, an involuntary case may be commenced by one creditor with a claim of at least ten thousand dollars that is not contingent as to liability and not subject to a bona fide dispute. n41 If a debtor has twelve or more creditors holding claims, three such creditors with claims aggregating at least ten thousand dollars more than the value of any liens against the debtor's property must join in an involuntary petition. n42 Under either scenario, the debtor must not be generally paying its debts as they come due. The debtor has twenty days after service of a summons commencing the involuntary case to contest or accept the involuntary petition. n43

n41 *Id.* § 303(b)(2).

n42 *Id.* § 303(b)(1).

n43 See generally FED. R. BANKR. P. 1010, 1011 (1998). While it appears relatively easy to meet the requirements for filing an involuntary petition against a financially troubled debtor, the potential penalties for the misuse of the involuntary bankruptcy process are great. See generally Brad R. Godshall & Peter M. Gilhuly, *The Involuntary Bankruptcy Petition: The World's Worst Debt Collection Device?*, 53 BUS. LAW. 1315 (1998).

Creditors may seek to liquidate a debtor by filing an involuntary petition under Chapter 7 or may seek to reorganize the debtor and preserve its value as a going concern by filing an involuntary petition under Chapter 11. However, creditors of any healthcare organization eligible for bankruptcy relief cannot file an involuntary bankruptcy petition against these organizations if they are non-profit institutions qualifying for tax exempt status under section 501(c)(3) of the Internal Revenue Code. n44 Courts also look to a debtor's charter, its treatment under state law, and its business activities when determining if an involuntary petition can be filed against an entity that is purportedly not-for-profit. n45

n44 11 U.S.C. § 303(a); see *In re United Kitchen Assocs., Inc.*, 33 B.R. 214 (Bankr. W.D. La. 1983).

n45 See, e.g., *In re Caucus Distributors, Inc.*, 83 B.R. 921, 930 (Bankr. E.D. Va. 1988).

C. ROLES AND RESPONSIBILITIES OF DEBTOR'S MANAGEMENT AFTER COMMENCEMENT OF A CHAPTER 11 CASE

1. Introduction

A Chapter 11 filing places a **company** under Bankruptcy Court protection to enable the **company** to attempt to reorganize its financial condition and to make provisions for paying its obligations. The Chapter 11 filing also places the **company** under the supervision of the Bankruptcy Court and imposes certain duties and restrictions upon the **company's** management. These duties and restrictions are the necessary price of obtaining the "breathing spell" from creditors granted by Chapter 11.

2. General Duties of a Debtor to Creditors

Courts have held that upon filing Chapter 11, a **company** (e.g., its board and officers) acquires responsibilities to its creditors that are similar to the fiduciary duties a corporation normally has to its shareholders. n46 Absent court order, a **company** in bankruptcy cannot show favoritism to one group of creditors. A debtor will be required to consult with representatives of creditors on a regular basis regarding operations, business strategies, and financial performance.

n46 See *Pepper v. Litton*, 308 U.S. 295, 307 (1939) (The "standard for fiduciary obligation [in bankruptcy] is designed for the protection of the entire community of interest in the corporation on creditors as well as stockholders.").

The commencement of a case under Chapter 11 creates an "estate" which includes "all legal or equitable interests of the debtor in property as of the commencement of the case." n47 Upon filing, unless otherwise ordered by the Bankruptcy Court, the debtor (through its board and officers) remains in control of its affairs for the benefit of the estate as a debtor in possession. n48 In other words, the Chapter 11 debtor retains possession of its assets and continues to operate its business. The alternative to "debtor in possession" status is the appointment of a trustee by the Bankruptcy Court to replace existing management. In a Chapter 11 case, trustees are usually appointed only in cases involving gross fraud, conflicts of interest, or other egregious conduct. Trustees are the exception, not the rule in Chapter 11 cases. On the other hand, in a Chapter 7 liquidation, a trustee is automatically appointed to liquidate the assets of the estate.

n47 11 U.S.C. § 541(a)(1) (1998).

n48 *See* Wolf v. Weinstein, 372 U.S. 633, 649-50 (1963) ("In practice these fiduciary responsibilities fall not upon the inanimate corporation but upon the officers and managing employees who must conduct the Debtors' affairs.").

Among other obligations, the Bankruptcy Code and Bankruptcy Rules impose the following duties upon a debtor in possession:

- * To be accountable for all property of the debtor and to file a complete inventory of the debtor's property if directed by the Bankruptcy Court;
 - * To keep a record of receipts and disbursements of money;
 - * To furnish such information concerning the debtor's estate and the estate's administration as is requested by a creditor or other party in interest (unless the Bankruptcy Court orders otherwise);
 - * To file periodic reports of operations, including a statement of receipts and disbursements, with the Bankruptcy Court and with applicable governmental agencies;
 - * To make a final report and file a final account of the administration of the debtor's estate with the court;
 - * To give notice of the bankruptcy to every person holding either the money or property of the debtor;
 - * To provide information to and otherwise cooperate with the creditors' committee and any professional persons retained by them;
 - * To verify all claims against the estate and object to any claims that do not appear to match the debtor's records. (a claims analyst can be retained to assist in this task);
 - * To formulate and propose a plan of reorganization and take all steps necessary for its consummation;
- and
- * Other procedural obligations once a plan has been confirmed.

3. Operating in the "Ordinary Course of Business"

The Bankruptcy Code requires a **company** in Chapter 11 to obtain Bankruptcy Court approval of all proposed actions or transactions that are not in the "ordinary course of business." n49 The Bankruptcy Code does not define "ordinary course of business." As defined by case law, "ordinary course of business" refers to all normal steps taken by the **company** in the conduct of its day-to-day business.

n49 11 U.S.C. § 363 (1998).

Action that is within the ordinary course of business would include the following: purchase of regularly used materials and supplies; renewing insurance and taking other short-term measures to protect **company** property; hiring additional employees as may be needed, generally on a replacement basis; paying for wages, salaries, and other employee expenses for services performed after the filing of the Chapter 11 case; and paying for goods and supplies delivered after the filing of Chapter 11, if purchased on a one-time purchase order or open account basis. "Ordinary course of business" generally does not include the following: bulk sales; sales or purchases of capital items (although relatively small expenditures on a replacement basis -- for example, the purchase of necessary office equipment to replace broken or obsolete equipment -- would be considered within the ordinary course); abandonment of property; significant changes in **company** policy, particularly if they are expected to increase operating costs or involve substantial expenditure; agreements with lessors or lessees to terminate leases of real property; and employment agreements. A further discussion of certain procedures concerning the sales of assets out of the ordinary course is set forth below.

Most expenses incurred by a debtor after the bankruptcy petition date become administrative expenses of the estate. These expenses must be paid in cash at the end of the case in order for a plan of reorganization to be confirmed and for the debtor to emerge from Chapter 11. Payment of certain administrative fees incurred, such as the payment of professionals, are usually applied every 120 days and must be paid by the debtor as ordered by the Bankruptcy Court.

D. CHAPTER 11 PROTECTION: THE "AUTOMATIC STAY"

1. General Scope of the Automatic Stay

One of the principal benefits a debtor receives from filing for bankruptcy is the effect of the "automatic stay."ⁿ⁵⁰ As soon as a bankruptcy petition is filed, all entities are automatically stayed or prevented from taking certain action against a debtor or its property to collect debts arising before the day the bankruptcy case was filed (i.e., "pre-petition"). The automatic stay has the effect of a court-ordered injunction and can be enforced by court order, if necessary. The stay may be lifted for cause by court order.ⁿ⁵¹

ⁿ⁵⁰ See *id.* § 362.

ⁿ⁵¹ *Id.* § 362(d).

Certain secured creditors will move during the course of the case for relief from the automatic stay to foreclose on their collateral. To maintain the automatic stay, a debtor may be required to present evidence regarding the value of any collateral in question and the necessity of retaining that collateral for the debtor's business and effective reorganization.ⁿ⁵² Other creditors may move for relief from the automatic stay for authority to continue pre-petition lawsuits against a debtor to liquidate, but not execute upon, a pre-petition claim.

ⁿ⁵² See *id.*

Types of actions covered by the automatic stay include the following: continuing or commencing pre-petition lawsuits against the **company**; taking action to attach the **company's** property by legal process; "self-help" by creditors to take possession of the **company's** property; actions to foreclose or otherwise enforce liens or mortgages on the **company's** property; and any action to set-off a pre-petition debt. As set forth below, some courts have held that the government's attempt to recover Medicare overpayments was a set-off subject to the automatic stay.

Note, however, that the automatic stay does not generally apply to actions taken against (1) individual members of a debtor's board of directors for breach of fiduciary duty; or (2) subsidiaries of the debtor that are neither (a) debtors in United States bankruptcy courts, nor (b) United States **companies**. Further, the automatic stay would not impact the ability of creditors to realize on the assets of the debtor's subsidiaries for such subsidiaries' independent obligations.

Certain other actions are not covered by the automatic stay, including actions to perfect liens of mechanics and material men, repossession of certain leased real estate when the lease has terminated pre-petition, and certain actions by regulatory agencies. The exercise of police powers by a governmental agency may also be exempt from the automatic stay.ⁿ⁵³ The automatic stay does not excuse a debtor from complying with government regulations concerning its business. Environmental controls, labor regulations, and safety requirements continue to apply to the debtor **company**.ⁿ⁵⁴ Government agencies may also be permitted to conduct investigations of the **company's** business and operations.

Moreover, the automatic stay does not apply to a state's post-petition action to revoke a healthcare provider's license to operate based on a debtor's post-petition conduct. n55

n53 *See id.* § 362(b)(4).

n54 *See, e.g.*, 28 U.S.C. § 959.

n55 *See, e.g.*, Nat'l Hosps. and Institutional Builders Co. v. Goldstein (*In re Nat'l Hosps. & Institutional Builders Co.*), 658 F.2d 39 (2d Cir. 1981).

While the automatic stay generally applies only to the debtor, on rare occasions the court will extend the stay to claims against third parties who would then have claims against the debtor. For example, in *Family Health Services, Inc. v. Centinela Mammoth Hospital*, n56 Maxicare sought a restraining order prohibiting all non-contract providers from collecting unpaid medical bills from the patients. Contract providers were already prohibited from seeking payment from patients by the terms of their contracts with Maxicare. If the stay had not been extended to non-contract providers, their ability to bill patients for claims that had not been paid would have reduced the willingness of employers and other persons covered by Maxicare to renew their contracts with Maxicare. This would have made it virtually impossible for Maxicare to reorganize. Accordingly, the court extended the stay. n57

n56 105 B.R. 937 (Bankr. C.D. Cal. 1989).

n57 *See generally* NATIONAL HEALTH LAWYERS ASS'N., 3 HEALTH LAW PRACTICE GUIDE, ch. 30 (1996).

2. Recoupment May Provide Medicare an Avenue Around the Automatic Stay

Recoupment is an equitable doctrine pursuant to which a creditor's pre- and post-petition claims may be set-off against debts it owes to a debtor, so long as the parties' claims arise out of an "identical transaction." If the "same transaction test" is met, a court may use the doctrine of equitable recoupment to exempt a creditor from application of the automatic stay, regardless of whether the provider has accepted the provider agreement. Notably, if such claims do not arise out of identical transactions, it would be a violation of the automatic stay for the creditor to set-off its pre-petition claims against post-petition obligations and vice versa. n58 Whether the government may recoup pre-petition overpayments under Medicare to a health provider post-petition has been a heavily litigated issue. n59

n58 *Cf.* 11 U.S.C. § 553 (1998) (providing that right of setoff is not affected by the filing of a bankruptcy case so long as mutual debts existed between the debtor and creditor before the commencement of the bankruptcy case).

n59 Cases finding that post-petition recoupment violated the automatic stay include *University Med. Ctr. v. Sullivan* (*In re University Med. Ctr.*), 973 F.2d 1065 (3d Cir. 1992) (holding it was a violation of the automatic stay for the Medicare program to recoup past overpayments through a reduction in current payments prior to the assumption of the Medicare provider agreement by the debtor); *In re Consumer Health Servs. of America*, 171 B.R. 917 (Bankr. D.C. 1994); *Kings Terrace Nursing Home & Health Related Facility v. N.Y. State Dep't of Social Servs.* (*In re Kings Terrace Nursing Home & Health Related Facility*), 1995 WL 65531 (Bankr. S.D.N.Y. Jan. 27, 1995), *aff'd*, 184 B.R. 200 (S.D.N.Y. 1995); *Tidewater Mem'l Hosp., Inc. v. Bowes* (*In re Tidewater Mem'l Hosp., Inc.*), 106 B.R. 876 (Bankr. E.D. Va. 1989); *In re Memorial Hosp.*, 82 B.R. 478 (W.D. Wisc. 1988). *See generally* Elizabeth Swinton Schoen & Samuel R. Maizel, *The Medicare Contract In Bankruptcy: In Which Direction Does University Medical Center Lead?*, 11 BANKR. DEV. J. 405 (1995).

In *University Medical Center v. Sullivan*, n60 for example, the Secretary of the Medicare program argued that the overpayments made to the Medicare provider in 1985 were part of the same transaction as the services given by the debtor post-petition in 1988. The court, however, found no basis for holding that the claims were part of a single transaction because the annual account reconciliation process defined the scope of any single transaction. According to the court, since the provider's account was reconciled each year, any particular pre-petition monthly payment should be deemed to apply to the services rendered that month and any prior overpayment that had given rise to a "retroactive adjustment." Thus, according to the court:

The fact that the same two parties are involved, and that similar subject matter gave rise to both claims . . . does not mean that the two arose from the "same transaction." . . . Rather, both debts must arise out of a single integrated transaction so that it would be inequitable for the debtor to enjoy the benefits of that transaction without also meeting its obligations. Use of this stricter standard for delineating the bounds of a transaction in the context of recoupment is in accord with the principle that this doctrine, as a non-statutory equitable exception to the automatic stay, should be narrowly construed. n61

n60 973 F.2d 1065.

n61 *Id.* at 1081.

In *Medicar Ambulance Co., Inc. v. Shalala*, n62 the court construed the "same transaction test" even more strictly. In that case, Medicar Ambulance, which provided ambulance services reimbursable by Medicare, contested the decision of the Department of Health and Human Service ("HHS") decision to withhold payments for claims submitted by Medicar Ambulance for post-petition services. The court held that the doctrine of recoupment was not available because, although Medicare reimbursement is governed by an overarching series of regulations, Medicar Ambulance was paid separately for each invoice it submitted to Blue Shield. Thus, each invoice was deemed to constitute a separate transaction.

n62 166 B.R. 918 (Bankr. N.D. Cal. 1994).

On facts identical to those in *University Medical Center*, however, the court in *United States v. Consumer Health Services of America, Inc.*, n63 rejected the notion that, "the frequency of the audit appropriately defines the 'transaction.'" n64 Instead, the court looked to the Medicare statute, not the audit frequency employed by the Medicare secretary, as controlling:

In determining whether the pre-petition and post-petition services should be thought of as one transaction, the key to us is the Medicare statute. Since it requires the Secretary to take into account pre-petition overpayments in order to calculate a post-petition claim, . . . Congress rather clearly indicated that it wanted a provider's stream of services to be considered one transaction for purposes of any claim the government would have against the provider. . . . In sum, it does not matter whether we consider the government's claim in terms of its statutory substantive liability or in terms of the equitable recoupment doctrine. Under either analysis, the automatic stay is of no consequence. n65

The court, however, expressly limited its holding to providers continuing to provide services post-petition. n66

n63 108 F.3d 390 (D.C. Cir. 1997).

n64 *Id.* at. 395.

n65 *Id.*

n66 *Id.* at 396 ("Our decision does not purport to govern the effect of a petition for bankruptcy on a claim by Medicare for reimbursement of prior overpayments when the provider in question does not continue to provide services post-petition."). *See also* Schoen & Maizel, *supra* note 59.

3. Ability to Use Cash for Operations Post-Bankruptcy

Once in bankruptcy, the debtor is limited in its access to sources of cash for operations. A debtor in possession may not use cash collateral pledged pre-bankruptcy to its lenders, absent consent of such lenders or order of the Bankruptcy Court. n67 Cash collateral includes revenue and income (including proceeds of accounts receivable) subject to a valid, perfected, and enforceable security interest. n68 The debtor in possession should file a motion for approval of use of cash collateral at the outset of the case so that there are no allegations of improper use of cash. Alternatively, a debtor in possession can negotiate stipulations with its lenders or other secured creditors concerning use of cash collateral.

n67 11 U.S.C. § 363(c)(2). A lender whose cash collateral is used by a debtor must receive "adequate-protection" (e.g., replacement collateral) in return.

n68 *Id.*

If the debtor in possession decides to obtain additional outside financing on anything but a general unsecured basis (e.g., on an equal footing with trade debt), the debtor will need Bankruptcy Court approval. Post-bankruptcy financing may also be obtained on a senior secured basis to the extent the debtor can pledge as collateral assets with sufficient equity (so that the imposition of a senior lien will not unduly impair a pre-existing secured creditor). It is up to the Bankruptcy Court to determine, however, whether a pre-bankruptcy secured creditor may be "primed," or subordinated, to post-bankruptcy financing. n69

n69 *See id.* § 364.

When strategizing pre-petition, one source of post-petition financing that should not be overlooked is accounts receivable generated post-petition. The Bankruptcy Code precludes the attachment of a pre-petition security interest on accounts receivable to accounts receivable generated post-petition. n70 Generally, however, a debtor in possession will grant replacement liens on post-petition accounts receivable to its pre-petition lenders as adequate protection for post-petition use of cash collateral.

n70 *See id.* § 552(b). *See also, e.g.,* Greyhound Real Estate Finance Co. v. Official Unsecured Creditors Comm. (*In re* Northview

Corp.), 130 B.R. 543, 548 (Bankr. 9th Cir. 1991).

4. Sales Outside the Ordinary Course of Business

The use, sale, or lease of a debtor's property outside the ordinary course of business requires court approval after notice to and a hearing for interested parties. For court approval to be obtained, the sale must be in the best interests of the estate, requiring findings of a fair and reasonable price and good faith.

If another party has a secured interest in the property to be sold, the sale can proceed with the consent of the secured party. Alternatively, if a secured party does not consent, the sale can still occur and the lien or security interest can attach to the proceeds of the sale. A court may require overbid or auction procedures. Any party, including the secured creditor, can attend the hearing on the sale and submit a competing bid for court review. As discussed more fully below, the Bankruptcy Code authorizes a secured creditor to "credit bid" the amount of its lien as part of a competing bid. n71

n71 *See infra* Section III.

III. Why Use Bankruptcy To Unwind an IDS?

One of the primary benefits of implementing the unwinding of an IDS through a bankruptcy case is the ability to sell all, or substantially all, of an IDS's assets, or the assets of the integrated subsidiary free and clear of liens, interests, and claims over the objection of third parties. Such ability, which is subject to Bankruptcy Court approval, places a powerful negotiating club in the hands of the debtor and its controlling shareholder, which is the hospital in most cases. These sales can be accomplished through a straight auction or a more complicated plan of reorganization, each of which is described in greater detail below.

A. SALES OF ASSETS: WHEN IS A DEBTOR BOUND TO A SALE?

As noted above, the debtor's ability to enter into a sales transaction outside the ordinary course of business requires court approval. n72 However, the law is not entirely clear as to whether, once a debtor has entered into an agreement, but before it has been approved by the court, the debtor can sell or enter into an agreement to sell to someone else. For example, in *In re Tidewater Group, Inc.*, n73 the debtor executed a proposed settlement with Providers Benefit Life Insurance **Company**. Although the settlement had been entered into by the parties, it was subject to court approval and had not yet been approved by the court. When the debtor decided not to proceed with the settlement, Providers sought an order enforcing the agreement, even though it had not yet been approved as required under former Bankruptcy Rule 919(a).

n72 *See* 11 U.S.C. § 363(b).

n73 8 B.R. 930 (Bankr. N.D. Ga. 1981).

The court ruled that debtor's counsel is not competent to enter into an agreement to bind the estate without court approval. However, the court stated that an agreement entered into by the debtor or trustee, without court approval, is binding on the purchaser, and in some instances may be binding on the trustee. n74 It is noteworthy that the court in *Tidewater* wrote that, "an agreement by a debtor in possession to compromise litigation should also be binding upon all

parties to the agreement pending a Court determination as to whether or not to approve the agreement." n75 Whether or not the agreement binds the estate "remains for the court, not the debtor in possession, to determine." n76 Since a sale of estate assets requires court approval, it is unclear how a debtor can bind itself to an agreement without such approval. However, *Tidewater* and its progeny suggest that the requirement of court approval in a given transaction will not necessarily insulate the debtor from unilaterally attempting to withdraw the agreement once it has been executed. n77

n74 *Id.* at 932.

n75 *Id.* at 933.

n76 *Id.* at 933.

n77 For example, in *Columbus Plaza, Inc. v. Kenney (In re Columbus Plaza, Inc.)*, 79 B.R. 710 (Bankr. S.D. Ohio 1982), the bankruptcy court addressed a situation in which a buyer entered into an agreement to purchase assets from the debtor. The debtor continued to search for another offer as a backup or higher bidder. Ultimately, the first buyer was the successful bidder yet refused to perform. The debtor then brought an action for specific performance. While the court denied specific performance, it did order that the debtor could retain the security deposit as liquidation damages, despite the buyer's contention that the debtor had defaulted by continuing to solicit other offers, which constituted a breach that excused the buyer's performance. In *In re Wintex, Inc.*, 158 B.R. 540 (Bankr. D. Mass. 1992), the court found that the debtor had appropriately accepted a higher offer for the sale of assets than the sale he had previously accepted.

B. ASSET SALES IN CHAPTER 11 UNDER SECTION 363: THE NUTS AND BOLTS OF CONSUMMATING AND OBTAINING COURT APPROVAL FOR THE SALE OF AN IDS OR ITS ASSETS

As noted above, the debtor in possession is generally authorized by section 363(c)(1) to sell, lease or use property of the estate in the ordinary course of business without notice or hearing when the debtor's business is authorized to be operated. n78

n78 *See, e.g., Pride Exploration, Inc. v. Marshall Exploration, Inc.*, 798 F.2d 864, 866 (5th Cir. 1986).

The Bankruptcy Code gives substantial discretion to the Bankruptcy Court in determining whether to approve a sale out of the ordinary course of business. n79 A sale of assets is warranted if all provisions of sections 363(b) and (f) are followed, the bid is fair, and the sale is in the best interests of the estate and its creditors n80 (that is, justified by a sound business purpose). n81

n79 *See, e.g., Matter of Embrace Sys. Corp.*, 178 B.R. 112 (Bankr. W.D. Mich. 1995); *In re Blue Coal Corp.*, 168 B.R. 553, 564 (Bankr. M.D. Pa. 1994). Note, however, that the protections afforded by Chapter 11 do not insulate a debtor in possession or the purchaser from regulatory requirements concerning transfer of ownership. *See Jennifer Stiller & Natalie D. Ramsey, Bankruptcy*, in *HOSPITAL LAW MANUAL P3-1*, at 32 (Cynthia Conner ed., 1998).

n80 *See, e.g., Matter of Embrace Sys. Corp.*, 178 B.R. 112.

n81 *In re Continental Air Lines, Inc.*, 780 F.2d 1223 (5th Cir. 1986); *In re Lionel Corp.*, 722 F.2d 1063 (2d Cir. 1983).

1. Section 363(b) Requirements

Section 363(b) of the Bankruptcy Code bars a debtor from selling, using or leasing property, other than in the ordinary course of business, without a court order entered after "notice and a hearing." n82 Section 363(b) protects the reasonable expectations of creditors and shareholders that a debtor in possession's business will be operated in the normal course. n83 The notice and hearing requirement in the statute is intended "to give the creditors, who have a vital interest in maximizing realization from the assets of the estate, an opportunity to review the terms of any proposed sale, and to object thereto, if they deem the terms and conditions not to be in their best interests." n84 Thus, Federal Rules of Bankruptcy Procedure 6004 and 2002(a)(2) direct that an application under section 363(b) be provided to the debtor, the trustee, all creditors, and any indenture trustee. n85

n82 11 U.S.C. § 363(b).

n83 *See, e.g.,* McLean Indus., Inc. v. Medical Lab. Automation, Inc. (*In re* McLean Indus., Inc.), 96 B.R. 440, 444 (Bankr. S.D.N.Y. 1989) (statute bars debtor "from removing the horse from the barn prior to notifying parties in interest and affording them an opportunity to be heard before the court"); *In re* Johns Manville Corp., 60 B.R. 612, 615-18 (Bankr. S.D.N.Y. 1986) (analyzing use of term "ordinary course of business" in § 363(b)).

n84 *In re* Sapolin Paints, Inc., 11 B.R. 930, 936 (Bankr. E.D.N.Y. 1981). However, the authority to sell property of the estate out of the ordinary course of business is not subject to shareholder approval. *See, e.g., In re* Entz, 44 B.R. 483, 485 (Bankr. D. Ariz. 1984).

n85 FED. R. BANKR. P. 6004(a); FED. R. BANKR. P. 2002(a) (1998), requires twenty days notice by mail to all creditors, the debtor, the trustee and indenture trustees. The court may shorten the notice period. Moreover, the court may direct that notice be mailed only to official creditors' committees and creditors and equity security holders who file a request for notice.

Once the debtor accepts a proposed bid, the debtor must demonstrate that the proposed purchase price is the highest and best offer. The debtor, as a fiduciary to the estate, "has a duty to make inquiry as to the value of property sought to be transferred; [the debtor] must do at least as much as he would if the sale were in his own interest in the Debtor's capacity." n86 "When a debtor desires to sell an asset, its main responsibility, and the primary concern of the Bankruptcy Court, is the maximization of the value of the asset sold." n87 The debtor must also act in good faith; namely, there can be no lucrative deals with insiders that are not disclosed and approved by the Bankruptcy Court. n88 However, even when unfairness or bad faith is found, the Bankruptcy Court retains "discretion to approve the sale should the estate be so desperate for a buyer that a rejection of the offer would be devastating to creditors." n89 The requirement that a purchaser act in good faith speaks to the integrity of his conduct in the course of the sale proceedings. In order for conduct to rise to the level of bad faith sufficient to implicate section 363(m), the conduct must involve the "integrity of [the purchaser's] conduct in the course of the sale proceedings." n90 Conduct of the purchaser prior to the sale is irrelevant to the question of bad faith. n91 Typically, the misconduct that would destroy a purchaser's good faith status at a judicial sale "involves fraud, collusion between the purchaser and other bidders or the trustee, or an attempt to take grossly unfair advantage of other bidders." n92

n86 *Matter of Embrace Sys. Corp.*, 178 B.R. at 124.

n87 *In re* Integrated Resources, Inc., 135 B.R. 746, 750 (Bankr. S.D.N.Y. 1992).

n88 *See, e.g., In re* Indus. Valley Refrigeration and Air Conditioning Supplies, Inc., 77 B.R. 15, 21 (Bankr. E.D. Pa. 1987).

n89 *Matter of Embrace Sys. Corp.*, 178 B.R. at 124 (quoting *In re* Blue Coal Corp., 168 B.R. at 569).

n90 *In re Rock Indus. Mach. Corp.*, 572 F.2d 1195, 1198 (7th Cir. 1978).

n91 *See Official Comm. Of Senior Unsecured Creditors of First RepublicBank Corp. v. First Republic Bank Corp.*, 106 B.R. 938, 942 (N.D. Tex. 1989).

n92 *Ewell v. Diebert (In re Ewell)*, 958 F.2d 276, 281 (9th Cir. 1992), (quoting *In re Suchy*, 786 F.2d 900, 902 (9th Cir. 1985)). *See also, e.g., In re Vetter Corp.*, 724 F.2d 52, 56 (7th Cir. 1983). Courts are split on whether a court must make an express finding that the purchaser acted in good faith. *Cf. In re Abbotts Dairies of Pennsylvania, Inc.*, 788 F.2d 143, 149-50 (3d Cir. 1985) ("When a bankruptcy court authorizes a sale of assets pursuant to section 363(b)(1), it is required to make a finding with respect to the 'good faith' of the purchaser."); *In re Revco D.S., Inc.*, 901 F.2d 1359, 1366 (6th Cir. 1990) ("An implicit finding of 'good faith' in a section 364(e) context is insufficient and that 'good faith' under that section should not be presumed."); *Matter of Andy Frain Servs., Inc.*, 798 F.2d 1113, 1126 (7th Cir. 1986); *In re Zinke*, 97 B.R. 155 (Bankr. E.D.N.Y. 1989) (The bankruptcy court is not required to make express finding of "good faith" prior to approving sale).

2. Sales May be Free and Clear of Liens and Other Interests

Section 363(f) of the Bankruptcy Code authorizes a debtor in possession to sell the property of the debtor free and clear of liens of an entity other than the estate only if:

- * applicable non-bankruptcy law permits sale of such property free and clear of such interest; n93
- * such entity consents; n94
- * such interest is a lien and the price at which such property to be sold is greater than the aggregate value of all liens on such property; n95
- * such interest is in bona fide dispute; n96
- * such entity could be compelled, in a legal or equitable proceeding, to accept a money satisfaction of such interest. n97

Section 363(f) is phrased in the disjunctive, such that only one of the enumerated conditions must be met in order for a court to approve the proposed sale.

n93 11 U.S.C. § 363(f)(1).

n94 *Id.* § 363(f)(2).

n95 *Id.* § 363(f)(3).

n96 *Id.* § 363(f)(4). The Bankruptcy Code does not define "bona fide dispute." However, "bona fide dispute" is also utilized in section 303 in connection with the nature of claims asserted as a basis for involuntary Chapter 7 petitions. Courts have found cases interpreting section 303 requirements illustrative in connection with section 364(f)(4). For example, the Seventh Circuit found that courts must find "whether there is an objective basis for either a factual or a legal dispute as to the validity of the debt." *In re Busick*, 831 F.2d 745, 750 (7th Cir. 1987). Courts need not resolve the underlying dispute, "just determine its existence." *In re Collins*, 180 B.R. 447, 452 (Bankr. E.D. Va. 1995).

n97 11 U.S.C. § 363 (f)(5). Although some courts have interpreted the "money satisfaction" requirement as requiring full payment to the lien holder (*see, e.g., Stroud Wholesale, Inc. v. Pitt County*, 47 B.R. 999, 1003 (E.D.N.C. 1985)), that "view of Section 363(f)(5) is now thought to be obsolete, inasmuch as it is inconsistent with the Bankruptcy Code." *In re Grand Slam U.S.A., Inc.* 178 B.R. 460, 461 (Bankr. E.D. Mich. 1995. *See also In re Healthco Int'l, Inc.*, 174 B.R. 174, 176 (Bankr. D. Mass. 1994) (construing "'money satisfaction of such interest' appearing in subparagraph (f)(5) to mean a payment constituting less than full payment of the underlying debt. Because any lien can always be discharged by full payment of the underlying debt [subparagraph (f)(3)], there would be no sense in subparagraph (f)(5) authorizing a sale only if that could be done."); *In re Heine*, 141 B.R. 185, 189-90 (Bankr. D.S.D. 1992) (Under Section 363 (f)(5),

"equitable considerations may allow a court to approve a sale free and clear of liens even though the creditors receive less than full satisfaction of their interests").

"Thus, it is clear that Section 363 (f)(5) allows trustees of an estate to sell property free and clear of liens when 'a legal or equitable proceeding' exists that will force the lien holder to accept less than full money satisfaction for their interest." *Grand Slam*, 178 B.R. at 462. "Cram down," under § 1129(b)(2), constitutes such a legal proceeding. *Grand Slam*, 178 B.R. at 462. *See* *Healthco Int'l*, 174 B.R. at 176; *see also* *Terrace Chalet Apartments, Ltd. v. Fed. Nat'l Mortgage Ass'n (In re Terrace Chalet Apartments, Ltd.)*, 159 B.R. 821 (N.D. Ill. 1993) ("cram downs" are legal proceedings within the meaning of section 363(f)(5)).

The determination of the value of all liens on the property required for a sale pursuant to section 363(f) is a frequently litigated issue. (The remaining conditions of section 363(f) are generally noncontroversial.) Several courts have construed "value" to mean the face amount of debts against the property. n98 Other courts, however, have found that "value" should be defined as the secured value, not the face amount of liens. Although the language of section 363(f)(3) would appear only to permit a sale free and clear when the price is "greater than the aggregate value of all liens on the property," courts regularly permit sales free and clear of liens where the proposed sale is justified by the circumstances and the sale price is a fair market price. n99 Utilizing an analysis focusing on section 506(a), courts have, under a number of different circumstances, approved sales where the price was lower than the face amount of liens, but greater than the secured value of the claims. n100

n98 *See, e.g., Matter of Riverside Inv. Partnership*, 674 F.2d 634, 640 (7th Cir. 1982) (court should not approve sale unless satisfied that the sale proceeds will fully compensate secured lien holder and produce some equity for the benefit of the estate); *In re Heine*, 141 B.R. 185, 189 (Bankr. D.S.D. 1992) ("value" is synonymous with amount); *Terrace Chalet Apartments, Ltd. v. Fed. Nat'l Mortgage Ass'n (In re Terrace Chalet Apts., Ltd.)*, 159 B.R. 821 (N.D. Ill. 1993); *Julien Co. v. Marlow (In re Julien Co.)*, 117 B.R. 910 (Bankr. W.D. Tenn. 1990) (sale not allowed when total liens are greater than the property).

n99 *See, e.g., In re Collins*, 180 B.R. 447, 451 (Bankr. E.D. Va. 1995) ("Factors for this Court to consider in determining whether 'special circumstances' exist [to allow sale for less than value of all liens] include what chapter the case is filed under, whether this is a major or sole asset of the estate, whether the proposed sale is a piecemeal substitution for a plan of reorganization, and the overall benefit to the estate"); *In re Terrace Gardens Park Partnership*, 96 B.R. 707 (Bankr. W.D. Tex. 1989) (sale price exceeded value of the property; market conditions reflected benefit of sale at this price; absent sale, debtor would lose tenant as well as buyer); *In re Beker Indus. Corp.*, 63 B.R. 474, 475 (Bankr. S.D.N.Y. 1986) (courts must not only find special circumstances justifying a sale for less than the amount of liens, but must also determine that the proposed sale price is the best price obtainable under the circumstances).

n100 *See, e.g., Milford Group, Inc. v. Concrete Step Units, Inc. (In re Milford Group, Inc.)*, 150 B.R. 904 (Bankr. M.D. Pa. 1992). For a detailed analysis of this latter approach, see *In re Collins*, 180 B.R. 447, 449-50 (Bankr. E.D. Va. 1995) (favoring latter approach, *inter alia*, because that analysis gives "deference to the congressional intent in utilizing the term 'value' rather than 'amount' in the statute").

Few cases address how to value an asset subject to sale under section 363(b), for the purpose of comparing it to the purchase price, in order to determine the reasonableness of the proposed sale. The question of how to value assets can perhaps best be answered by analogy to cases that address valuation in the context of section 363(m) appeals of orders approving sales. These latter cases, in which the value of the asset sold was relevant to the court's determination of whether a sale was conducted in good faith as required by section 363(m), have developed the following parameters for evaluating "value":

- * A sale price in the amount of at least seventy-five percent of the appraised value is presumptively reasonable. Courts interpreting section 363(m) have held that, "fair and valuable consideration is given in a bankruptcy sale when the purchaser pays 75% of the appraised value of the assets." n101
- * Appraisal reports are not always required in order to establish an asset's value. n102
- * The value of an asset for sale may be determined by the amount of the highest bid at an auction or, in the absence of an auction, a sale subject to an overbid procedure. "Generally speaking, an auction may be

sufficient to establish that one has paid 'value' for the assets of a bankrupt. . . . On the other hand, we reject the assertion that the 'auction' . . . necessarily establishes that [the purchaser] paid 'value' [if, for example, collusion existed between the purchaser and seller]." n103

* The general rule is that an asset must be sold for its fair market value in order for it to be approved. n104 However, under certain circumstances it is permissible to sell property for less than the fair market value. n105

* The general rule is that an asset should be sold to the entity willing to pay the highest price. n106

n101 *In re Abbotts Dairies of Pennsylvania, Inc.*, 788 F.2d 143, 149 (3d Cir. 1986). *See also* *Bel Air Ass'n, Ltd. v. Frey (In re Bel Air Ass'n, Ltd.)*, 706 F.2d 301, 305 n. 12 (10th Cir. 1983); *Greylock Glen Corp. v. Community Sav. Bank*, 656 F.2d 1, 4 (1st Cir. 1981); *In re Rock Indus. Mach. Corp.*, 572 F.2d 1195, 1197 n. 1 (7th Cir. 1978). *In re Karpe*, 84 B.R. 926, 933 (Bankr. M.D. Pa. 1988); *In re Snyder*, 74 B.R. 872 (Bankr. E.D. Pa. 1987); *In re Pisces Leasing Corp.*, 66 B.R. 671 (E.D.N.Y. 1986). *But see In re Vanguard Oil & Serv. Co.*, 88 B.R. 576, 580 (E.D.N.Y. 1988).

n102 *See Ewell v. Diebert (In re Ewell)*, 958 F.2d 276 (9th Cir. 1992) (upholding bankruptcy court's finding that the trustee's evidence (in the form of his declaration) as to the value of the asset being sold was more probative than the debtor's appraisal report, and accordingly, the bankruptcy court's order approving the sale was affirmed).

n103 *In re Abbotts Dairies*, 788 F.2d at 149. *See In re Silver Bros. Co., Inc.*, 179 B.R. 986 (Bankr. D.N.H. 1995); *In re Karpe*, 84 B.R. at 933.

n104 *In re Theroux*, 169 B.R. 498 (Bankr. D.R.I. 1994).

n105 *Matter of Quarter Moon Livestock Co., Inc.*, 116 B.R. 775 (Bankr. D. Idaho 1990) (sale approved in the amount of \$ 35,000, cash, despite testimony that value was \$ 43,000 because of evidence that equipment, if not sold, could decline in value due to lack of demand).

n106 *In re Integrated Resources, Inc.*, 135 B.R. 746 (Bankr. S.D.N.Y.), *aff'd*, 147 B.R. 650 (S.D.N.Y. 1992), *appeal dismissed*, 3 F.3d 49 (2d Cir. 1993). Sometimes, however, the highest price is not the "best" price. *See, e.g., In re Diebart Bancroft*, No. 92-3744, 92-3745, 1993 U.S. Dist. LEXIS 836, at * 13 (E.D. La. Jan. 26 1993) ("The best price depends on the circumstances of each particular case." Since the highest bid had not materialized due to non-performance of the purchaser, the court found that acceptance of the next highest bid was appropriate.).

3. Break-Up Fees: Dual Protection and Incentive to a Buyer

As with sales outside of bankruptcy, a bidder may have an incentive through break-up fees to be a "stalking horse" against which subsequent bidders can be measured. A break-up fee is a payment designed to compensate the initial bidder for its expenses and reward it for serving as the stalking horse. Thus, break-up fees are designed to mitigate the risk taken by a potential acquirer that "another party will come in and outbid you and all that time and money will have been spent for naught." n107 Break-up fee arrangements outside of bankruptcy are presumptively valid as an exercise in "business judgment." n108 Under the business judgment rule, there "is a presumption that in making a business decision, the directors of a corporation acted on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the **company**." n109 The primary factor for the court to consider in examining a break-up fee is whether the offer made by the party seeking the fee enhanced or impeded the bidding process, and whether the fee agreement was in the best interests of the seller's shareholders. Generally, break-up fees are allowed as long as they "enhance" the bidding, and are reasonable in relation to the bidder's efforts and the size of the transaction. n110 Once an asset is up for sale, the corporate directors' fiduciary duty is to maximize the price received for the benefit of the shareholders. n111 Bankruptcy courts have analyzed break-up fees under that standard in the context of Chapter

11. n112

n107 *In re* S.N.A. Nut Co., 186 B.R. 98, 101 (Bankr. N.D. Ill. 1995) (quoting *Beebe v. Pacific Realty Trust*, 578 F. Supp. 1128, 1150 (D. Or. 1984)).

n108 *Cottle v. Storer Communication, Inc.*, 849 F.2d 570, 574 (11th Cir. 1988); *CRTF Corp. v. Federated Dep't Stores, Inc.*, 683 F. Supp. 422, 440 (S.D.N.Y. 1988).

n109 *Smith v. Van Gorkom*, 488 A.2d 858, 872 (Del. 1985).

n110 *Cottle*, 849 F.2d at 578.

n111 *See, e.g., Revlon, Inc. v. MacAndrews & Forbes Holdings, Inc.*, 506 A.2d 173 (Del. 1985).

n112 *See, e.g., In re* 995 Fifth Ave. Assoc. L.P., 96 B.R. 24, 28 (Bankr. S.D.N.Y. 1989) (upholding break-up fee as appropriate and holding that corporate principles in the takeover arena should "have [full] vitality by analogy in the chapter 11 context"); *In re* Integrated Resources, Inc., 147 B.R. 650 (S.D.N.Y. 1992) (same); *In re* Crowthers McCall Pattern, Inc., 114 B.R. 877 (Bankr. S.D.N.Y. 1990) (approving \$ 500,000 break-up fee in a \$ 45 million sale, without discussing merits of the fee).

Certain bankruptcy courts, however, have refused to apply the business judgment rule as the standard in connection with break-up fees. For example, in *In re America West Airlines, Inc.*, n113 the court held that:

In a transaction of the size and nature proposed here, the Court must take into consideration what is in the best interests of the estate. As stated, the standard is not whether a break-up fee is within the business judgment of the debtor, but whether the transaction will "further the diverse interests of the debtor, creditors and equity holders, alike." The proposed break-up fee must be carefully scrutinized to insure that the Debtor's estate is not unduly burdened and that the relative rights of the parties in interest are protected. The analysis conducted by the Court must therefore include a determination that all aspects of the transaction are in the best interests of all concerned. n114

The court proceeded to deny the requested \$ 4 million break-up fee. According to the court, the payment of the contemplated break-up fee, *in any amount*, would not be in the best interests of the estate because the debtor had been "thoroughly marketed and that the proposed break-up fee will not induce further bidding or bidding generally." n115 Moreover, the court found that the proposed break-up fee "unnecessarily chills bidding." n116

n113 166 B.R. 908 (Bankr. D. Ariz. 1994).

n114 *Id.* at 912 (citations omitted).

n115 *Id.* at 913.

n116 *Id.* *See also, e.g., In re* S.N.A. Nut Co., 186 B.R. 98, 103 (Bankr. N.D. Ill. 1995) (citing *In re* Am. West with approval); *In re* Hupp Indus., Inc., 140 B.R. 191 (Bankr. N.D. Ohio 1992) (rejecting business judgment standard). For a criticism of the application of the business judgment rule in bankruptcy cases, see generally Bruce A. Markell, *The Case Against Breakup Fees in Bankruptcy*, 66 AM. BANKR. L.J. 349 (1992) (arguing in part that break up fees as liquidated damages are inappropriate because no enforceable contract exists until court approval has been obtained).

4. Sale of All or Substantially All Assets of the IDS: Sub Rosa Plan?

Under what circumstances may a bankruptcy court authorize a sale of all, or a major portion of, a Chapter 11 debtor's assets outside a plan of reorganization? The generally accepted relevant factors to be considered include (1) "the proportionate value of the asset to the estate as a whole;" (2) "the amount of elapsed time since the filing;" (3) "the likelihood that a plan of reorganization will be proposed and confirmed in the near future;" (4) "the effect of the proposed disposition on future plans of reorganization;" (5) "the proceeds to be obtained from the disposition vis-a-vis any appraisals of the property;" (6) "which of the alternatives of use, sale or lease the proposal envisions;" and (7) "most importantly perhaps, whether the asset is increasing or decreasing in value." n117 These factors are non-exhaustive, and each of them need not always be required. Nor must each factor considered be given equal weight. n118 When a Chapter 11 sale is requested, the unique facts and circumstances must be considered and weighed rather than applying some concrete predetermined formula. n119

n117 *Stephens Indus., Inc. v. McClung*, 789 F.2d 386, 389 (6th Cir. 1986) (quoting *In re Lionel Corp.*, 722 F.2d 1063, 1071 (2d Cir. 1983)).

n118 *See, e.g., Matter of Embrace Sys. Corp.*, 178 B.R. at 125.

n119 *Id.*

Courts may uphold a sale of all, or substantially all, of a debtor's assets under section 363 if justified by an emergency or by a sound business reason. n120 Courts taking this position rely on an inferred congressional intent not to overrule *In re Solar Manufacturing Corp.*, n121 in which the court limited a Chapter X trustee's authority to sell all of a debtor's assets outside a plan "to emergencies where there is imminent danger that the assets of the ailing business will be lost if prompt action is not taken." n122

n120 *See, e.g., Stephens Indus., Inc.*, 789 F.2d at 389-91 (sale of radio station for articulated business reason upheld); *In re Lionel*, 722 F.2d 1063 (2d Cir. 1983); *In re Weyland*, 63 B.R. 854, 861-63 (Bankr. E.D. Wis. 1986) (sale of debtor's dairy herd pursuant to federal Dairy Termination Program approved in view of emergency presented by time limits imposed by program, the business justification for the sale, and the fact that the debtor would remain in business with its other assets); *In re Chism*, 48 B.R. 445, 447 (Bankr. M.D. Ala. 1985) (sale of farm upheld in liquidating Chapter 11 case in view of the resulting reduction of debtor's interest, tax, and administrative expense burden and removal of mortgage from land not sold).

n121 176 F.2d 493, 494 (3d Cir. 1949).

n122 *Id.*

5. Other Sale Issues to Consider

Courts have the authority under section 363(e) to condition or prohibit any sale of property as is necessary to provide adequate protection to the secured party's interest. The commonly accepted method for adequately **protecting** a secured creditor when a sale is authorized under section 363(f) is to order the liens to attach to the proceeds of the sale. n123

n123 See *In re Collins*, 180 B.R. at 452; H.R. REP. No. 595, at 345 (1977).

At any sale of property under section 363(b) securing an allowed claim, the claim holder may set-off his claim against the bid if he is the purchaser. n124 The creditor, even if under-secured, may bid the unsecured portion as well as the secured portion of his allowed claim. n125

n124 11 U.S.C. § 363(k).

n125 See 124 Cong. Rec. 32396 (Sept. 28, 1978) (statement of Rep. Edwards); 124 Cong. Rec. 33995 (Oct. 6, 1978) (statement of Rep. DeConcini).

To object to an asset sale in bankruptcy, a party must be a creditor or shareholder of the debtor. Otherwise, it is not "within the zone of interests protected by the statute." n126 However, one can obtain standing by purchasing a claim. An interested party who buys a claim in order to gain standing in a bankruptcy case should proceed with caution. Bankruptcy courts have denied standing if it is determined that the creditor's true intent is to harass the debtor or to gain an unfair advantage at the expense of the debtor and other creditors. n127 Nonetheless, bidders for assets frequently purchase claims in order to gain standing to object to an asset sale.

n126 *In re Caldor, Inc.*, No. 95-B-44080, 1996 Bankr. U.S. Dist. LEXIS 244, at * 11-12 (Bankr. S.D.N.Y. 1996).

n127 See, e.g., *In re Keyworth*, 47 B.R. 966 (Bankr. Colo. 1985); *In re Allegheny Int'l, Inc.*, 118 B.R. 282, 290 (Bankr. W.D. Pa. 1990).

Thus, voting or purchasing a claim and voting to block a plan in order to acquire control of the debtor for oneself is viewed as an ulterior motive sufficient to disqualify the vote of a creditor. n128

n128 *In re Allegheny Int'l, Inc.*, 118 B.R. 282. See *In re Dune Deck Owners Corp.*, 175 B.R. 839, 844 (Bankr. S.D.N.Y. 1995) (bad faith exists where the claim holder attempts to extract or extort personal advantage not available to other creditors, or acts under some ulterior motive such as to procure some collateral or competitive advantage that does not relate to its claim); *In re Landing Assoc., Ltd.*, 157 B.R. 791, 808 (Bankr. W.D. Tex. 1993).

C. TAX CONSIDERATIONS, ANTITRUST ISSUES

Purchasing a **company** through bankruptcy may also permit a buyer to gain the benefit of the purchased **company's** net operating loss ("NOL"). The requirements for preservation of the NOL are complex and include requirements regarding percentages of stock that can, or must, be held by the purchaser and the seller subsequent to the sale. There is also a requirement that the purchased **company** continue to operate.

The Bankruptcy Code allows for shortened notice periods for Hart-Scott-Rodino antitrust disclosure in the context of a sale under section 363. n129 A Bankruptcy Court order also impairs or bars antitrust actions that are not brought before the court approves the sale. n130

n129 11 U.S.C. § 363(b)(2) (providing for a 15 day waiting period).

n130 *See In re Int'l Nutronics, Inc.*, 28 F.3d 965 (9th Cir. 1994). In *Nutronics*, the Ninth Circuit stated that a bankruptcy court's confirmation of a sale is ordinarily *res judicata* with regard to matters of collusive bidding. *Id.* at 970. *See also In re Financial News Network, Inc.*, 126 B.R. 157, 160 (S.D.N.Y. 1991) (bankruptcy court had jurisdiction to issue order requiring that antitrust objections or actions be brought in bankruptcy court).

D. MEDICARE AND MEDICAID: SALE FREE AND CLEAR OF MEDICARE RECAPTURE

Prior to the 1997 Budget Reconciliation Act, hospitals that participated in Medicare, and which retained ownership of the capital assets used to provide services to their Medicare recipients, were entitled to periodic reimbursement for estimated actual depreciation on those assets, as determined under accepted accounting practices. n131 When a hospital closes, either in or outside of bankruptcy, so does its participation in the Medicare program. HHS administrative regulations allow a one-year post-termination period within which hospitals that previously participated in the Medicare program must sell their Medicare-related capital assets as a precondition to recapturing any pretermitted capital asset depreciation credits from HHS. n132 Thus, a hospital that closed would have been eligible for further depreciation reimbursements from HHS on a Medicare-related capital asset that was sold for less than its depreciated basis within one year after the hospital's closure. This one year time frame *was not extended* in the event the hospital became a debtor in a bankruptcy case. n133

n131 *See* 42 U.S.C. § 1395x(v)(1)(O)(ii) (1998) (Medicare statute authorizing HHS Secretary to implement regulations detailing asset-depreciation methodologies).

n132 42 C.F.R. § 413.134(f)(3) (1998).

n133 *See In re Ludlow Hosp. Soc'y, Inc.*, 124 F.3d 22 (1st Cir. 1997).

Under certain state Medicaid programs, moreover, a hospital must reimburse the state Medicaid agency for the amount of depreciation previously allowed as a reasonable cost of providing services to the program if the hospital realizes a gain on the sale of the property. If the hospital fails to make appropriate reimbursement, the state agency may collect it by any means available by law, including a set-off against future Medicaid reimbursement to be paid to the purchaser of the facility under the program. A hospital-debtor, however, may sell its facility free and clear of the state agency's interest and claim to reimbursement from a purchaser if the provisions of section 363(f) are satisfied. n134 While the law concerning depreciation capture may have changed, these cases demonstrate the significant benefit of selling assets free and clear of interests under section 363, namely, providing a unique framework within which to maximize the potential sale price.

n134 *See In re P.K.R. Convalescent Centers, Inc.*, 189 B.R. 90, 96 (Bankr. E.D. Va. 1995) (authorizing sale of facility free and clear of agency interest and enjoining agency from pursuing reimbursement from purchaser of facility).

E. INSULATING THE SALE FROM APPEAL

Section 363(m) provides:

The reversal or modification on appeal of an authorization under subsection (b) or (c) of this section of a

sale or lease of property does not affect the validity of a sale or lease under such authorization to an entity that purchased or leased such property in good faith, whether or not such entity knew of the pendency of the appeal, unless such authorization and such sale or lease were stayed pending appeal. n135

Thus, failure to obtain a stay of a bankruptcy court's order authorizing the sale of the debtor's property to a good faith purchaser renders the appeal of that sale moot. n136 The policy underlying this rule is to afford finality to orders and judgments of the bankruptcy court upon which third parties rely. n137 By lending finality to the bankruptcy court's orders, this rule maximizes the value of a debtor's estate by encouraging purchasers of the debtor's property to submit bids based on the fair market value of the property. n138 Without the measure of finality provided by this rule, purchasers would demand a discount in the price of the debtor's property, thereby short-changing the creditors. n139

n135 11 U.S.C. § 363(m).

n136 *See, e.g.,* United States v. Salerno, 932 F.2d 117, 123 (2d Cir. 1991); Stadium Mgmt. Corp. v. Miller (*In re Stadium Management Corp.*), 895 F.2d 845, 848 (1st Cir. 1990) (appeal of trustee's sale of bankruptcy assets is moot after sale is complete); Matter of Andy Frain Services, Inc., 798 F.2d 1113, 1126 (7th Cir. 1986). For a discussion of the "good faith" requirement, see *supra* notes 87-92 and accompanying text.

n137 *See* Onouli-Kona Land Co. v. Estate of Richards (*In re Onouli-Kona Land Co.*), 846 F.2d 1170, 1172 (9th Cir. 1988) ("Finality in bankruptcy has become the dominant rationale for our decisions; the trend is towards an absolute rule that requires appellants to obtain a stay before appealing a sale of assets.").

n138 *See, e.g., In re Sax*, 796 F.2d 994, 997 (7th Cir. 1986).

n139 *Id.* at 998. Few exceptions to the section 363(m) mootness rule exist. *See, e.g., In re Ewell*, 958 F.2d 276, 280 (9th Cir. 1992) ("Indeed, we have recognized only two exceptions to the section 363(m) mootness rule: (1) where real property is sold subject to a statutory right of redemption, and (2) where state law otherwise would permit the transaction to be set aside."). *See also, e.g., Mann v. Alexander Dawson, Inc. (In re Mann)*, 907 F.2d 923, 926 (9th Cir. 1990) (same).

IV. Other Benefits of a Bankruptcy "Unwind"

A. THE BANKRUPTCY CODE EMPOWERS A DEBTOR TO REJECT, ASSUME, OR ASSIGN CONTRACTS (INCLUDING PROVIDER CONTRACTS) AND REAL PROPERTY LEASES

The Bankruptcy Code provides special treatment for contracts entered into prior to the filing of the Chapter 11 case when material performance remains incomplete for both parties ("executory contracts") and for unexpired non-residential real property leases. n140 Examples of an IDS's executory contracts might include provider agreements with the Medicare or Medicaid programs or with other third-party payors or delivery systems, n141 employment and independent contractor agreements, joint venture agreements, supply contracts, and leases of real or personal property. It is unlikely, however, that any contract with a specific doctor, as compared with a practice group, can be assumed and assigned over the objection of the contracting physician. n142

n140 *See generally* Vern Countryman, *Executory Contracts in Bankruptcy: Part 1*, 57 MINN. L. REV. 439, 460 (1973).

n141 To qualify for reimbursement under Part A of Medicare, a provider must enter into a provider agreement with HCFA. Medicare provider agreements require performance on both sides and thus, most courts hold that such agreements are "executory." *See also* Schoen,

supra note 59.

n142 *See* 11 U.S.C. § 365(e)(2)(A) (1998).

The debtor has until the date the reorganization plan is confirmed to assume or reject executory contracts unless the Bankruptcy Court orders otherwise. n143 The debtor must assume or move to extend the time to assume leases within sixty days of the petition date; otherwise, such leases are deemed rejected. n144 So-called "ipso facto" clauses, which provide for automatic termination of a contract or lease upon the commencement of a bankruptcy case, are generally unenforceable. n145

n143 *Id.* § 365(d)(2). It has been reported that traditional Chapter 11 cases lasted an average of thirty months until confirmation. Elizabeth Tashjian et al., *Prepacks: An Empirical Analysis of Prepackaged Bankruptcies*, 40 J. FIN. ECON. 135, 142 (1996).

n144 *See* 11 U.S.C. § 365(d)(4).

n145 *See id.* § 365(e)(1).

A debtor may treat executory contracts and non-residential real property unexpired leases in one of three ways: 1) the debtor can assume them, so that they constitute ongoing, post-petition obligations of the **company**; 2) the debtor can assume and then assign them to other parties; or 3) the debtor can reject them, in which case the contract or lease ceases to bind the **company**. n146 A rejection is treated as a material breach of the contract by the debtor. n147 The damages for breach of a contract or lease, upon rejection, become a pre-petition claim to be dealt with in a plan of reorganization on the same basis as any other unsecured claim. However, the Bankruptcy Code imposes certain and often dramatic limitations on a claim of a lessor for damages resulting from the termination of a non-residential real property lease. n148

n146 *Id.* § 365(a)-(c), (f).

n147 *Id.* § 365(g).

n148 *See* 11 U.S.C. § 502(b)(6) (1998).

The Bankruptcy Code imposes three requirements for assumption by a debtor of executory contracts or unexpired leases. n149 First, if the contract or lease is in default at the time of intended assumption (other than as a result of a breach of an insolvency or bankruptcy clause), the debtor must promptly cure, or provide adequate assurance that the default will be promptly cured. Second, the debtor must compensate or provide adequate assurance of prompt compensation for "actual pecuniary loss" to the non-debtor party resulting from such default. This includes compensation for damages suffered by such contracting party as a consequence of such default. Third, the debtor must provide adequate assurance of future performance under the contract. Once a debtor assumes an executory contract or unexpired lease, the contract or lease must be fully performed just as it would have been if it had been entered into outside of the bankruptcy case.

n149 *Id.* § 365(b).

The debtor (or its assignee) must satisfy the preceding conditions if the debtor moves to assume and then assign an executory contract or unexpired lease. However, the debtor must also demonstrate adequate assurance of the future performance of the assignee. n150 This is particularly important because, once a contract is assigned, the debtor has no further future liability on such contract. With certain limited exceptions, the Bankruptcy Code nullifies any clauses that attempt to prohibit assignment of such contracts or leases, or which will terminate the contract or lease upon assignment. n151

n150 *See id.* § 365(f)(2).

n151 *See id.* § 365(f)(3).

The ability to reject executory contracts and unexpired leases enables the debtor to avoid burdensome, long-term obligations. Courts have applied a loose "business judgment" test to motions to reject executory contracts and leases, under which the business determination of the debtor is ordinarily respected. Pending assumption or rejection, however, the non-debtor party to the contract generally must continue to perform. The non-debtor party to an executory contract can move the court for an order compelling assumption or rejection of the contract. n152 For example, in the case of certain contracts between a hospital and a third-party payor, the non-debtor party may need to know the status of the agreement so it can contract with another hospital or third party in the event the contract is not assumed. This is particularly true when there may be limited windows of time during which the non-debtor party can contract with an alternative hospital or third-party payor in the event the contract is rejected by the debtor. n153

n152 *See id.* § 365(d)(2).

n153 *See generally* NATIONAL HEALTH LAWYERS ASS'N., *supra* note 57, at 30-19.

B. AN "UNWIND" OF AN IDS CAN BE IMPOSED ON DISSENTING CREDITORS (INCLUDING DOCTOR GROUPS) THROUGH THE "CRAMDOWN" PROVISIONS OF A PLAN OF REORGANIZATION

The ultimate goal of a debtor in a Chapter 11 bankruptcy case is to file and confirm a plan of reorganization. The plan of reorganization can provide for the IDS debtor to consummate virtually any corporate transaction, including, for example, the sale of assets to a third party, and a merger into a new entity. The plan of reorganization serves as the contract by which a debtor sets out what, and when, creditors and shareholders will receive on account of their claims and interests. A plan divides creditors holding different types of claims and interests into separate "classes" for repayment or other treatment. Each member of a class must receive identical treatment. Generally, each secured creditor is considered to be in a separate class, while unsecured, non-priority claims are placed in the same class. A Chapter 11 plan must provide for each class to receive at least as much as it would have received under a Chapter 7 liquidation, unless the class consents to receive less. n154 The specific requirements for plan confirmation are numerous but beyond the general scope of this Article. n155 It is important to note, however, that the Bankruptcy Code does not require unanimous creditor support for plan confirmation. Instead, a plan can be approved if at least half in number and two-thirds in dollar amount of claims in each class vote in favor of the plan. n156 All dissenters within a consenting class are bound to the plan terms. If a class rejects the plan, the plan can be "crammed down" over dissenting classes so long as the plan does not discriminate unfairly and is fair and equitable to each impaired dissenting class, at least if one

impaired non-insider class votes for the plan. n157

n154 11 U.S.C. § 1129(a)(7) (1998).

n155 For the detailed requirements, see, *e.g.*, 7 COLLIER ON BANKRUPTCY, ch. 1129 (15th ed. 1997).

n156 11 U.S.C. § 1126(c) (1998).

n157 *Id.* § 1129(b).

Generally, only a debtor may propose a plan of reorganization during the first 120 days of the case. n158 This so called "exclusivity period" was designed to provide a debtor, at the outset of a case, an opportunity to negotiate a settlement and propose a plan of reorganization without interference from creditors and other interests. Any party in interest (including a creditor or equity security holder) may file a plan only if (1) a trustee has been appointed; (2) the debtor has not filed a plan within the 120-day period discussed above; or (3) the debtor has filed a plan within the 120-day period but such plan has not been accepted by holders of claims in impaired classes within 180 days after the commencement of the case. A court, on request of a party in interest within the foregoing time periods, may reduce or increase the 120 and/or 180 day time limits "for cause." n159 An IDS-debtor and its "friendly" strategic partner should make every effort to protect and extend the exclusivity period. n160 Conversely, hostile bidders should object to extensions of exclusivity and possibly move to reduce or terminate exclusivity. n161

n158 *Id.* § 1121(b).

n159 *Id.* §§ 1121(b)-(d).

n160 In contrast to asset sales outside of a plan, a buyer of the IDS through a plan rarely is faced with overbids.

n161 For a discussion of grounds to extend or shorten exclusivity, see generally Robert A. Klyman & Michael S. Lurey, *The Revlon Duty as Cause to Terminate Exclusivity: A New Strategy For Effecting Corporate Change in Chapter 11*, 4 J. BANKR. L. & PRAC. 621 (1995).

Debtors in large and complex cases request extensions of exclusivity as a matter of course. These requests are routinely granted, in some cases for years, particularly when the court believes the debtor is making good faith progress towards reorganization and the debtor has been paying its post-petition debts as they come due. On the other hand, cases in which the exclusivity period was reduced involved egregious factors, such as gross mismanagement of the debtor's operations or acrimonious feuding among the debtor's principals, which served as a major obstacle to a successful reorganization. A debtor does not lose its exclusivity advantage, however, merely because it co-proposes a plan with its major creditor or shareholder. Generally, therefore, when a motion to terminate exclusivity does not allege a gross breach of duty or law, or fails to present unusual facts, courts will deny that motion subject to the passage of time and additional requests to extend exclusivity. n162 In layman's terms, the debtor should remain in control of the plan process for at least for the first six to twelve months of a complex bankruptcy.

n162 *See id.*

1. Secured Claims May Be Stretched Out Over Time with a New Lower Interest Rate; Interest May Stop Accruing During the Bankruptcy Case

The plan process may enhance an IDS transaction because of the potential restructure of pre-bankruptcy secured claims. As an initial matter, the allowed claim of a creditor holding a security interest is divided into two parts: (1) a secured claim to the extent of the value of the collateral pledged pursuant to that security interest; and (2) an unsecured claim for the remainder. n163 Only an over-collateralized creditor is entitled to interest accrual and reasonable fees, costs, and charges provided under the loan agreement as part of its claim during the pendency of the bankruptcy case, and then only to the extent of any equity cushion in the collateral. n164 Moreover, interest on an over-secured creditor's claim may not necessarily be allowed at the contract rate. n165 The plan of reorganization can be imposed over a secured creditor's objection if (a) the creditor (i) retains its lien on existing or equivalent value replacement collateral, and (ii) receives cash payments over time providing the present value of its secured claim, or (b) its collateral is sold and its lien attaches to the proceeds of such collateral. n166 Alternatively the debtor can satisfy a secured creditor's claim by returning the underlying collateral to that creditor. Accordingly, an IDS debtor frequently will be able to stretch out the maturity date of its secured debt at a market rate of interest. Such reconfiguration of payment terms may be another benefit to a purchaser of the entirety of an IDS to consummate its transaction through the bankruptcy process.

n163 11 U.S.C. § 506(a) (1998).

n164 *See id.* § 506(b).

n165 *See* United States v. Ron Pair Enter., Inc., 489 U.S. 235 (1989); *In re* Terry Ltd. Partnership, 27 F.3d 241, 244 (7th 1994) (authorizing payment of higher contractual rate because such rate was reasonable).

n166 11 U.S.C. § 1129(b).

2. Unsecured Creditors -- Including Providers and Parties to Rejected Contracts -- May Be Forced to Accept a Significantly Reduced Return

Under the "cramdown" provision of Chapter 11, a court may confirm a plan of reorganization even when a class of creditors adversely affected by the plan objects, so long as the plan does not discriminate unfairly and is "fair and equitable" with respect to the class that has rejected the plan. To satisfy the "fair and equitable" requirement, a plan may not violate the "absolute priority rule." The absolute priority rule has been interpreted as requiring creditors or interest holders with legal or contractual seniority to be fully compensated before junior interest holders receive value, unless all senior classes consent to such distribution. Thus, in a "cramdown" situation, if a senior class dissents, the plan must eliminate junior claims and shareholders, unless the dissenting class is fully paid (such payment, however, may be made over time). Dissenting classes are entitled only to receive at least what they would receive in a Chapter 7 liquidation.

C. THE THREAT OF PREFERENCE RECOVERY MAY PROVIDE ENHANCED PRE-BANKRUPTCY BARGAINING POWER

If within ninety days before the filing of a bankruptcy petition, a creditor (1) receives a payment on unsecured debt; (2) is granted collateral for a previously unsecured debt; or (3) is granted additional collateral for an under-secured debt, the effect of which would be to permit that creditor to receive a higher percentage recovery on its pre-petition claim against the debtor than other similarly situated creditors, the debtor can, under certain circumstances, avoid and recover such

payments or collateral for the benefit of the estate. These pre-petition transfers are referred to as preferences. n167 For payments to an insider, the reach-back period extends a year. n168 While fully secured creditors are generally unaffected by preferences, under-secured creditors may be subject to preference attack. In addition, doctors and practice groups who receive payments from an IDS may be the prime targets for preferential recovery. The threat of recovery may induce negotiation and consensus from recalcitrant doctors and practice groups.

n167 *See id.* § 547.

n168 *Id.* § 547(b)(4). A corporation's "insider" includes any officer, director, or holder in excess of 20% of the corporation's voting securities. *See id.* § 101(31).

There are six elements that must be present before a preference is subject to avoidance. n169 First, the transfer must be of property of a debtor. Thus, a transfer is not made until the debtor has acquired rights in the property transferred. Consequently, funds held in a trust or escrow may fall outside preference liability.

n169 *See* 11 U.S.C. § 547(b). Note, however, a debtor must commence an action to recover a preference within the earlier of (a) the later of two years after the entry of the order for relief in a case or (b) the time the case is closed or dismissed.

Second, the transfer must be to or for the benefit of a creditor. A payment to a creditor is clearly a transfer to the creditor. In addition, a payment on a loan subject to guaranty is not only a potential preference as to the lender but could also be a preference to a guarantor of the indebtedness because the payment was for the benefit of the guarantor by virtue of its release from liability.

Third, the transfer must be for or on account of an antecedent debt owed by the debtor to the creditor before the transfer was made. Substantially contemporaneous exchanges are excepted from preferential attack. n170

n170 *Id.* § 547 (c)(1).

Fourth, the transfer must be made while the debtor is insolvent (a financial condition where the sum of the entity's debt is greater than all of the entity's property, at fair valuation). Insolvency, however, is presumed for the ninety-day period preceding the filing. n171

n171 *Id.* § 547(f).

Fifth, the transfer must be made on or within ninety days before the date of the filing of the petition, or within one year if the creditor was an insider at the time of the transfer. In connection with payment by check, a transfer is deemed to occur upon the date the check is honored, rather than the date of the payee's receipt of the check.

Sixth, the transfer must enable the creditor to receive more than the creditor would receive in a liquidation case under Chapter 7 of the Bankruptcy Code.

There are several safe harbors that insulate from preference attack prepetition transfers otherwise satisfying the foregoing elements. The most common are the "ordinary course of business" exception n172 and the "new value" exception. n173 The former excepts transfers in the ordinary course of business if made in payment of a debt incurred in the ordinary course of business or financial affairs of the debtor and of the transferee, and if the transfers were made according to ordinary business terms. This section will protect the supplier of goods or services to the debtor on credit terms who receives a prepetition payment on that debt if the credit terms are in the ordinary course of business of both the supplier and the debtor. Untimely or late payments, however, are more likely to be considered outside the ordinary course.

n172 *Id.* § 547(c)(2).

n173 *Id.* § 547(c)(4).

The other most commonly used exemption from preference liability is "new value." If a creditor receives a payment that would otherwise be deemed a preference, but thereafter makes a new loan (or extends new credit or other "new value"), the amount of new value will cancel an equivalent preference. For example, Vendor receives an otherwise preferential payment of \$ 100. Thereafter, Vendor provides services (for which he receives no payment) valued at \$ 80. The amount of the preference would be only \$ 20. With an open credit line, a creditor can calculate the difference between total preferences and total advances during the entire ninety day preference period, provided that each advance is used to offset prior preferences.

D. PRE-BANKRUPTCY TRANSFERS FOR "LESS THAN REASONABLY EQUIVALENT VALUE," INCLUDING GUARANTEES OF PARENT OR SISTER CORPORATION DEBTS, MAY BE AVOIDABLE AS FRAUDULENT TRANSFERS

The Bankruptcy Code authorizes a debtor to recover "fraudulent transfers," which are transfers of an interest in a debtor's property made within one year of the commencement of a bankruptcy case either (a) designed to hinder, delay or defraud creditors; or (b) that were made (i) at a time when the debtor was insolvent or rendered insolvent by the transfer, and (ii) for less than reasonably equivalent value. n174 The "interest in a debtor's property" can be a guarantee, payment of funds or granting of a security interest. State law may provide a broader window for recovery, as shown by California's four year look-back period. n175

n174 11 U.S.C. § 548(a) (1998).

n175 CAL. CIV. CODE § 3439.09 (West 1997).

Under the Bankruptcy Code, a debtor must commence an action to recover a fraudulent transfer within the earlier of (a) the later of two years after the entry of the order for relief in a case or (b) the time the case is closed or dismissed. n176

n176 11 U.S.C. § 546(a) (1998).

Guarantees provided by a subsidiary for debts incurred by a parent corporation ("upstream guarantees") are fertile grounds for fraudulent transfer litigation. n177 Similarly, guarantees between sister corporations (such as a hospital and

an MPO in a horizontal IDS) may also be set aside as fraudulent transfers. Thus, doctors whose practices were purchased by an MPO, but whose purchase payments were guaranteed by the MPO's sister corporation hospital, may find themselves with reduced payment protection upon their guarantor's bankruptcy filing. Generally, however, guarantees by a parent corporation of the obligations of a wholly-owned subsidiary are outside the scope of fraudulent transfer law.

n177 See Brad R. Godshall & Robert A. Klyman, *Wading "Upstream" in Leveraged Transactions: Traditional Guarantees v. Net Worth Guarantees*, 46 BUS. LAW. 391 (1991).

V. Impact of Bankruptcy on Board Members and Shareholders

A. ROLE IN CORPORATE GOVERNANCE AS BOARD MEMBER SHOULD CONTINUE UNABATED

Outside of bankruptcy, the behavior of corporate management is governed by certain fiduciary obligations, including a duty of care and duty of loyalty. The duty of care generally provides that directors, in performing their duties, exercise the care that an ordinarily prudent person would exercise under similar circumstances, and that directors do so in a manner which would reasonably be believed to be in the best interests of the corporation by an ordinarily prudent person. A director's conduct in bankruptcy is measured against the same duties. In fact, "normal corporate governance" generally continues unabated in Chapter 11. n178 For example, a debtor-in-possession must "manage and operate the property [of the estate] . . . according to the requirements of the valid laws of the State in which the property is situated." n179 Further, the Supreme Court affirmed the proposition that property rights and interests should be afforded the same protection in bankruptcy court as under applicable state law. n180

n178 See, e.g., *Saxon Indus. v. NKF Partners*, 488 A.2d 1298, 1301 (Del. 1985).

n179 28 U.S.C. § 959.

n180 *Butner v. United States*, 440 U.S. 48, 55 (1979) ("Uniform treatment of property interests in both state and federal courts within a State serves to reduce uncertainty, to discourage forum shopping, and to prevent a party from receiving a 'windfall merely by reason of the happenstance of bankruptcy.'").

A board member's good faith post-petition actions with respect to the formulation of and solicitation of votes on a plan of reorganization are generally immunized from liability. n181 Most plans of reorganization also include releases for directors and officers of the debtor with respect to post-bankruptcy action.

n181 11 U.S.C. § 1125(e) (1998).

B. THE EXERCISE OF SHAREHOLDER RIGHTS SHOULD ALSO CONTINUE

Shareholders of a bankrupt corporation maintain their state law rights to control the debtor by calling shareholder meetings and voting shares. n182 Only if the shareholders attempting to compel a shareholder's meeting are guilty of "clear abuse" or are creating a real jeopardy to reorganization prospects will the court enjoin a meeting. The mere exercise of shareholder bargaining power, whether by replacing individual directors or the board as a whole, does not

constitute clear abuse. n183 Instead, such equity holders must be acting in bad faith, such as by demonstrating a willingness to risk rehabilitation altogether in order to win a larger share for equity, to be deemed clearly abusive. However, some courts have suggested that if a corporation is insolvent as a going concern, denial of a shareholder rights may be proper since such shareholders may no longer be real parties in interest. n184

n182 *Butner v. United States*, 440 U.S. at 56 (The commencement of a bankruptcy case did not exempt the bankruptcy court from taking "whatever steps [were] necessary to ensure that the mortgagee [was] afforded in federal bankruptcy court the same protection he would have [had] under state law if no bankruptcy had ensued.").

n183 *See, e.g., Saxon Indus. v. NKF Partners*, 488 A.2d 1298, 1301 (Del. 1985). *But cf. Johns-Manville Corp. v. Equity Sec. Holders Comm. (In re Johns Manville Corp.)*, 801 F.2d 60, 64-65 (2d Cir. 1986) (2-1 decision) (stockholders have an absolute right to conduct a stockholders' meeting to elect a new board of directors during a Chapter 11 case unless either (1) the meeting would constitute a "clear abuse" by the stockholders or (2) the debtor is determined to be insolvent); *Lionel Corp. v. Comm. of Equity Sec. Holders (In re Lionel Corp.)*, 66 B.R. 327 (Bankr. S.D.N.Y. 1983) (annual stockholder meeting permitted in the absence of any showing that it would be prejudicial to the debtor or the case).

n184 *In re Johns-Manville Corp.*, 801 F.2d at 65 n.6 (2d Cir. 1986) (shareholders would be denied right to call a meeting if the debtor were found to be insolvent because they "would no longer be real parties in interest"); *In re Emons Indus., Inc.*, 50 B.R. 692, 694 (Bankr. S.D.N.Y. 1985) ("No equity committee should be appointed when it appears that a debtor is helplessly insolvent because neither the debtor nor the creditors should have to bear the expense of negotiating over the terms of what is in essence a gift.").

VI. Strategies for Providers in Anticipation of and During an IDS Bankruptcy

A. IMPLEMENT RED FLAGS TO TERMINATE CONTRACTS PRE-PETITION/COLLATERALIZE CONTRACTS AND LEASES TO ENSURE SOURCE OF REPAYMENT FOR DAMAGES

As noted above, "ipso facto" clauses, which provide for automatic termination of a contract upon the commencement of a bankruptcy case, are generally unenforceable. n185 Thus, providers cannot unilaterally terminate their provider contracts when an IDS files for relief under the Bankruptcy Code. However, nothing in the Bankruptcy Code prohibits the termination of a contract upon the triggering of certain prebankruptcy conditions, such as poor financial ratios n186 or other "red flags" of financial distress. Accordingly, doctors and practice groups may want to consider including such conditions in their contracts and require periodic financial reports. n187 Moreover, in anticipation of the IDS filing for bankruptcy and rejecting the provider agreement as an executory contract, the non-debtor providers may wish to take a pre-petition security interest in the property of the IDS in order to secure payment of the potential damages arising from such rejection. The collateral for the security interest should include all property that the IDS has acquired in connection with its performance of duties.

n185 *See* 11 U.S.C. § 365(e)(1) (1998).

n186 Financial ratio tests include a current ratio test (current assets divided by current liabilities), which is an indication of the IDS's ability to pay its current or short term liabilities, as well as other tests to measure financial leverage, accounts receivable turnover (*i.e.*, the collections), or profitability. *See generally* ROSENBERG, ET AL., COLLIER LENDING INSTITUTIONS AND THE BANKRUPTCY CODE P2.02[3] (1997).

n187 These reports should include not only a balance sheet, which presents the assets and liabilities as of the date of such statement, but also an income statement to show revenues and expenses over a period of time, a statement of changes in financial position, and an aging of accounts payable and receivable.

B. DEMAND BOARD REPRESENTATION

An acquired physician group or other provider may also increase its ability to protect itself from the implications of a bankruptcy filing by obtaining, at the time of integration into the IDS, a seat on the IDS board of directors and requiring, as part of the charter documents for the IDS, a unanimous vote by the board to commence a bankruptcy case, engage in a merger or consummate a sale of all, or substantially all of, the IDS assets. Alternatively, the physician group can require the placement on the board of a so-called "independent director" and the unanimous board vote for bankruptcy set forth above. n188

n188 As explained by one commentator:

An "independent director" is a director who is not at the time of initial appointment and has not been at any time during the preceding five years: (a) a stockholder, director, officer, employee or partner of the borrower, general partner or affiliate of any of them: (b) a customer, supplier or other person who derives more than 10 percent of its purchases or revenues from its activities with the borrower, general partner or affiliate of any of them: (c) a person or other entity controlling or under common control with any such stockholder, partner, customer, supplier or other person, or: (d) a member of the immediate family of any such stockholder, director, officer, employee, partner, customer, supplier or other person. The term "control" means the possession, directly or indirectly, of the power to direct or cause the direction of management policies or activities of a person or entity, whether through ownership of voting securities, by contract or otherwise.

Sheryl A. Gussett, *On the Edge: A Not-So-Independent Independent Director in a Bankruptcy Remote Structure*, AM. BANKR. INST. J., available in LEXIS, 1998 ABIJNL. LEXIS 64, at note 1.

C. HOSPITAL GUARANTEES OF IDS DEBTS TO PROVIDERS

The automatic stay described above does not prevent a creditor from realizing on a guarantee from a non-debtor party. n189 Accordingly, a provider should consider bargaining pre-petition for a guarantee and demand that either (a) his underlying obligations must be accelerated upon the obligor's bankruptcy, or (b) he has the right to accelerate the guarantee upon the obligor's bankruptcy. Otherwise, the doctor may be limited to seeking recovery of the debt from the guarantor as installments of interest or principal come due. n190 So long as the hospital is solvent at the time it executes the guarantee, the guarantee should be safe from fraudulent transfer attack.

n189 *See, e.g.*, *GATX Aircraft Corp. v. M/V Courtney Leigh*, 768 F.2d 711 (5th Cir. 1985); *In re Rohnert Park Auto Parts, Inc.*, 113 B.R. 610 (Bankr. 9th Cir. 1990) (holding that § 362(a) does not apply to co-debtors); *United States v. Tharp.*, 973 F.2d 619 (8th Cir. 1992) (bankruptcy of underlying obligor does not relieve non-debtor guarantor of obligations under separate guaranty agreements).

n190 ROSENBERG, ET AL., *supra* note 186, P2.02[7].

D. PROVIDERS SHOULD CONSIDER FILING A COMPETING PLAN OF REORGANIZATION TO IMPLEMENT AN IDS UNWIND

Providers should consider seizing control of their creditor destiny by moving to terminate the debtor's right of exclusivity for filing a plan of reorganization. Once exclusivity expires or is terminated, courts view creditor plans as encouraging "creditor democracy." n191 The creditor plan can provide for, among other things, the sale or reorganization of an IDS.

n191 *See, e.g., Matter of Mother Hubbard, Inc., 152 B.R. 189, 196 (Bankr. W.D. Mich. 1993)* (Here, the exclusivity period had expired; with competing plans on same time schedule, "creditors and interest holders will be able to review and analyze both plans (on equal footing) and decide which plan best satisfies their interests. This result comports with the Code, is not prejudicial to the Debtor, and promotes collective decision-making in a creditor democracy.").

E. BANKRUPTCY MAY CREATE A FORUM FOR CLAIMS AGAINST THE NON-DEBTOR HOSPITAL OR HOLDING COMPANY

1. Generally

Any claim that the IDS or its creditors and shareholders have against the non-debtor hospital/parent which arose prior to the commencement of an IDS bankruptcy case remains unaffected by the bankruptcy of the IDS.

2. The Hospital Will Be Closely Scrutinized as an IDS "Insider"

The hospital in a typical IDS will be deemed an "insider of the IDS." This status arises from, among other things, the hospital's significant equity interest in the IDS and its board representation. n192 There are several adverse consequences of being determined to be an insider of a debtor under the Bankruptcy Code. First, the preference period is extended to one year from the usual ninety days. Second, the votes of insiders are not counted in determining whether a Chapter 11 plan of reorganization has received the requisite votes for acceptance. Third, an insider has no right to vote for a trustee in a Chapter 7 case. Fourth, the claim of an insider for services rendered is limited to the reasonable value of such services. In addition, an insider is more likely to encounter allegations that its claim or stockholder interest should be equitably subordinated to other claims or interests, respectively, or that it is otherwise liable to creditors for controlling the debtor under various common law theories, such as breach of fiduciary duty or interference with contractual or business relationships.

n192 *See* 11 U.S.C. § 101(31)(B) (1998).

3. Equitable Subordination of the Hospital's Claims May Provide Doctors with a Greater Return

The Bankruptcy Code recognizes the doctrine of equitable subordination, pursuant to which an allowed claim can be subordinated to the claims of otherwise junior creditors or an allowed shareholder interest can be subordinated to the interests of other shareholders. Equitable subordination is an equitable remedy governed by section 510(c) of the Bankruptcy Code. n193 11 U.S.C. § 510(c) (1998). Although § 510(c) neither defines the term "equitable subordination" nor sets out the elements required to establish equitable subordination, the legislative history makes clear that the section merely codifies judicial interpretation of the term. In very general terms, invocation of the doctrine of equitable subordination is limited to cases involving (i) an element of "inequitable conduct" on the part of the subordinated insider that has either resulted in actual injury to other creditors or conferred an unfair benefit on the insider, or (ii) undercapitalization of the bankrupt entity by its controlling shareholder. This doctrine may be "invoked to the end that fraud will no prevail, that substance will not give way to form, that technical considerations will not prevent substantial justice from being done." n194

n193 This section states in relevant part:

Notwithstanding subsections (a) and (b) of this section, after notice and a hearing, the court may --

(1) under principles of equitable subordination, subordinate for purposes of distribution all or part of an allowed claim to

all or part of another allowed claim or all or part of an allowed interest to all or part of another allowed interest; or

(2) order that any lien securing such a subordinated claim be transferred to the estate.

n194 *Pepper v. Litton*, 308 U.S. 295, 305 (1939).

Although equitable subordination is not defined in the Bankruptcy Code, most courts apply the following three-part test:

- (1) The claimant must have engaged in some type of inequitable conduct;
- (2) The conduct must have resulted in injury to the creditors of the bankrupt or conferred an unfair advantage on the claimant; and
- (3) Equitable subordination of the claim must not be inconsistent with the provisions of the Bankruptcy Act. n195

n195 See *Westgate-California Corp. v. Smith (In re Westgate-California Corp.)*, 642 F.2d 1174, 1178 (9th Cir. 1981); *Pacific Express, Inc. v. Pioneer Comm'l Funding Corp. (In re Pacific Express, Inc.)*, 69 B.R. 112, 116 (Bankr. 9th Cir. 1986); *C.P.C. Dev. Co. v. Fed. Sav. and Loan Ins. Corp. (In re C.P.C. Dev. Co.)*, 113 B.R. 637, 641 (Bankr. C.D. Cal. 1990).

The moving party bears the burden of establishing each prong of the foregoing test by a preponderance of evidence. n196 Typical situations in which courts have effectuated equitable subordination are, (a) when a fiduciary of the creditor misuses his or her position to the disadvantage of other creditors; (b) when a third party controls the debtor to the disadvantage of other creditors; and (c) when a third party actually defrauds other creditors. The success of any such litigation will rest on whether a plaintiff can demonstrate that such control actually damaged other creditors.

n196 See, e.g., *Friedman v. Sheila Plotsky Brokers, Inc. (In re Friedman)*, 126 B.R. 63, 71 (Bankr. 9th Cir. 1991) ("The burden of establishing all the elements of subordination by a preponderance of evidence is on the objecting party.").

There was some sentiment expressed during the drafting of the Bankruptcy Code for a rule automatically subordinating insider claims, but that view did not prevail. n197 If the claimant at issue is an insider, however, his dealings with the debtor will be subjected to exacting scrutiny. A fiduciary is not free to act solely with regard to his own interests, and if the objecting party produces evidence that the fiduciary-claimant used his position to harm those to whom he had a fiduciary obligation, the burden shifts to the fiduciary to establish that the challenged transaction had all of the earmarks of an arms-length bargain. n198

n197 See generally COOK, BANKRUPTCY LITIGATION MANUAL § 8.02[B] (1995-96); *Octagon Roofing v. WMR Partners (In re Octagon Roofing)*, 157 B.R. 852 (N.D. Ill. 1993).

n198 See, e.g., *Matter of Teltronics Services, Inc. v. Hessen*, 29 B.R. 139 (Bankr. E.D.N.Y. 1983), *aff'd* 762 F.2d 185 (2d Cir. 1985).

When a claimant is not an insider, an objector seeking to invoke equitable subordination "must prove that the claimant is guilty of gross misconduct tantamount to 'fraud, overreaching or spoliation to the detriment of others.'" n199 It is

insufficient for the "objectant in [cases involving non-insiders] merely to establish sharp dealing." n200

n199 *In re* Friedman, 126 B.R. at 71.

n200 *In re* Pacific Express, 69 B.R. at 116.

Equitable subordination is intended to be remedial rather than punitive, and a claim should be equitably subordinated only to the extent necessary to rectify harm suffered by the debtor and its creditors as a result of the claimant's misconduct.

A provider, on the other hand, may be at risk for equitable subordination if its contract violates the Anti-Kickback Statute. n201 If a contract violates that statute, it is unenforceable. The debtor may argue that a violation of law is sufficient justification to either disallow or equitably subordinate a provider's claim.

n201 *See* 42 U.S.C. §§ 1320(a)-7(b) (1998) (Among other things, it is a criminal offense for anyone to offer, solicit, give or receive anything of value in return for arranging the referral of Medicare and Medicaid patients or patient care opportunities.).

4. The Assets of the Hospital or Holding Company May Be Put at Risk and Substantively Consolidated with Those of the Debtor Affiliate

A bankruptcy court has the power to invoke its equitable powers, on the basis of factors similar to those considered in "corporate veil piercing" cases, in order to consolidate the assets and liabilities of the bankrupt IDS with those of its parent holding **company** or affiliate. n202 The effect is to bring the parent, for example, into the subsidiary's bankruptcy proceeding and permit the subsidiary's creditors to share in the assets of the parent **company** along with the parent **company's** creditors. Creditors of single entities before consolidation become joint creditors with all creditors of the consolidated debtors after the proceeding. n203 Substantive consolidation also eliminates inter-**company** claims. n204 Because substantive consolidation dramatically affects the rights and interests of creditors and affiliated debtors, the process is typically used sparingly.

n202 *See* 11 U.S.C. § 105(a) (1998).

n203 *See, e.g., In re* Augie/Restivo Banking Co., 860 F.2d 515 (2d Cir. 1988); *Parkway Calabasas, Ltd. v. Sierra Pacific Constr., Inc. (In re Parkway Calabasas, Ltd.)*, 89 B.R. 832 (Bankr. C.D. Cal. 1988).

n204 *See, e.g., Chemical Bank New York Trust Co. v. Kheel*, 369 F.2d 845 (2d Cir. 1966); *In re Parkway Calabasas, Ltd.*, 89 B.R. at 836-37.

Creditors may assert that substantive consolidation is warranted in an IDS-related bankruptcy in which the hospital and the IDS-debtor were operated as a single entity, and were known by the vast majority of their creditors as a single entity. Creditors will also contend that the allocation of specific assets and contract rights on the books of the IDS was done for business reasons and convenience, rather than from any economic reality. Pursuant to a plan of reorganization, creditors may seek to merge the two entities together as in the best interests of the estate and their creditors because it will alleviate the expense associated with untangling the debtor's and hospital's financial books and records, assets, and

business operations.

Courts generally look to seven key factors in considering a motion for consolidation: n205

- * The presence or absence of consolidated financial statements;
- * The unity of interests and ownership between various corporate entities;
- * The existence of parent and intercorporate guarantees on loans;
- * The degree of difficulty in segregating and ascertaining individual assets and liabilities;
- * The existence of transfers of assets without formal observance of corporate formalities;
- * The commingling of assets and business functions;
- * The profitability of consolidation at a single physical location.

n205 See, e.g., *Holywell Corp. v. Bank of New York*, 59 B.R. 340, 347 (S.D. Fla. 1986) (noting that many courts apply a seven-part objective inquiry into the interrelationships of the entities to be consolidated, but "not all of [the factors] must be found to support consolidation).

Several courts have noted that the respective analyses of the foregoing factors are merely efforts to determine two critical facts: (1) whether creditors dealt with the entities as a single economic unit and did not extend credit to the entities with reliance on their separate entities; and (2) whether the economic affairs of the debtors are so entangled that consolidation will benefit all creditors. n206

n206 *In re Augie/Restivo*, 860 F.2d at 518; see *Lease-A-Fleet, Inc. v. Robins LeCocq (In re Lease-A-Fleet, Inc.)*, 141 B.R. 869 (Bankr. E.D. Pa. 1992) (finding substantive consolidation permissible only if non-debtor is an alter ego of the debtor); *In re 1438 Meridian Place, N.W., Inc.*, 15 B.R. 89, 97 (Bankr. D.D.C. 1981) (deciding to substantively consolidate non-debtor affiliates with a debtor because such non-debtors were the alter egos of the debtor's shareholders). See generally J. Stephen Gilbert, *Substantive Consolidation in Bankruptcy: A Primer*, 43 VAND. L. REV. 207 (1990); Patrick C. Sargent, *Bankruptcy Remote Financing Subsidiaries: The Substantive Consolidation Issue*, 44 BUS. LAW. 1223 (1989).

VII. A Prepackaged Bankruptcy May Provide an Expedited Strategy for the Unwinding of an IDS

The legal advantages of implementing the unwinding of an IDS through a bankruptcy may come at a high price. If the goal is to operate and reorganize the IDS. A traditional bankruptcy case may be disruptive and expensive. It may diminish doctor and patient confidence in the core business. All **companies** that go through a bankruptcy lose some measure of good will with vendors because pre-petition trade creditors typically recover only cents on the dollar. Further, bankruptcies divert management attention and, because of the need to move for court approval of many decisions, impair management's ability to take advantage of business opportunities and to respond to competitive threats. Finally, the Bankruptcy Code provides a debtor with the exclusive right to propose a plan of reorganization only during the first four months of a case. As noted above, if the debtor cannot obtain confirmation of a plan during the four-month exclusivity period or convince the court and relevant constituencies to extend such period, the debtor could face a plan of reorganization proposed by a creditor.

IDSs should, therefore, examine the substantial benefits of restructuring their debt or consummating a corporate transaction through a "prepackaged" plan of reorganization, a plan in which all creditor approvals necessary for confirmation are obtained before the **company** files for relief under Chapter 11, resulting in a very short Chapter 11 proceeding. A prepackaged plan of reorganization is a technique designed to allow **companies** to take advantage of the substantial legal benefits of the bankruptcy laws while minimizing the length, expense, and risks inherent in traditional

bankruptcy cases. n207

n207 See generally John Huber et al., *Restructuring High-Yield Securities Through Prepackaged Bankruptcies*, 5 INSIGHTS 3 (May 1991).

By using a prepackaged plan, a **company** reduces the length and costs of a traditional Chapter 11 proceeding by completing the bulk of the restructuring process -- the preparation and proposal of a reorganization plan and disclosure statement, negotiations with creditors, and solicitation of creditor acceptances -- before submitting to the jurisdiction of a bankruptcy court. In addition to reducing the length and expense of a bankruptcy proceeding, the prepackaged technique enables management to stay in control of the restructuring process by giving it the time necessary to formulate, negotiate, and obtain acceptances of a restructuring plan without running up against the artificial deadline created by the four-month exclusivity period. In addition, prepackaging permits management to continue to operate the business and to engage in necessary transactions prior to the filing without having to seek approval of the bankruptcy court.

In addition, unlike most traditional plans, trade creditors in prepackaged bankruptcies generally receive full payment on their prepetition claims, thereby preserving good will and the core business. A prepackaged Chapter 11 case, if successful, solves the hold-out problems inherent in an out-of-court restructuring without the cost, delay, and uncertainty of a traditional Chapter 11 case.

Other variations on the prepackaged theme include "partial prepacks," "pre-negotiated," and "pre-discussed" Chapter 11 cases. For example, a debtor may pursue a "partial prepack" in which it pursues solicitations of key creditor classes prior to filing the Chapter 11 petition, and then seeks acceptances from the remaining debt or equity classes after a petition has been filed and a disclosure statement has been approved by the court. Use of such a procedure may enable a **company** with public stock to speed up the overall restructuring process by avoiding lengthy SEC review of the disclosure statement under the federal proxy rules and as a registration statement under the Securities Act of 1933, but still reduce the risks of a traditional Chapter 11 case by locking in creditor approvals before filing for Chapter 11. Another alternative to a traditional bankruptcy plan is a "pre-negotiated" plan, which is a plan that is supported, but not officially accepted, by the debtor's creditors and equity security holders prior to the filing of a bankruptcy petition. The debtor must still obtain court approval of a disclosure statement and then solicit formal acceptances of the plan after filing for relief under Chapter 11, but the consensus achieved prior to filing will facilitate rapid post-petition acceptance and confirmation.

A prepackaged plan is specifically contemplated by the Bankruptcy Code. n208 Such plans are considered preferable in most instances because they are generally well thought-out and reduce the time and expense of litigation, thereby allowing the debtor to commence its reorganized operations as soon as possible. n209 As one court stated, the Bankruptcy "Code, in several specific respects, contemplates that workouts will be a prelude to, yet consummated in, bankruptcy. . . . Indeed, incentives to use 'prepackaged plans' are 'written all through the [Bankruptcy Code].'" n210 These incentives include, among others, authorization to solicit votes on a plan of reorganization prepetition, to file a plan of reorganization concurrently with a bankruptcy petition and the use of a prepetition committee as the official unsecured creditors' committee.

n208 See, e.g., 11 U.S.C. § 1126(b) (1998).

n209 See, e.g., *In re Southland Corp.*, 124 B.R. 211, 225 (Bankr. N.D. Tex. 1991) ("The prepetition negotiation and solicitation of acceptances of a plan is an admirable process. It saves time and expense and the various problems of an ongoing Chapter 11 proceeding.").

n210 *In re Colonial Ford*, 24 B.R. 1014, 1017 (Bankr. D. Utah 1982).

It is the limited time which a **company** spends in bankruptcy that makes a prepackaged bankruptcy case so appealing as a corporate tool. Because the tough negotiations and voting on the plan itself occur before bankruptcy, most "prepackaged debtors" emerge from bankruptcy within forty-five days of the petition date. n211 The debtor's management usually need only prepare for two hearings. The first occurs on, or around, the first day of the bankruptcy case and focuses on approval of short-term bankruptcy financing, retention of counsel, payment of pre-petition vendors, and other procedural motions. The second hearing -- at which confirmation of the plan of reorganization occurs -- can take place as early as thirty days after the petition date. Once a plan is confirmed and goes "effective," the reorganized debtor can operate free from bankruptcy restrictions. This streamlined process enables debtors to restructure and prosper without the pain of a drawn-out bankruptcy case.

n211 See Tashjian, *supra* note 143, at 142.

VIII. Conclusion

Bankruptcy provides an effective method for implementing the unwinding, through sale or otherwise, of an IDS. Although the bankruptcy process is not cost-free, those costs can be mitigated with careful pre-bankruptcy planning. Thus, an IDS would be rmiss not to consider the significant bankruptcy benefits described in this article.

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TEXT:

INTRODUCTION

The long-awaited Medicare/Medicaid Fraud and Abuse "Safe Harbor" regulations, which provide exceptions to the Medicare and Medicaid prohibitions on kickbacks, were published in final form on July 29, 1991. [n1] These regulations may prove to be of mixed benefit to health care providers, practitioners, and their advisors. From one perspective, the narrow scope of the final regulations, together with the absence of an advisory opinion mechanism, limits the practical value of the eleven Safe Harbors created by the final regulations. From another perspective, the comments provided in the final regulations by the Office of Inspector General (OIG) provide a wealth of information on regulatory intent and perceived abusive practices, and can be of substantial benefit to providers, practitioners, and their counsel. The following discussion explores these two perspectives in greater detail.

BACKGROUND

The final regulations are intended to specify various payment practices that, although potentially capable of inducing Medicare or Medicaid business, will be protected from criminal or civil prosecution under the Medicare and Medicaid "Anti-Kickback" statute. [n2] The final regulations do not expand the scope of activities prohibited by the Anti-Kickback statute; rather, the Anti-Kickback statute itself describes the scope of illegal activities. [n3] Hence, any conduct that constitutes a violation of the Anti-Kickback statute after the publication of the final regulations still would have been considered illegal at any time since the Anti-Kickback statute was enacted in 1977. [n4] Illegal arrangements entered into in the past were done so with the risk of prosecution. [n5] The final regulations are intended to provide a mechanism for avoiding risk in the future.

The Anti-Kickback statute [n6] was added to the Social Security Act [n7] in 1972, and was amended in 1977 and again in 1980 to impose criminal penalties against individuals and entities participating in Medicare or Medicaid that knowingly and willfully offer, pay, solicit or receive remuneration in order to induce the furnishing of an item or service for which payment may be made by the Medicare or Medicaid program. [n8] These prohibited activities are felony offenses subject to fines of up to \$ 25,000 or imprisonment for up to five years, or both, for each offense. [n9]

In enacting the Anti-Kickback statute, Congress sought to prevent unnecessary escalation of health care costs by providing penalties for practices deemed abusive or unethical. [n10] In addition, 1987 legislation authorized the OIG to exclude an individual or entity from participation in the Medicare and Medicaid programs if the OIG determines the party has engaged in a remuneration scheme prohibited under the Anti-Kickback statute. [n11] To address this concern, section 14(a) of the Medicare and Medicaid Patient Protection Act of 1987 [n12] required the promulgation of regulations specifying those payment practices not subject to criminal prosecution under the Anti-Kickback statute and which will not provide a basis for exclusion from Medicare or Medicaid.

The publication history of the final regulations reflects their controversial nature and also serves as a warning to those who would rely too heavily on proposed regulations or on "advance" copies of regulations. The regulations were first published in proposed form by the OIG in the Federal Register of January 23, 1989. [n13] Preliminary, internal Department of Health and Human Services (HHS) working drafts of the proposed regulations had been made available in August 1988. An earlier set of proposed regulations had been published in the December 23, 1988 Federal Register, but were withdrawn without comment on December 28, 1988. [n14] The final Safe Harbor regulations were developed in consultation with the United States Department of Justice, and with the assistance of 754 letters of comment submitted by interested parties in response to the proposed regulations. [n15]

CLARIFICATION OF RELEVANT ISSUES

The final regulations attempt to clarify the effect of not having a business arrangement specifically protected by a Safe Harbor. [n16] Clearly, in order for a business arrangement to qualify for Safe Harbor protection, full compliance with the relevant provisions must be established. [n17] Nevertheless, where the particular arrangement involves a "multi-purpose" payment practice, it will be necessary to document separately that each purpose served by a payment qualifies under a given Safe Harbor. [n18] Therefore, fully complying with the terms of one Safe Harbor does not insulate an entire multi-purpose payment practice where another purpose of the practice violates the Anti-Kickback statute. [n19]

If the parties to a business arrangement do not intend to induce the referral of business reimbursable under Medicare or Medicaid, the Anti-Kickback statute is not implicated and there is no reason to comply with a Safe Harbor. In these cases, there is "no risk of prosecution." [n20]

Where the business arrangement does come within the scope of the Anti-Kickback statute and where there is less than full compliance with a Safe Harbor, the parties involved risk OIG scrutiny and may be subject to civil or criminal enforcement action. [n21] In the case of a clear statutory violation and an arrangement that is "obviously abusive," prosecution would be "very likely." [n22] Where the noncomplying arrangement violates the Anti-Kickback statute in a less egregious manner, prosecutorial discretion may be exercised. [n23] Nevertheless, it should be noted that, through the final regulations, the OIG specifically declined to adopt a standard which would assure protection in all instances of "substantial compliance," "technical violations," or "*de minimis* payments." [n24]

The final regulations reflect the decision of OIG not to provide a mechanism for responding to individual requests for advisory opinions concerning the legality of a particular business arrangement under the Anti-Kickback statute. [n25] A variety of reasons were cited as the basis for this decision. In particular, the OIG believes that its "Fraud Alert" program is the most effective mechanism "for imparting practical and continuing guidance to individuals and entities seeking to avoid violations of [the Anti-Kickback statute]." [n26] Although the OIG's rationale for not creating an advisory mechanism is certainly justifiable, it is necessarily a disappointment to health care providers who must deal with the vicissitudes of an extremely broad statute, and who are familiar with access to advisory vehicles on other issues, such as compliance with the Internal Revenue Code. [n27] Without an advisory mechanism for Safe Harbor compliance, providers and practitioners will be forced to develop, in conjunction with counsel, detailed file documentation supporting compliance claims.

The final regulations also reflect a general rule not to require health care providers to disclose to patients any

financial relationships with sources of referrals as a condition for Safe Harbor treatment. [n28] The only exception applies to referral services, because in that instance, disclosure would provide "meaningful added protection." [n29]

THE SAFE HARBOR FOR SALE OF PRACTICE

The combination of economic pressures and competitive reality suggests the "sale of a medical practice" Safe Harbor will be of limited value to providers and practitioners. However, the commentary regarding this Safe Harbor is significant, because it questions the legality of the current actions of many hospitals that purchase (or are being urged to purchase) practices from physicians who continue to practice on the hospital's medical staff.

This Safe Harbor exists only for payments made to a practitioner by another practitioner when the former practitioner is selling his practice to the latter, and then only under certain circumstances. [n30] The purpose of this particular Safe Harbor is to protect the sale of physician practices which occur because of retirement or other events which result in the withdrawal of the physician from the practice of medicine, or from the service area in which the physician was practicing. [n31]

This Safe Harbor regulation reflects a concern that, in certain situations, the purchase and sale of a medical practice is made primarily for the purpose of obtaining an ongoing source of patient referrals. [n32]

Analysis

As noted above, the protection afforded by this Safe Harbor is quite limited. The comments to the regulations provide some comfort to hospitals that purchase the practices of retiring physicians who would no longer make referrals to the hospital. In addition, the sale of an individual's practice to a group practice or the sale of a part of a practice to another physician or group practice when the selling physician chooses to change the scope of his or her practice also appears protected under the comments. [n33]

On the other hand, the Safe Harbor provides no "Anti-Kickback" comfort to hospitals that purchase physicians' practices for fair market value and then retain the physicians on staff. [n34] The comments decline "to protect a practice that often leads to the very abuses that the statute is designed to prevent." [n35] While the comments refer to protection for hospital acquisitions of medical practices as part of physician recruitment programs and to a proposed Safe Harbor for such physician recruitment programs, these references should be discounted. [n36]

Finally, where local law permits, this Safe Harbor could prompt greater use of hospital-controlled professional corporations as a means of acquiring practices. The OIG may challenge such transactions, particularly if the hospital funds the professional corporation. Given the relationship between the OIG and the Internal Revenue Service (IRS), this Safe Harbor might also prompt greater scrutiny by the IRS of the federal income tax implications of the practice acquisition activity. [n37]

THE SAFE HARBOR FOR INVESTMENT INTERESTS

Perhaps the most controversial of the new Safe Harbors is the one revised most from proposed to final form, relating to payments from investment interests. [n38] In particular, the final regulations address payments from investments in large, publicly traded **companies**; payments from investments in small entities such as limited partnerships; the possibility of **protecting** payments from other interests; and the definition of the terms "investor" and "investment interest."

The final regulations define the term "investment interest" to include both debt and equity investments, and the term "investor" to include both individuals and entities who either directly or indirectly hold an investment interest in the entity. [n39] Investment interests are considered indirectly held in a variety of different ways, including through a family member of the referring physician, or through an ownership interest in an entity that directly holds the investment interest. [n40] In both cases, the physician would nevertheless be considered as holding the ownership

interest in the joint venture.

The final regulations also draw a distinction between investors who "do business" with the entity in which they have invested, and those investors who are exclusively seeking a return on their investment. The former are perceived to be more "at risk" under the Anti-Kickback statute. Investors "doing business" with the entity are described as those "who [are] in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity." [n41] This classification is designed to include "all investors who do business in any manner with the entity," and may include not only physicians, but also hospitals and other entities capable of influencing referrals. [n42] This Safe Harbor was designed to protect profit distributions made to referring investors in large, publicly traded corporations where the investment interest was obtained at fair market value through trading on a publicly regulated exchange.

Two definitional prerequisites must be met for an entity to qualify under this Safe Harbor: (1) the assets of the entity must be measured any time within the previous fiscal year or previous twelve month period; and (2) the entity must possess \$ 50 million in the form of undepreciated net tangible assets. [n43] The Safe Harbor then has five standards that must be satisfied: (1) investment interests in equity securities must be registered with the Securities and Exchange Commission; [n44] (2) the investment interest of an investor in a position to make or influence referrals to, furnish items and services to, or otherwise generate business for the entity must have been obtained on terms equally available to the public through a nationally recognized securities exchange; [n45] (3) the entity or any investor must not market or furnish the entity's items or services to passive investors in any manner differently than to non-investors; (4) the entity may not loan funds to or guarantee a loan for an investor to use for the purpose of obtaining the investment interest; [n46] and (5) the amount of payments in return for the investment interest must be directly proportional to the amount of the capital investment. [n47]

By negative inference, this Safe Harbor highlights the potential abuse arising from a number of situations involving investments in larger entities. One such situation is where the entity obtains capital by self-selecting investors based on their status as sources of referrals. The OIG plans to "strictly scrutinize" attempts to circumvent the second standard which requires physicians and others in a position to influence referrals to obtain their investment interest through public trading. [n48] Another potentially abusive situation involves fraudulent cross-referral arrangements whereby investors in entity "A" are required to refer to entity "B" in exchange for entity "A" obtaining referrals from investors of entity "B." [n49] A third potentially abusive scenario is where an entity uses a separate marketing approach or provides a different level of service to passive investors as opposed to non-investors. [n50] Abuse may also be found where the investor borrows from the entity or a corporate affiliate and makes an investment in the entity with the loan proceeds. [n51]

Analysis

Primarily, the final regulations recognize the limited value of the relationship between the Securities Exchange Commission (SEC) rules and the Safe Harbor rules that had originally been set forth in the proposed regulations. [n52] This is demonstrated by the increase in the net asset threshold level from \$ 5 million to \$ 50 million, by the elimination of the 500 minimum shareholder requirement, and the distinction drawn between investment interests traded on a publicly regulated exchange, and those traded "through the so-called pink sheets" or those "non-NASDAQ" securities that are traded through the Over the Counter (OTC) Bulletin Board Service. [n53] After all, the original purpose of this Safe Harbor was to avoid application of the Anti-Kickback Statute to a physician who receives a dividend payment from a large publicly traded pharmaceutical **company** if the physician prescribed the **company's** product for a Medicare or Medicaid patient. [n54]

THE SAFE HARBOR FOR INVESTMENT INTERESTS IN SMALL ENTITIES

The Safe Harbor created for investment interests in small entities contains significant differences from the regulations in proposed and "unofficial" [n55] forms. These changes may have a dramatic impact on the structure of

existing and proposed joint ventures and other "small entities." They may also force some joint venture promoters and owners to make a business decision concerning the utility of compliance with this Safe Harbor.

The purpose of this particular Safe Harbor is to protect payments from legitimate investments in small entities, typically joint ventures, where safeguards are present to minimize any corrupting influence the investment interest may have on the physician-investor's decision with respect to patient referral. [n56]

These investors must meet eight standards. [n57] Because some of these standards apply only to persons defined as "passive investors," the regulations differentiate between such and those referred to as "active" investors. [n58] "Active investors" include persons or entities regarded as "bona fide general partners" who are responsible for the day-to-day management of the entity, and those who otherwise agree in writing to undertake liability for the partnership. [n59] "Passive" investors are not active investors, such as limited partners or shareholders. [n60] It is important to note that the standards for this Safe Harbor must be met by all investors in the entity. To the extent that one class of investors, such as active investors, qualifies, but passive investors do not so qualify, no payments from the entity will receive Safe Harbor treatment. Moreover, the commentary to the regulations suggests that the OIG will pay close attention to ownership interests held indirectly through other entities. [n61]

The eight Safe Harbor standards are structured into three separate categories, each reflecting areas of particular concern with joint venture arrangements: (1) the manner in which investors are selected and retained; (2) the nature of the business structure; and (3) the financing and profit distributions. [n62] These areas are summarized below.

Retention and Selection of Investors

No more than 40 percent of the value of investment interests of each class of investments may be held in the previous fiscal year or previous twelve month period by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity (henceforth, "to do business with the entity"). [n63]

The terms on which an investment interest is offered to a passive investor, if any, who is in a position to "do business with the entity" must: (1) not be different from the terms offered to other passive investors; [n64] and (2) must not be related to the previous or expected volume of referrals, items or services furnished, or the amount of business otherwise generated from that investor to the entity. [n65] A passive investor cannot be required to "do business with the entity" as a condition for remaining as an investor. Neither the entity nor any investor may market or furnish the entity's items or services, or those of another entity as part of a cross-referral arrangement, to passive investors differently than to noninvestors.

Business Structure

No more than 40 percent of the gross revenue of the entity in the previous fiscal year or previous twelve month period may come from referrals, items or services furnished, or business otherwise generated from investors. [n66]

Financing and Profit Distributions

The entity may not loan funds to an investor in a position to "do business with the entity" if the investor uses any part of the loan to obtain the investment interest. [n67] The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of capital investment of that investor. [n68]

This Safe Harbor regulation reflects a concern with the possibility of widespread abuse in joint ventures that have been designed to include physicians or investors specifically to induce them to use the entity in which they have invested. [n69] According to the regulations, many such ventures cannot exist without referrals from their investing physicians, calling into question their business purpose. [n70] The OIG's concern is based in part on an investigation of what it considers to be abusive joint venture arrangements, the published "Fraud Alert" describing "suspect" features of

certain joint ventures, and the 1988 Report to Congress, "Financial Arrangements Between Physicians and Health Care Businesses." [n71]

Several additional Safe Harbors have been proposed in the comments. One would address business structures composed entirely of active investors, such as general partnerships, and might include fewer restrictions than the current Safe Harbor for investment interests in small entities. [n72] Another possible Safe Harbor would address payments to physician/investors from ambulatory surgical centers and similar entities, under certain circumstances. [n73]

Analysis

As noted above, the narrow scope of this Safe Harbor (particularly, the two 60-40 tests) may make it very difficult for otherwise legitimate joint ventures to obtain Safe Harbor protection. The narrow scope of this Safe Harbor may force otherwise legitimate joint ventures to document the reasonableness of the arrangement and the extent to which they comply with the Safe Harbor criteria. Investors considering capitalizing "sweat equity" should be particularly careful with documentation of the reasonableness of the pre-operational services rendered, as there is the potential for abuse in this area.

Several other related matters are worth noting. First is the new emphasis on investors who "do business with the entity." The final regulation makes clear that this category of "at risk" investor extends not only to investors who actually make referrals, but others, *i.e.*, hospitals, capable of influencing referrals, those investors who furnish items or services to the entity, and those who otherwise generate business for the entity.

Also, the OIG is scheduled to report to HHS within 180 days of publication of the final regulations, whether the "60-40" rules are adequate or need to be more stringent.

THE SAFE HARBOR FOR SPACE RENTAL

In response to an overwhelming number of critical comments on the space rental provision of the Proposed Safe Harbors, the OIG revised the definition of "fair market value" in the space rental Safe Harbor to permit consideration of the intended use of rental property in determining the fair market value of the property. Nevertheless, the Safe Harbor does not permit any adjustment to the value that either the lessor or lessee would attribute to the property as a result of its proximity or convenience to sources of referrals or business reimbursable under Medicare or a state health program. The OIG also removed from the space rental Safe Harbor as redundant the confusing requirement in the proposed regulations that the "periodicity" of part-time access arrangements be specified in advance in the lease agreement. This Safe Harbor protects some legitimate space rental arrangements which could otherwise technically violate the Anti-Kickback statute, while leaving unprotected sham space rental arrangements and arrangements keyed to referrals of Medicare and state health care program business between the parties.

The Safe Harbor covers payments for rental of space if all of the following requirements are met: signed written lease agreement; specific identification of leased premises; schedule of rental intervals and rent for each interval in part-time leases; lease term of not less than one year; and aggregate rental charge set out in advance, consistent with fair market value in arm's-length transactions, and not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a state health care program. [n74] For purposes of this Safe Harbor, the final regulations define "fair market value" as the "value of the rental property for general commercial purposes." [n75]

Analysis

The Safe Harbor regulations reflect a concern that, in some cases, payments ostensibly for rental of space are really payments to induce referrals of Medicare or state health care program business or to compensate one party to the rental arrangement for such referrals. Examples of these abusive arrangements are cited in the comments on the Safe Harbor regulations. [n76] In addition, the comments to the Safe Harbor regulations identify certain types of arrangements the

OIG believes can be used to mask abuse, including: (1) percentage leases; (2) "per use" rental arrangements; and (3) part-time, periodic, and "as-needed" access arrangements. [n77]

Despite the omission of some of the most confusing provisions of the Proposed Safe Harbor, uncertainty remains as to how the space rental Safe Harbor will be applied. For example, the requirement, that fair market value not include any value that either party would attribute to the proximity or convenience of the rental property to sources of Medicare, state health program referrals, or business otherwise generated between the parties, injects a subjective element into the definition of "fair market value." This subjective element makes the fair market value of rental property very difficult to determine, and makes unclear the extent to which the location of rental property may be considered in determining its rental value. The location of property is normally a key element in real estate valuations.

The final regulations permit consideration of the use of rental property in determining its fair market value. The comments clarify that the cost of building out to make the space suitable for furnishing medical services may be considered in determining "fair market value." [n78]

The comments also reflect the OIG's decision to exclude from Safe Harbor protection any rent concession given by a hospital to a medical staff physician leasing space in the hospital's on-campus medical office building. The OIG, however, left open the possibility that a future Safe Harbor might protect some rent concessions granted by a hospital as part of a physician recruitment package. [n79]

The Safe Harbor requirement that the aggregate rent for the entire lease period be set out in advance rules out protection for payments under "shopping-center" [n80] style leases in which some part of the rental charge is based on the gross volume of the lessee's business. Furthermore, this advance payment requirement may also leave payments under triple net leases unprotected, depending on whether the OIG considers expenses such as taxes, utilities, and insurance that are either passed through to the lessee or assumed by the lessee to be rent, or classifies them as nonrent expenses.

THE SAFE HARBOR FOR EQUIPMENT RENTAL

The equipment rental Safe Harbor is intended to protect certain legitimate equipment rental arrangements, while leaving unprotected both abusive arrangements entered into as a means of paying for Medicare or state health program referrals and other arrangements that may be abusive. As in the space rental Safe Harbor, the equipment rental Safe Harbor drops the requirement of the Proposed Safe Harbor that "periodicity" be specified in advance for part-time use arrangements.

The Safe Harbor for equipment rental protects payments made pursuant to equipment rental arrangements which meet certain criteria including: signed written lease agreement; specific identification of leased equipment; schedule of rental intervals and rent for each interval in part-time leases; lease term of not less than one year; and aggregate rental charge set out in advance, consistent with fair market value in arm's-length transactions, and not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a state health care program. [n81]

For purposes of this Safe Harbor, "fair market value" means "the value of the equipment when obtained from a manufacturer or professional distributor," not adjusted to reflect any additional value that "one party (either the prospective lessee or lessor) would attribute to the equipment as a result of its proximity or convenience to sources of referrals or business generated for which payment may be made in whole or in part under Medicare or a state health care program." [n82]

Analysis

Although the comments to the Safe Harbor regulations do not cite specific examples of abusive arrangements involving rental of equipment, the comments do list types of equipment rental arrangements particularly prone to abuse.

The concern expressed in the comments is that, even though lessor/lessee arrangements may be legitimate, they may also be used to conceal illegal payments for referrals or provide improper incentives to refer Medicare or state health program patients or business. [n83]

The comments describe and label as "troublesome" an arrangement in which a partnership of radiologists on a hospital's medical staff leases a magnetic resonance imaging (MRI) scanner to the hospital under an arrangement requiring higher rent be paid when more than a predetermined number of MRI scans are performed. The concern stated in the comments is that the radiologists will have a clear incentive for over-utilization. [n84] The OIG recognizes that legitimate considerations, such as the depreciation of equipment, could result in some part of the payment being based on use without influencing or being influenced by Medicare or Medicaid referrals. Nevertheless, the more the payments appear to reflect the volume of referrals from a financially-interested party, the more suspect the arrangement becomes, and the more likely the OIG will examine the arrangement carefully.

The OIG refused to protect any equipment leases containing wear and tear clauses. This means that many legitimate equipment lease arrangements will fall outside the Safe Harbors.

In addition, this Safe Harbor fails to address important elements of equipment lease arrangements. The basic definition of "fair market value" of rental equipment as "the value of equipment when obtained from a manufacturer or professional distributor" does not provide much guidance for determining the fair market rental charge for equipment. Equipment leases generally are financing vehicles and may be structured in many different ways. In order to make a proper determination of fair market rental payments under an equipment lease, one must consider not only the value of the equipment in the hands of a manufacturer or distributor, but also market interest rates and the economic effects of particular lease arrangements. Another important consideration in determining the fair market rental charge is the length of the lease term in relation to the useful life of the equipment. Equipment leases may vary widely in their provisions for the parties' rights and obligations at the end of the lease term.

Because the definition of "fair market value" in the equipment rental Safe Harbor only addresses the value of the equipment in the hands of a manufacturer or professional distributor (which is the fair market sale value of equipment rather than the fair market rental value), it is virtually impossible to predict how this definition will be applied to specific lease arrangements and whether Safe Harbor protection will be available for equipment leases. Providers and suppliers entering into lease arrangements with the intent of claiming Safe Harbor protection will be well advised to document that the interest rate applied to the lease is a fair market rate of interest, other lease arrangements affecting the rental charge are arm's-length in nature, and the resulting rental charge is within the range of fair market rental rates for similar arrangements between parties not in a position to influence the flow of Medicare or state health program business to each other.

Neither the space rental nor the equipment rental Safe Harbor will provide protection for payments pursuant to many part-time or periodic rental arrangements because of the stringent requirement of both Safe Harbor provisions that leases providing periodic, rather than full-time access, must specify in advance the exact schedule of the intervals, their precise length, and the exact rent for such intervals. The advance scheduling of intervals of use required for such arrangements will generally be infeasible or impracticable.

THE SAFE HARBOR FOR PERSONAL SERVICES AND MANAGEMENT CONTRACTS

This Safe Harbor protects joint ventures and other arrangements involving payments for personal services or management contracts when such arrangements meet standards that limit the opportunity to provide illegal financial incentives for referrals. The Proposed Safe Harbor regulations listed five criteria for the personal services and management contract Safe Harbor, [n85] and the final regulations add a sixth requirement. This additional requirement is aimed at arrangements in which promoters or consultants engage in activities that encourage health care providers and others to violate the Anti-Kickback statute. [n86]

This Safe Harbor provides that payments by a principal to an agent for compensation for the services of the agent will not constitute "remuneration" under the Anti-Kickback statute if the following requirements are met: signed written agreement; specific identification of services; schedule of service intervals for part-time arrangements and exact charge for each interval; term of not less than one year; and aggregate compensation set out in advance, consistent with fair market value in arm's-length transactions, and not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a state health care program, and services to be performed do not involve counseling or promotion of an illegal business arrangement or activity. [n87]

Analysis

In the comments to the Safe Harbor regulations, the OIG stated that its refusal to protect compensation for personal services where the aggregate amount of payments is not set out in advance does not mean that percentage contracts which are based on overall volume are *per se* violations of the Anti-Kickback statute. Nevertheless, the comments state that, historically, percentage contracts have been rife with abuse. [n88] In addition, the comments list other potentially abusive arrangements: (1) commission sales arrangements with independent contractors; [n89] (2) agreements of short duration and agreements renegotiated frequently; [n90] (3) arrangements in which compensation is set on a "per-procedure" basis; [n91] and (4) part-time and as-needed arrangements. [n92]

In the comments, the OIG stated the requirement of a term not less than one year for personal services or management contracts refers to the period in which such an agreement may not be changed and does not mean that agreements which provide for shorter-term services will fall outside the Safe Harbors. [n93] In addition, the OIG provided clarification on the relationship between early-termination clauses and the one-year term requirement of both the personal services and management contract Safe Harbor and the space and equipment rental Safe Harbors. The OIG acknowledged that early termination clauses may be included in agreements for legitimate tax or other regulatory reasons. The OIG also indicated termination "for cause" clauses may not preclude Safe Harbor protection for an agreement if the clause is included in order to comply with tax or other regulatory requirements, and not to facilitate renegotiation of the terms of the agreement. [n94] The OIG concluded that, in cases where an agreement is terminated under early termination clauses, "failure to renew the contract would provide evidence that the termination was effectuated for a legitimate purpose." [n95]

Interestingly, some persons commenting on the Proposed Safe Harbors asked the OIG to clarify whether contracts containing a 90-day termination clause in order to comply with the standards of Revenue Procedure 82-15 would fall outside the Safe Harbors. [n96] Revenue Procedure 82-15 requires 90-day termination only in contracts containing percentage compensation arrangements. Such contracts cannot qualify for Safe Harbor protection, because they do not meet the requirement that the aggregate compensation to be paid to the agent be set in advance.

The OIG refused to extend blanket protection to payments for marketing and advertising services. Many payments for such services technically violate the Anti-Kickback statute because they are payments to induce the marketer or advertiser to recommend "purchasing, leasing, or ordering" a service or item reimbursable under Medicare or Medicaid. The comments to the Safe Harbor regulations state that many marketing and advertising activities do not warrant prosecution because they do not involve direct contact with program beneficiaries by a health care provider who is in a position of public trust when recommending or ordering items or services for patients. Nevertheless, the OIG has encountered many examples of promoters and consultants who encourage health care providers to violate the Anti-Kickback statute by developing abusive joint ventures or routinely waiving Part B coinsurance and deductibles. [n97] Therefore, the OIG added the sixth requirement to the Safe Harbor for personal services and management contracts, namely, the services performed under such agreements must not involve "the counseling or promotion of a business arrangement or other activity that violates any state or federal law." [n98]

It is important to note arrangements involving counseling or promotion of violations of statutes other than the Anti-Kickback statute will not qualify for Safe Harbor protection. Thus, payments to a consultant who assists a

provider in setting up a medical clinic in violation of state corporate practice of medicine prohibitions will not be protected.

THE SAFE HARBOR FOR EMPLOYEES

Technically, the employee Safe Harbor is an interpretive regulation and does not provide additional protection to the employment exception of the Anti-Kickback statute. [n99] The purpose of the Safe Harbor for employees is to define the term "employee" for purposes of the employment exception to the Anti-Kickback statute.

The employee Safe Harbor defines the term "employee" as section 3121(d)(2) of the Internal Revenue Code. [n100] Section 3121(d)(2) defines an employee as "any individual who, under the usual common law rules applicable in determining the employer-employee relationship, has the status of an employee." [n101] The regulations interpreting section 3121(d)(2) state that an employer-employee relationship exists: "When the person for whom services are performed has the right to control and direct the individual who performs the services, not only as the result to be accomplished by the work but also as to the details and means by which that result is accomplished." [n102]

The IRS, in a 1990 private letter ruling, found that a physician providing part-time services at a clinic was an employee of the corporation owning the clinic, despite the corporation's limited control over the physician as to matters of professional judgment. [n103]

Under the IRS regulations, the parties' characterization of a relationship as an independent contractor relationship would not control. Rather, the regulations provide that, if the employer-employee relationship exists, "it is of no consequence that the employee is designated as a partner, coadventurer, agent, independent contractor, or the like." [n104]

Analysis

The OIG declined to extend Safe Harbor protection to any payments to independent contractors, stating "[W]e are confident that the employer-employee relationship is unlikely to be abusive, in part because the employer is generally fully liable for the actions of its employees and is therefore more motivated to supervise and control them." [n105]

Conversely, the comments clearly reflect the OIG's concern that it is difficult to predict with reasonable certainty which arrangements with independent contractors are not abusive. The OIG specifically cited commission sales arrangements with independent contractors as one type of arrangement prone to abuse. Nevertheless, arrangements with independent contractors will be protected under the personal services and management contract Safe Harbor if they meet the requirements of that Safe Harbor. [n106] The OIG specifically refused to extend Safe Harbor protection to payments under independent contractor relationships with physicians who cannot be employed by hospitals under state laws prohibiting the corporate practice of medicine, unless the arrangement meets the requirements of the personal services and management contract Safe Harbor. [n107]

Some commenters asserted, probably erroneously, that the OIG is without legal authority to limit the meaning of the term "employee" as used in the Anti-Kickback statute. Fortunately for providers, the definition of "employee" adopted by the OIG is fairly broad and will cover some arrangements even if they are not characterized by the parties as an employer-employee relationship.

The definition of "employee" used by the IRS for employment tax purposes includes all individuals who are employees under the usual common law rules for determining employee status, even if they are otherwise characterized as independent contractors. This opens the theoretical possibility that physicians who must be characterized as independent contractors by hospitals to comply with state prohibitions on the corporate practice of medicine may nevertheless be employees for employment tax purposes and, thus, be employees for Safe Harbor purposes, as well. On the other hand, if the hospital does not treat such a physician as an employee for tax purposes, the OIG may refuse to treat the physician as an employee.

The employee Safe Harbor provides no guidance on what constitutes a *bona fide* employment relationship or "employment in the provision of covered items or services" for purposes of the employment exception to the Anti-Kickback statute. Parties wishing to structure relationships that come within the employment exception to the Anti-Kickback statute would be well advised to avoid extending the employment relationship to cover payments for services falling outside the scope of an employee's employment or to expect the OIG to adopt a broad definition of what constitutes employment in the provision of covered items or services. For example, physicians employed by a hospital often conduct private medical practices in an independent capacity as well. The employing hospital should not count on an employment exception to the Anti-Kickback statute for payments which, under the employment agreement, also relate to referrals from the physician's private practice.

THE SAFE HARBOR FOR REFERRAL SERVICES

Unlike its approach with most of the Safe Harbors, the OIG slightly expanded the coverage of the referral service Safe Harbor. The Unofficial Safe Harbor had narrowed the scope of protection from the Proposed Safe Harbor to entities whose "primary service" is to refer patients to health care providers. The final regulation, however, extends protection to any entity serving as a "referral service." [n108] As a result, the final regulation will provide protection to entities, such as hospitals, that operate referral services as a small portion of their overall operations. In addition, this is the only Safe Harbor which requires disclosure of financial relationships to a beneficiary. Without proper disclosure, the OIG believes a consumer would lack information upon which to base his or her trust in the practitioner being referred. [n109] The purpose of this Safe Harbor is to eliminate any financial incentive for a referral service to recommend one health care provider over another.

The Safe Harbor protects payments from all types of providers (physicians, chiropractors, dentists, podiatrists, psychiatrists, etc.), or from entities to a referral service, if the referral service does not exclude qualified individuals from participation, assesses and collects payments equally, bases payments only on operating costs, and does not impose requirements on the provision of services, except participants may be required to bill all patients the same rate or to provide services to referred patients at reduced rates. Additionally, the referral service must disclose the following information to a referred patient: (1) the manner in which the service selects the group of participating providers; (2) the relationship between the service and the group of participating providers; (3) whether a participant has paid a fee to the service; (4) the manner in which the service selects a specific provider for a referral; and (5) any restrictions which would exclude an individual or entity from continuing as a provider. [n110] The referral service must also maintain written documentation, signed by the patient or individual making the disclosure, certifying the disclosure was made.

The comments to the final regulation indicate this Safe Harbor is not intended to prevent referral services from serving a discrete group of providers. For example, a hospital may institute a referral service exclusively for members of its medical staff, *i.e.*, only medical staff members are "qualified." A referral service may establish its own criteria for determining who is qualified to participate. [n111] As long as all participants meet the restricted or narrow criteria, the criteria are disclosed to a patient, and the other requirements of the Safe Harbor are met, a private or institutional-based referral service will not violate the Anti-Kickback statute.

The Safe Harbor also provides protection to referral services do not charge a fee to its participating providers. Nevertheless, where a provider indirectly provides services to a "free" referral service, Safe Harbor protection may not be available. For example, a hospital may operate a free referral service for its medical staff. The hospital also may require certain members of the medical staff to provide services to the hospital, such as service on a hospital committee, as a condition of medical staff membership. The comments to the final regulations indicate the service provided to the hospital may constitute illegal remuneration in return for referrals by the hospital's service. [n112]

Analysis

While the OIG expanded the coverage of this Safe Harbor, it also imposed additional disclosure requirements on and created additional record keeping obligations for referral services. Entities providing referral services will be

required to maintain documents certifying that the mandatory disclosures were made. In addition, the referral service must make the required disclosures prior to making a referral or scheduling an appointment for a patient.

Entities providing referral services also must ensure fees charged to providers are based only upon the service's cost of operation and that the fee is charged and assessed equally. The comments to the final regulations provide little guidance as to what is a permissible fee. The Proposed Safe Harbor only required that the fee be "reasonably related" to the referral service's cost of operation. [n113] The final regulation, however, states the fee must be based only on the service's cost of operation. In contrast, the Safe Harbor pertaining to group purchasing organizations provides guidelines on the percentage fee a vendor may charge. The referral service Safe Harbor, however, provides no objective standard for computing an appropriate fee. Therefore, the OIG may challenge referral services whose fees incorporate a large profit margin.

THE SAFE HARBOR FOR WARRANTIES

The Safe Harbor for warranties has undergone substantial revisions from its originally proposed form. Most notably, the final regulation imposes certain reporting requirements on both the manufacturer or supplier of the warranted item and the purchaser of the item. These expanded reporting requirements parallel the reporting requirements found in the discount Safe Harbor.

This Safe Harbor defines a warranty as any agreement that meets the requirements for written warranties under the Magnuson-Moss Warranty Act [n114] or any agreement to replace another manufacturer's or supplier's defective item, which item itself is covered by a warranty that qualifies under the Safe Harbor, on terms equal to the original manufacturer's or supplier's warranty. [n115] The Safe Harbor then imposes certain reporting requirements on both the buyer and the manufacturer or supplier. The buyer must fully and accurately report any price reduction, including free items, obtained under the warranty in the buyer's applicable cost report or claim for payment, and provide, upon request by the Secretary of HHS or a state agency, information provided by the manufacturer or supplier to the buyer as part of the manufacturer's or supplier's reporting requirements. [n116]

The manufacturer or supplier of the warranted item must comply with either one of the following requirements: (1) it must fully and accurately report any price reduction including a free item, which is given under the warranty, on the invoice or statement submitted to the buyer, and inform the buyer of the buyer's disclosure obligations under the Safe Harbor; or (2) if the amount of the price reduction is not known at the time of the sale, it must fully and accurately report the existence of the warranty on the invoice or statement, inform the buyer of the buyer's disclosure obligations under the Safe Harbor, and, when the price reduction is known, provide the buyer with documentation of the calculation of the reduction. [n117]

Finally, the Safe Harbor prohibits a manufacturer or supplier from making payments to any individual or entity for medical, surgical, or hospital expenses incurred by a beneficiary other than for the cost of the warranted item. [n118]

The purpose of this Safe Harbor is to encourage manufacturers and suppliers to offer warranties as an inducement for consumers to purchase their products, without unnecessarily increasing program costs. [n119]

The comments to the final regulations indicate that the OIG is concerned with arrangements known as a "competitive replacement agreement" (CRA). Under a CRA, a manufacturer offers incentives to encourage providers to replace another manufacturer's defective item, *e.g.*, a pacemaker, with one made by the new manufacturer. The OIG's concern is CRAs may provide additional incentives beyond the original manufacturer's warranty, or they may impose additional costs on Medicare or Medicaid programs. [n120] Safe Harbor treatment is available to CRAs only when the CRA honors the original manufacturer's warranty, which itself qualifies under the Safe Harbor, and the CRA provides remuneration on the same terms as the original warranty. [n121] Therefore, if a CRA offers to replace a defective item at a price below the original warranty's replacement price, the CRA is not covered by the Safe Harbor.

In addition, warranties are not protected if the manufacturer or supplier makes any payment to a provider for the

cost of a beneficiary's medical care. For example, some CRAs reimburse physicians directly for a patient's medical expenses, thus, ensuring against the patient's bad debt. The Safe Harbor only protects payments to providers or discounts for the warranted item itself. [n122]

Analysis

The final regulation on warranties is similar in many respects to the final regulation on discounts. The warranty Safe Harbor forces both the buyer and seller to disclose the existence of the warranty. In addition, the buyer must fully report on its applicable cost report any discount or free item provided under the warranty, thereby passing the benefit of the warranty onto the Medicare or Medicaid program. Although this concept was present in the Proposed Safe Harbor on discounts and the Unofficial Safe Harbor on warranties, it was not a part of the Proposed Safe Harbor on warranties.

The comments to the final regulation also emphasize that the Safe Harbor provides protection for "middlemen" or wholesalers which offer extended warranties. The OIG does not view the expansion of a warranty as abusive, as long as the middleman or wholesaler complies with the requirements of the Safe Harbor. [n123]

THE SAFE HARBOR FOR DISCOUNTS

Discounts are a statutory exception to the Anti-Kickback statute. [n124] Both the statutory exception and the final regulation again reflect the principle that transactions will be protected only if the economic benefit received by providers is passed through to the Medicare or Medicaid programs. As a result, the discount Safe Harbor has detailed requirements for both the manner and timing of reporting discounts on a provider's cost report or claim form. The Safe Harbor also creates new reporting requirements for sellers, which were not a part of the Proposed Safe Harbor on discounts. The purpose of this Safe Harbor is to meet Congress' legislative intent of encouraging price competition that benefits the Medicare and Medicaid programs. [n125]

The Safe Harbor defines a "discount" as any reduction in the amount a seller charges a buyer for a good or a service based upon an arm's-length transaction. [n126] A discount may take the form of a rebate, check, credit, or coupon directly redeemable from the seller, but only to the extent that the discount is related to the original good or service purchased. [n127] The following are specifically excluded from the definition of a discount: cash payments; furnishing one good or service without charge or at a reduced charge in exchange for any agreement to buy a different good or service; a reduction in price applicable to one payor but not to Medicare or Medicaid; a reduction in price offered to a beneficiary -- *i.e.*, a routine reduction or waiver of deductible or coinsurance owed by a program beneficiary; warranties; services provided in accordance with a personal or management services contract; or other remuneration in cash or in kind not explicitly described in this Safe Harbor. [n128]

The Safe Harbor imposes certain reporting requirements on both the buyer and seller of a discounted good or service. Buyers are divided into three categories and the reporting requirements vary depending upon the type of buyer. If a buyer is a cost-reporting entity, then the buyer must comply with four standards: (1) discount must be earned based on purchases of the same good or service bought within a single fiscal year of the buyer; (2) buyer must claim the benefit of the discount in the fiscal year in which the discount is earned or the following year; (3) buyer must fully and accurately report the discount in the applicable cost report; and (4) upon request by the OIG Secretary, the buyer must provide certain information about the seller. [n129]

If the buyer is a health maintenance organization (HMO) or a competitive medical plan (CMP) with a Medicare or Medicaid risk contract, the buyer has no reporting requirements other than those required in the contract. [n130] Finally, if the buyer is any other type of entity, then the buyer must comply with three standards: (1) discount must be made at the time of the original sale of the good or service; (2) if the item or service is separately claimed for payment with Medicare or Medicaid, the buyer must fully and accurately report the discount on that item or service; and (3) upon request by the OIG Secretary, the buyer must provide certain information about the seller. [n131]

The seller's reporting requirements also depend upon the category of buyer. If the buyer is an HMO or CMP with a

Medicare or Medicaid risk contract, then the seller has no additional reporting requirements. [n132] For any other type of entity, if the buyer is required to report the discount to Medicare or Medicaid, the seller must fully and accurately report the discount on the invoice or statement submitted to the buyer and inform the buyer of the buyer's reporting requirements. If the amount of the discount is not known at the time of the sale, the seller must fully and accurately report the existence of a discount on the invoice or statement, inform the buyer of the buyer's reporting requirements, and, when the amount of the discount becomes known, provide the buyer with documentation of the calculation of the discount identifying the specific goods to which the discount applies. [n133]

The OIG added the requirement to the final regulation that a discount be negotiated at arm's-length. This requirement gives the OIG the ability to challenge a discount that otherwise meets the objective criteria of the Safe Harbor. For example, the OIG may claim that discounts offered by related entities are not based on an arm's-length transaction. [n134]

Discounts that are offered to certain payors but not to the Medicare or Medicaid program are not covered by the Safe Harbor. For example, a laboratory may offer discounts on services to private payment patients, but not to Medicare patients. Such a discount does not benefit the Medicare program and, therefore, is inconsistent with Congress' intent for discounts. [n135]

An area of particular concern to the OIG is the offering of discounts related to goods other than those purchased. For example, goods may be "bundled," such as surgical packs which include some items that are paid for and other items that are free. The definition of a discount now excludes such practices from Safe Harbor protection. The OIG believes these practices, although cost effective in many instances, create potential for abuse. Therefore, in cases where free goods are offered, the OIG will closely scrutinize the arrangement for possible violation of the Anti-Kickback statute.

Two other areas of potential abuse involve year-end discounts and prompt pay discounts. Year-end discounts are permitted within the Safe Harbor only for providers that file cost reports. Prompt pay discounts, while not explicitly covered by the Safe Harbor, are permissible because the OIG believes they are designed solely to induce timely payment of a bill and not referrals. Nevertheless, the OIG intends to closely scrutinize prompt pay arrangements for abuses. [n136]

Analysis

The Safe Harbor for discounts protects those arrangements where the benefit of the discount is passed on to the Medicare or Medicaid program. The only exception to this policy involves discounts on items that are included in a provider's professional service charge. The OIG admits it would be impractical to require providers to reflect the amount of this discount. [n137] Therefore, charge-based payors are required to report discounts only on items that are separately claimed. For example, a surgeon who performs a cataract operation in his or her office and implants an intraocular lens must report any discount received on the price of the lens.

The new reporting requirements applicable to sellers are designed to ensure that buyers accurately report discounts on their cost reports or claim forms. Initially, the OIG did not intend to hold sellers liable for reporting errors. [n138] Nevertheless, the OIG has reversed its initial decision and placed limited reporting requirements on sellers. These requirements are consistent with the reporting requirements placed on manufacturers and suppliers offering warranties.

Despite the complexity of this Safe Harbor, the final regulation is no more clear than earlier versions. The addition of the "arm's-length" requirement enables the OIG to attack discounts based on subjective criteria. Furthermore, determining what is a discount may be difficult. For example, rebates are permitted, but cash payments are not, and the Safe Harbor fails to distinguish between the two. Finally, discounts and price reductions negotiated by HMOs, PPOs, and other health care plans offer unique situations. Therefore, these types of discounts will be the subject of a new Safe Harbor. [n139]

THE SAFE HARBOR FOR GROUP PURCHASING ORGANIZATIONS

Payments by vendors to group purchasing organizations (GPOs) are one of the statutory exceptions to the Anti-Kickback statute. [n140] The Safe Harbor defines a GPO as any entity authorized to act as a purchasing agent for a group of individuals or entities who are furnishing Medicare or Medicaid services. [n141] The entities served by the GPO, however, cannot be wholly-owned subsidiaries of the GPO or subsidiaries of a parent corporation that wholly owns the GPO, either directly or indirectly. [n142] The OIG views the purchasing agent and the subsidiary or affiliate hospitals as one entity and, therefore, outside the scope of the Safe Harbor. [n143]

Payments by a vendor to a GPO, as part of agreement to provide goods or services, do not violate the Anti-Kickback statute if the following requirements are met: (1) the GPO has a written agreement with each individual or entity providing either: (a) the participating vendors will pay a fee to the GPO of no more than 3 percent of the purchase price of the goods provided by the vendor or (b) if the fee paid to the GPO is not fixed at 3 percent or less, the agreement specifies the amount (or if not known, the maximum) the GPO will be paid by each vendor, where such amount may be a fixed sum or fixed percentage of the value of purchases; and (2) the GPO discloses to each entity that is a health care provider, and to the Secretary of HHS upon request, the amount received from each vendor with respect to purchases made by or on behalf of the entity. [n144]

The definition of a GPO reflects the OIG's concern with entities which serve as a purchasing agent for other entities within the same corporate system. For example, the parent corporation of a multi-hospital system cannot qualify as a GPO with respect to its subsidiary or affiliate hospitals.

In addition, the Safe Harbor does not apply to transactions in which the vendor, and not the health care provider, furnishes services directly and bills Medicare or Medicaid. For example, a laboratory or a durable medical equipment **company** may provide services to several **nursing homes'** patients. The payment of a fee by the laboratory or **company** to a GPO acting on behalf of the **nursing homes** is not within the scope of the Safe Harbor. [n145]

Analysis

Congress' intent in enacting the statutory exception for GPOs was to ensure that excessive fees are not paid by vendors to GPOs. [n146] Congress' concern was that fees exceeding 3 percent might be excessive. Therefore, the final regulations adopt the 3 percent test as a safe harbor within a safe harbor. Fees exceeding 3 percent are permissible, but may be subject to closer scrutiny.

In many cases, both this Safe Harbor and the discount Safe Harbor may be implicated in a transaction. For example, a vendor may pay a fee to a GPO and also offer a discount to an entity represented by the GPO. In this case, both the GPO Safe Harbor and the discount Safe Harbor are applicable. Therefore, the vendor, the GPO, and the purchasing entity must ensure that the requirements of both Safe Harbors are satisfied. Simply complying with the GPO Safe Harbor will not protect the discount offered to the purchasing entity.

THE SAFE HARBOR FOR WAIVER OF DEDUCTIBLE AND COPAYMENT AMOUNTS

This Safe Harbor was added as a result of comments specifically solicited by the OIG. The Proposed Safe Harbors, therefore, did not contain a provision or comments concerning waiver of deductible and copayment amounts. As discussed below, the resulting Safe Harbor is a reflection of both current practice by hospitals and the law pertaining to Medicare's separate reimbursement under PPS of hospitals' bad debt.

The Safe Harbor only protects the waiver or reduction of deductible and copayment amounts for inpatient hospital services and for services provided under the Public Health Services Act in a federally qualified health care center. The waiver or reduction of deductible and copayment amounts for inpatient hospital services is protected only if the hospital does not later claim the waived amount as reimbursable bad debt or otherwise shift the burden onto Medicare, a state program, other payors, or individuals; the hospital offers to waive the deductible or copayment without regard to reason

for admission, length of stay, or the applicable diagnostic related group (DRG); and the hospital's offer to waive the deductible or copayment is not made as part of a price reduction agreement between the hospital and a third-party payor. [n147]

The protection afforded federally qualified health care centers is simply a recognition of a statutory exception to the Anti-Kickback statute. OBRA 1990 [n148] amended the Anti-Kickback statute to provide for this fourth statutory exception which exempts the waiver of Medicare Part B copayments.

The purpose of this Safe Harbor is to permit hospitals to waive or reduce inpatient deductible or copayment amounts where the cost of such waiver or reduction is not borne by Medicare or any other payor.

The OIG believes that the unique nature of inpatient hospital services merits safe harbor protection. The comments to the final regulations state that, because a beneficiary cannot admit himself or herself as an inpatient, an inpatient overnight stay is undesirable, PPS limits payment to hospitals, and the PRO review process monitors appropriateness of admission and potential over-utilization, the waiver or reduction of deductibles and copayments does not induce further purchases of services or lead to increased costs to the Medicare program. [n149] On the other hand, the amount waived by a cost-based or charge-based reimbursed provider is more likely to be passed on to Medicare as a component of the provider's cost or charge.

This Safe Harbor prevents a hospital's waiver of deductible or copayment amounts for select DRGs. For example, a hospital cannot waive deductible and copayment amounts solely for DRGs on which the hospital's costs are lower than the DRG reimbursement. Decisions to waive amounts should be consistent.

The comments again emphasize that this Safe Harbor applies only to the waiver or reduction of deductible or copayment amounts, and not to other free gifts or services. For example, the provision of free blood tests, free meals, or free presurgical overnight stays is not within the scope of this or the discount Safe Harbor. [n150]

Analysis

Many commenters on the Proposed Safe Harbors attempted to persuade the OIG to provide Safe Harbor treatment for various activities that do not increase Medicare's cost or result in over-utilization as a result of the activity. In refusing to do so, the OIG repeatedly stated that increased costs to Medicare and over-utilization should not be used as the basis for determining whether an activity violates the Anti-Kickback statute. [n151] Nevertheless, the OIG seemingly relies on these two factors as the sole basis for providing Safe Harbor treatment for waiver of inpatient deductibles and copayments.

It also is important to note that the discount Safe Harbor specifically excludes from the definition of a "discount" a "reduction in price offered to a beneficiary [] such as a routine reduction or waiver of any coinsurance or deductible amount." [n152] Therefore, for example, a physician cannot argue a waiver or reduction of Medicare Part B deductible or copayment amounts qualifies as a discount.

Finally, the Safe Harbor applies only if a hospital does not shift the burden for the waiver onto any other payor. This suggests that hospitals cannot adjust charges to third party payors to reflect the cost of the waived amounts.

REFERENCE: [n2.] 56 Fed. Reg. 35,952 (1991) (citing Social Security Act § 1128B(b), 42 U.S.C. § 1320a-7b(b) (1988) ["the Anti-Kickback statute"].

[n1.] DEPARTMENT OF HEALTH AND HUMAN SERVICES, Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952 (1991). The final Safe Harbor regulations are to be codified at 42 C.F.R. § 1001.952 (1991) [hereinafter the " Safe Harbors," "final regulations" or "Safe Harbor regulations"]. The Anti-Kickback statute can be found at 42 U.S.C. §§ 1320a-7a, 7b (1988).

[n3.] Id. at 35,954.

[n4.] Id. at 35,955.

[n5.] Id.

[n6.] 42 U.S.C. §§ 1320a-7a, 7b (1988).

[n7.] Id.

[n8.] 42 U.S.C. § 1320a-7b(b) (1988).

[n9.] Id. There are four statutorily-recognized exceptions to the Anti-Kickback prohibitions: (1) a properly disclosed discount or other reduction in price obtained by a provider of services; (2) any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered services; (3) certain group purchasing activities; and (4) waiver of Part B coinsurance by federally qualified health centers. 42 U.S.C. §§ 1320a-7b(b)(3)(A) - (D) (1988).

[n10.] 54 Fed. Reg. 3,091 (1989).

[n11.] 42 U.S.C. § 1320a-7(b)(7) (1988) (Medicare and Medicaid Patient Protection Act of 1987).

[n12.] Id.

[n13.] 54 Fed. Reg. 3,088-93 (1989) [hereinafter Proposed Safe Harbors, proposed regulations, or Proposed Safe Harbor regulations].

[n14.] 53 Fed. Reg. 52,448 (1988).

[n15.] 56 Fed. Reg. 35,952 (1991).

[n16.] In doing so, the comments note that the regulation "does not expand the scope of activities that the statute prohibits. The statute itself describes the scope of illegal activities. The legality of a particular business arrangement must be determined by comparing the particular facts to the proscriptions of the statute." Id. at 35,954.

[n17.] Id.

[n18.] Id. at 35,947.

[n19.] Id.

[n20.] Id. at 35,954.

[n21.] Id.

[n22.] Id.

[n23.] Id. One example of a less egregious violation might be where there was a good faith effort to comply with the terms of a Safe Harbor, but compliance was not achieved for reasons beyond the party's control or where the arrangement is innocuous.

[n24.] Id. (citing *United States v. Bay State Ambulance & Hosp. Rental Serv.*, 874 F.2d 20 (1st Cir. 1989)).

[n25.] Id. at 35,959.

[n26.] Id. The only Fraud Alert to date on Anti-Kickback issues was released on April 24, 1989, and dealt with "Joint Venture Arrangements."

[n27.] See infra note 103.

[n28.] Id. at 35,960.

[n29.] Id.

[n30.] 56 Fed. Reg. 35,985 (1991) (to be codified at 42 C.F.R. § 1001.952(c) (1991)). The Safe Harbor lists two criteria: (1) the period of time between the execution of the first purchase agreement pertaining to the sale and the completion of the sale is not more than one year; and (2) the practitioner who is selling his or her practice will no longer be in a professional position to make Medicare/Medicaid referrals to, or otherwise generate such business for, the purchasing practitioner after one year from the date of that first agreement.

[n31.] 54 Fed. Reg. 3,091 (1989).

[n32.] Id.

[n33.] 56 Fed. Reg. 35,975 (1991). The comments, however, note that no protection is afforded by any Safe Harbor in the situation where a practitioner purchases another practitioner's practice, makes payments (relating to the purchase) to that practitioner which continue for some period of time, and retains the (selling) practitioner on his or her staff as an employee.

[n34.] Id.

[n35.] Id.

[n36.] Prior drafts of a "physician recruitment" Safe Harbor have made no specific mention of this practice.

[n37.] J. Burke, Assistant Commissioner (Employee Plans and Exempt Organizations), Internal Revenue Service, Statements Before the House Committee on Ways and Means (July 10, 1991).

[n38.] 56 Fed. Reg. 35,985 (1991) (to be codified at 42 C.F.R. § 1001.952(a)(2) (1991)). The final regulations define the term "investment interest" to include both debt and equity investments, and the term "investor" to include both individuals and entities who either directly or indirectly hold an investment interest in an entity.

[n39.] 42 C.F.R. § 1001.952(a)(2) (1991).

[n40.] For example, a physician is deemed to hold an investment interest that is held by his or her group practice, a trust or a holding **company**. 56 Fed. Reg. 35,964 (1991).

[n41.] Id.

[n42.] Id. Thus, the focus is on the status of the investor and its ability to influence the referral stream or level of its business activity for the entity. This Safe Harbor has been revised from its originally proposed form to provide "greater clarity" consistent with OIG's original intent.

[n43.] 56 Fed. Reg. 35,984 (1991) (to be codified at 42 C.F.R. § 1001.952(a)(1) (1991)).

[n44.] This requirement is not applicable to investments in debt securities. Id. at 35,965.

[n45.] It is expected that the public will have a "genuine opportunity" to invest in these entities. Id.

[n46.] However, Safe Harbor protection is available where the investor borrows from other sources, such as a broker or a bank. Id. at 35,966.

[n47.] Id. at 35,984 (to be codified at 42 C.F.R. § 1001.952(a)(1)(V) (1991)).

[n48.] Id. at 35,965.

[n49.] Id. at 35,566.

[n50.] Id.

[n51.] Id. This abusive situation may arise where the entity or corporate affiliate merely guarantees the loan.

[n52.] Id.

[n53.] Id. at 35,965.

[n54.] Id.

[n55.] An unofficial version of the final regulations was widely circulated in the summer of 1990 [hereinafter the Unofficial Safe Harbors or the Unofficial Safe Harbor regulations].

[n56.] 56 Fed. Reg. 35,966 (1991).

[n57.] Id. at 35,967.

[n58.] Id.

[n59.] Id.

[n60.] Id.

[n61.] Id. The example is provided of a group of individuals who are passive investors in entity "A," which in turn is the active investor in entity "B." In order for "B" to qualify for Safe Harbor treatment, "A" must meet all the requirements of an active investor in "B," and the individual investors of "A" must meet all the requirements of passive investors in "B."

[n62.] Id.

[n63.] Id. at 35,968. It should be noted that the first standard, the "60-40 Investment Interest" test, reflects the OIG's switch from a "process" measure to an "outcome" measure. The original proposal, which would have insisted on an equal number of referring and non-referring investors being given an opportunity to invest, was discarded as unworkable. By limiting the number of investors who make referrals, the regulations seek to assure that the profits from these entities are distributed to a wider group than referring physician investors. Id. at 35,967.

[n64.] Id. at 35,968. The second standard, dealing with discriminatory marketing strategies, is not imposed upon active investors because the OIG recognizes that it is precisely because of a physician's particular expertise that he or she may be selected as a general partner and offered different investment terms than those offered to passive investors. This logic is also applied with respect to the fourth and fifth standards. Id. at 35,969.

[n65.] Id. at 35,968. The third standard demonstrates OIG's unwillingness to protect all investments where any investor, including a general partner, can obtain more shares because he or she can be expected to generate more business for the entity.

[n66.] Id. In this way, the regulations seek to assure that revenues of these joint ventures come from a wider group than just referrals from investors. As with the "60-40 Investment Interest" standard, a joint venture may apply the internal accounting principles of its choice, as long they are not used to manipulate data to obscure noncompliance. Id.

[n67.] This standard is designed to make certain that investors' funds are genuinely at risk, that physicians and other investors in fact provide new needed capital, and that the joint venture is not a sham which facilitates the distribution of payments for referrals. Id. at 35,960.

[n68.] Distributions from the venture to investors may reflect the fair market value of pre-operational services rendered by those investors, the so-called "sweat equity." Id. A distinction is drawn with payments to active investors for operational services rendered; Safe Harbor protection for such payments is available only from those which are available for "personal services and management contracts." Id. at 35,970-71, 84 (to be codified at 42 C.F.R. § 1001.952(a)(2) (1991)). The amount of capital investment includes the fair market value of any pre-operational services rendered.

[n69.] Id.

[n70.] Id. at 35,969.

[n71.] The 1988 Report to Congress discloses the widespread ownership of joint ventures by physicians, and the additional services received by patients of those physicians as compared to all Medicare patients generally. Id. at 35,967.

[n72.] Id.

[n73.] Id. at 35,971.

[n74.] Id. at 35,985 (to be codified at 42 C.F.R. § 1001.952(b) (1991)).

[n75.] Id. Fair market value cannot be adjusted to reflect the additional value that "one party (either the prospective lessee or lessor) would attribute to the property as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under Medicare or a state health care program."

[n76.] Id. at 35,972-74. These examples include:

A group of physicians own a medical arts building and rents space to a diagnostic laboratory. The rent is substantially above the laboratory's cost of renting the same size of space at a nearby location.

A physician, a diagnostic services **company**, or a clinical laboratory enters into a sham lease with a physician for office space not actually used as a means of paying the lessor physician kickbacks for patient referrals.

A physician rents space to a clinical laboratory, ostensibly to provide space for the furnishing of laboratory services, but the space is a closet or anteroom not usable for furnishing laboratory services.

A health care provider rents office space to another individual with whom the provider has an ongoing referral relationship. The parties alter the terms of the rental arrangement frequently in response to the volume or value of referrals between the parties.

An optometrist pays ad hoc rent to an ophthalmologist for time spent in the ophthalmologist's office examining only patients referred by the ophthalmologist.

[n77.] Id. at 35,973-74.

[n78.] Id. at 35,972.

[n79.] Id.

[n80.] Id. at 35,973. Shopping-center style leases are a variation on the percentage lease arrangements that the OIG has found so prone to abuse.

[n81.] Id. at 35,985 (to be codified at 42 C.F.R. § 1001.952(c) (1991)).

[n82.] Id.

[n83.] Id. at 35,973-74. Such abusive arrangements include: (1) leases requiring payment "per use" or "per procedure," or in which the amount of compensation fluctuates with the use of the equipment or the frequency of services performed; (2) percentage equipment lease or use arrangements; (3) part-time and "as-needed" use arrangements; and (4) short-term lease arrangements and arrangements amended frequently.

[n84.] Id. at 35,973. Much of this concern may be unwarranted, as most MRI scans are probably ordered by the physician caring for the patient rather than by the radiologist interpreting scan results.

[n85.] See *infra* note 87 and accompanying text.

[n86.] 56 Fed. Reg. 35,974 (1991).

[n87.] Id. at 35,985 (to be codified at 42 C.F.R. § 1001.952(d) (1991)). For purposes of the personal services and management contract Safe Harbor, an agent of a principal is "any person, other than a bona fide employee of the principal, who has an agreement to perform services for, or on behalf of, the principal."

[n88.] Id. at 35,973.

[n89.] Id. at 35,981.

[n90.] Id. at 35,973. The OIG's concern is that such arrangements may be renegotiated in response to changing referral patterns or volume of referral business.

[n91.] Id.

[n92.] Id. at 35,974.

[n93.] Id. at 35,973.

[n94.] Id. at 35,973-74.

[n95.] Id. at 35,974.

[n96.] Rev. Proc. 82-15, 1982-1 C.B. 460.

[n97.] 56 Fed. Reg. 35,974 (1991).

[n98.] Id. at 35,985 (to be codified at 42 C.F.R. § 1001.952(d)(6) (1991)).

[n99.] 42 U.S.C. § 1320a-7b(b)(3)(B) (1988). The employment exception to the Anti-Kickback statute provides that the term "remuneration" does not include "any amount paid by an employer to an employee (who has bona fide employment relationship with such employer) for employment in the provision of covered items or services."

[n100.] 26 U.S.C. § 3121(d)(2) (1988).

[n101.] Id.

[n102.] 26 C.F.R. § 31.3121(d)-1(c)(2) (1991).

[n103.] Priv. Ltr. Rul. 90-18-054 (Feb. 6, 1990). In discussing the degree of direction and control that is required to find that a professional is an employee rather than an independent contractor, the IRS stated:

In determining what constitutes the requisite degree of direction and control, it must be borne in mind that the methods by which professional men work are prescribed by the techniques and standards of their profession, and the high degree of skill required by a professional sometimes makes it difficult or impossible for the employer to supervise his services. Therefore, the control of an employer over the manner in which professional employees shall conduct duties of their positions must necessarily be more general than the control over nonprofessional employees.

Id. (citing *James v. Commissioner*, 25 T.C. 1296 (1956)). Of course, private letter rulings have no precedential value, but they do generally reflect the thinking of the IRS at the time they are issued.

[n104.] 26 C.F.R. § 31.3121(d)-1(a)(3) (1991).

[n105.] 45 Fed. Reg. 35,981 (1991).

[n106.] Id.

[n107.] Id. at 35,981-82.

[n108.] Id. at 35,985 (to be codified at 42 C.F.R. § 1001.952(f) (1991)). The term "referral service" is not defined in the Safe Harbors.

[n109.] Id. at 35,960.

[n110.] Id. at 35,986 (to be codified at 42 C.F.R. § 1001.952(f) (1991)).

[n111.] Id. at 35,975.

[n112.] Id. at 35,976.

[n113.] 54 Fed. Reg. 35,986 (1991) (to be codified at 42 C.F.R. § 1001.952(g) (1991)).

[n114.] See 15 U.S.C. § 2301(6) (1988).

[n115.] 54 Fed. Reg. 35,986 (1991) (to be codified at 42 C.F.R. § 1001.952(g) (1991)).

[n116.] Id. (to be codified at 42 C.F.R. § 1001.952(g)(1) & (2) (1991)).

[n117.] Id. (to be codified at 42 C.F.R. § 1001.952(g)(3)(i) & (ii) (1991)).

[n118.] Id. (to be codified at 42 C.F.R. § 1001.952(g)(4) (1991)).

[n119.] 54 Fed. Reg. 3,092 (1989).

[n120.] 45 Fed. Reg. 35,976-7 (1991).

[n121.] Id.

[n122.] Id. at 35,977.

[n123.] Id.

[n124.] 42 U.S.C.A. § 1320a-7b(b)(3)(A) (West Supp. 1991).

[n125.] 54 Fed. Reg. 3,092 (1989).

[n126.] 45 Fed. Reg. 35,987 (to be codified at 42 C.F.R. § 1001.952(h)(3) (1991)).

[n127.] Id.

[n128.] Id.

[n129.] Id. at 35,986 (to be codified at 42 C.F.R. § 1001.952(h)(1)(i) (1991)).

[n130.] Id. (to be codified at 42 C.F.R. § 1001.952(h)(1)(ii) (1991)).

[n131.] Id.

[n132.] Id. (to be codified at 42 C.F.R. § 1001.952(h)(2)(i) (1991)).

[n133.] Id. (to be codified at 42 C.F.R. § 1001.952(h)(2)(ii) (1991)).

[n134.] See 45 Fed. Reg. 35,977-78 (1991).

[n135.] Id. at 35,977. The OIG has clarified the discount Safe Harbor to exclude service contracts from the definition of discounts. Therefore, service contracts should be analyzed under the Safe Harbor pertaining to personal service agreements. The OIG also has clarified the definition of a discount to exclude warranties. Therefore, warranties must be analyzed under the warranty Safe Harbor.

[n136.] Id. at 35,979.

[n137.] Id. at 35,980-81.

[n138.] Id. at 35,980.

[n139.] Id. at 35,977.

[n140.] See 42 U.S.C.A. § 1320a-7b(b)(3)(C) (West Supp. 1991).

[n141.] 56 Fed. Reg. 35,987 (to be codified at 42 C.F.R. § 1001.952(j) (1991)).

[n142.] Id.

[n143.] Id. at 35,982.

[n144.] Id. at 35,987 (to be codified at 42 C.F.R. §§ 1001.952(j)(1) & (2) (1991)).

[n145.] See id.

[n146.] Id. at 35,982 (citing H. Conf. Rep. 1012, 99th Cong., 2d Sess. 310-11 (1986)).

[n147.] Id. at 35,987 (to be codified at 42 C.F.R. §§ 1001.952(k)(1)(i)-(iii) (1991)).

[n148.] Omnibus Budget Reconciliation Act of 1990 § 4161(a)(4), Pub. L. 101-508, 104 Stat. 1388-94, codified at 42 U.S.C. § 1320a-7b(b)(3)(D) (1988).

[n149.] 56 Fed. Reg. 35,962 (1991).

[n150.] Id. at 35,963. 151. See id. at 35,954-55.

[n152.] Id. at 35,987 (to be codified at 42 C.F.R. § 1001.952(h)(3)(iv) (1991)).

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LENGTH: 34519 words**TITLE:** Owning a Piece of the Doc: State Law Restraints on Lay Ownership of Healthcare Enterprises**AUTHOR:** Andrew Fichter *

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TEXT:

ABSTRACT: This Article provides an analytical framework for assessing state regulation regarding lay ownership of healthcare entities. The author suggests there are three categories of state regulation restraining lay ownership, each focused on a particular stakeholder in healthcare transactions: provider, patient, and payor. These regulatory paradigms are analyzed through a discussion of three state approaches (California, Illinois, and Florida), each exemplifying a particular stakeholder schema. The Article then highlights shortcomings of the three schemas, pointing out formal frustrations, application inequities, and doctrinal flaws. The author concludes that any successful state regulation of lay ownership in healthcare should incorporate aspects of all approaches in pursuit of accommodating the needs of all three stakeholders.

Our federalist system has produced a variety of state laws, rules, and regulations concerning ownership or control of entities that provide healthcare by persons who are not themselves licensed to provide such services. Some states prohibit lay-owned corporations from hiring physicians to provide medical services; some prohibit professionals from sharing their fees with lay persons; and some use variations and combinations of such strategies. Regulation of the ownership of physician practices and other healthcare entities by nonprofessionals is a subject of enduring concern, and particularly relevant in an era searching for new models for delivering quality healthcare on a cost-effective basis. If the search seems to have stalled since the spectacular rise and fall of the largest publicly-held practice management **companies** in 1999, the regulatory environment is at least partly responsible. Rules that purport to preserve professional integrity by restricting lay ownership also have the effect of restricting access to the capital and operational resources lay investors can provide. To a lay-owned entity developing a business plan subject to these laws on a multi-jurisdictional scale, the legal impediments are at best confusing. In many respects, such laws are as ineffectual as they are confusing, and at worst they unnecessarily impede progress towards solutions to the problems embedded in the national quest for access to high quality healthcare at a reasonable cost. Despite their failings, and despite repeated pronouncements of their demise, these laws persist, and courts continue to insist that they reflect public policy. This Article undertakes to explain why state restraints on lay ownership of healthcare enterprises endure, why they fail, and how they might better be conceived.

This Article advances an analytical framework for assessing regulatory restraints on lay ownership of healthcare provider entities. There are essentially three categories of state regulation of lay ownership of healthcare entities, focused respectively on the interests of the three parties typically involved in health-care transactions: the provider, the

patient, and the payor. This will become evident through analysis of the regulatory schema of three representative jurisdictions, California, Illinois, and Florida. Each regulatory program reflects a crucial policy need (hence the resilience of these rules), but each is, in and of itself, flawed. A regulatory program constructed from the singular perspective of the provider tends to overvalue professional autonomy and undervalue the needs of the payor, such as cost control and rational allocation of goods and services. Similarly, a regulatory program focused on the payor's need to constrain utilization, as through rules aimed at fee-splitting, kickbacks, and physician self-referrals, may undervalue provider autonomy and quality assurance; and a program aimed at promoting the patient's need for quality assurance, as through licensure, may undervalue both issues of resource allocation and those of provider autonomy. Taken alone, each such regulatory program fails because it does not harmonize with the reality of healthcare, which of necessity involves all three perspectives.

Put another way, any successful program seeking to regulate lay involvement with healthcare should accommodate the needs of all three participants, the provider, the patient, and the payor. n1 In a conceptually complete program, a healthcare provider should be required to take into account not only the need for quality assurance, but also the cost of healthcare, and the need to allocate healthcare goods and services rationally. The duty of the physician should be expressed not only in terms of the best interests of the patient, but also in terms of cost. The provider should be able to, indeed should be required to, consider allocation and access issues while evaluating her patient's need for quality care. The physician ultimately stands in a fiduciary relationship to the payor as well as the patient. For its part, the payor has a duty to consider the patient's needs, even while negotiating with the provider of healthcare services for coverage and cost. The patient, moreover, should accept a degree of responsibility for cost, particularly when circumstances (pure indemnity insurance, for example) put him in a position to conspire with the provider for coverage and access at the expense of the payor. Similarly, a regulator standing in the shoes of the patient to assure quality should be required to consider both the needs of the patient and the provider. Healthcare regulation should not create monopolies through licensure without considering as well the scope of services thereby made available to the public, and the patient's rights to healthcare self-determination. Nor should regulators insist on quality assurance at the expense of professional autonomy, the engine that drives innovation in healthcare. As they currently stand, state laws regulating lay participation in healthcare evidence the dangers of excessive protectionism. Regulators have an obligation to give healthcare professionals sufficient scope to evolve their profession. To the extent that all regulatory restrictions on lay ownership claim to serve public policy, these claims should be reviewed in the light of what is evident from the experiments that have historically been conducted throughout our federalist system, namely that any such policy--indeed, perhaps any healthcare policy--must accommodate the perspectives of all the participants in healthcare transactions: the provider, the patient, and the payor.

n1 The payor is not always a third-party, of course; but even when the patient is the payor, the patient is acting in a separate capacity, which for purposes of the paradigm under consideration in this Article, may be envisioned as a third-party, such as an insurer.

I. Public Policy in the Managed Care Era

The enactment of health maintenance organization (HMO)-enabling legislation in the 1970s n2 should have ushered many other successful models for lay ownership of healthcare delivery enterprises into the market. Before the passage of this legislation, before nearly every state followed suit with its own HMO legislation, n3 and before the advent of profit, as well as nonprofit, multi-conglomerate hospital systems employing house physicians, n4 it was relatively easy to articulate principled and reasoned objections to the employment of physicians by corporations. n5 Commercialism was said to be essentially incompatible with professionalism. The profit motives of lay-owned organizations could corrupt the judgment of a healthcare provider and impair professional autonomy, and the loyalty a physician employee would owe to a commercial employer would conflict with her duty to her patient. n6 Arrangements pursuant to which lay-owned commercial entities sold medical services to the public, or by which industry groups contracted with physicians for discount, and, it was argued, low-quality, medical services for employees had long been discredited by professional societies such as the American Medical Association ("AMA"). n7 The protests of medical

professionals against lay control found expression in a variety of state laws, regulations, and court decisions limiting the ability of lay-owned corporations to employ or control healthcare professionals or share in revenues from healthcare services. Such arrangements were generally and collectively known as the "corporate practice of medicine."

n2 Federal legislation enabling the establishment of HMOs was passed in 1973. Health Maintenance Organization Act of 1973, Pub. L. No. 93-222, 87 Stat. 914 (codified as amended at 42 U.S.C. §§ 300e to e-17 (2005)).

n3 Mark S. Joffe, *Current Developments in State and Federal Regulation of Managed Care Organizations*, in THE INSIDER'S GUIDE TO MANAGED CARE: A LEGAL AND OPERATIONAL ROADMAP 37, 42-52 (Nat'l Health Lawyer's Ass'n ed., 1990).

n4 U.S. CENSUS BUREAU, STATISTICAL ABSTRACT OF THE UNITED STATES: 2004-2005, at 107 tbl.149 (2005), available at www.census.gov/prod/2004pubs/04statab/health.pdf (last visited on Jan. 3, 2006) (reporting in excess of 45,000 full-time non-federal hospital staff physicians in 2002).

n5 See, e.g., Jeffrey F. Chase-Lubitz, *The Corporate Practice of Medicine Doctrine: An Anachronism in the Modern Health Care Industry*, 40 VAND. L. REV. 445 (1987). "Commentators advocating a prohibition generally advance three considerations: (1) lay control over professional judgment; (2) commercial exploitation of the medical practice; and (3) division of the physician's loyalty between patient and employer." *Id.* at 467 (citing Alanson W. Willcox, *Hospitals and the Corporate Practice of Medicine*, 45 CORNELL L.Q. 432, 442-443 (1960)).

n6 NAT'L HEALTH LAWYER'S ASS'N/AM. ACADEMY OF HEALTHCARE ATTORNEYS, INC. (NHLA/AAHA), PATIENT CARE AND PROFESSIONAL RESPONSIBILITY: IMPACT OF THE CORPORATE PRACTICE OF MEDICINE DOCTRINE AND RELATED LAWS AND REGULATIONS 5 (1997) [hereinafter NHLA/AAHA].

n7 See PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 200-06 (1982); See also NHLA/AAHA, *supra* note 6, at 4 (noting that ethical principles established by the AMA in 1912 condemned corporate or industrial control of physicians as "unprofessional").

But of course everything has changed since then. n8 State and federal statutes authorizing the formation of HMOs have made it evident that public policy is not offended by every manifestation of the corporate practice of medicine. n9 Federal enabling legislation is explicit: federally-qualified HMOs are exempt from state laws prohibiting the corporate practice of medicine or similar arrangements. n10 The Model Health Maintenance Organization Act propounded by the National Association of Insurance Commissioners provides for explicit preemption of state corporate practice laws. n11 State HMO acts generally follow suit as required, which is general the case n12 because one of the organizational models contemplated for HMOs involves the direct employment of staff physicians, in contravention of the corporate practice of medicine doctrine. n13 Scholarly commentary has generally urged reconsideration of the doctrine due to its anachronism, its internal vagaries and inconsistencies, and its history of erratic enforcement. n14 Indeed, at one point in the not-too-distant past, Congress contemplated legislation that would have globally preempted state corporate practice bars, whether or not in a managed care context. n15

n8 See Arnold J. Rosoff, *The Business of Medicine: Problems with the Corporate Practice Doctrine*, 17 CUMB. L. REV. 485, 500-01 (1987) ("A 'free market' approach and entrepreneurship in health care delivery are not merely tolerated these days; they are openly encouraged by governmental and private actions at many different levels.").

n9 See Judith Parker, *Corporate Practice of Medicine: Last Stand or Final Downfall?*, 29 J. HEALTH & HOSP. L. 160, 161 (1996) (observing that "the prohibition against the corporate practice of medicine is not absolute . . .", as evidenced by selective laws permitting the employment of physicians by HMOs, professional medical corporations, non-profit corporations, fraternal organizations, and hospitals).

n10 42 U.S.C. § 300e-10(a) (2005).

n11 Section 26(c) of the National Association of Insurance Commissioners (NAIC) Health Maintenance Organization Model Act of 1990 (Act) provides as follows: "Any health maintenance organization authorized under this Act shall not be deemed to be practicing medicine and shall be exempt from the provision of [citation] relating to the practice of medicine." NAIC, HEALTH MAINTENANCE ORGANIZATION MODEL ACT § 26(c) (1991), *reprinted in* HEALTH CARE CORPORATE LAW: MANAGED CARE app. A at 1-172 (Mark A. Hall & William S. Brewbaker eds., vol. ed. 1996). In addition, Section 3(a) of the Act provides: "Notwithstanding any law of this state to the contrary, any person may apply to the commissioner [director, superintendent] for a certificate of authority to establish and operate a health maintenance organization in compliance with this Act." *Id.* at 1-133. The Act defines a "health maintenance organization" as "any person that undertakes to provide or arrange for the delivery of basic health care services to enrollees on a prepaid basis, except for enrollee responsibility for copayments and/or deductibles," and further defines a "person" as "any natural or artificial person including but not limited to individuals, partnerships, associations, trusts or corporations." *Id.* at 1-131 to -132.

n12 For a list of state HMO acts creating exceptions to corporate practice bars, see Parker, *supra* note 8, at 170 n.47. *See, e.g.*, 40 PA. CONS. STAT. § 1554(a) (1999) ("Any law to the contrary notwithstanding, any corporation may establish, maintain and operate a health maintenance organization upon receipt of a certificate of authority to do so in accordance with this act."). *But cf.* Mo. REV. STAT. § 538.205(4) (2005) (defining "health care provider" as including HMOs for the purpose of tort actions based on improper health care); 1997 Mo. Legis. Serv. 302 (West) (revising prior language stating that HMOs "should not be deemed to be practicing medicine" in order to clarify that they are subject to tort actions as healthcare providers).

n13 BARRY R. FURROW ET AL., HEALTH LAW § 9-11, at 509 (2d ed. 2000) The principal models are (i) staff model HMOs, which directly employ physicians to provide healthcare services; (ii) group model HMOs, which contract with an independent multi-specialty physician group; (iii) network model HMOs, which contract with multiple groups on a non-exclusive basis; and (iv) individual practice association ("IPA") model HMOs, which contract with an IPA that in turn contracts with individual healthcare providers. *Id.*

n14 *See* Michael A. Dowell, *The Corporate Practice of Medicine Doctrine Must Go*, HEALTHSPAN, NOV. 1994, at 7, 8; Chase-Lubitz, *supra* note 5, at 475-87. *See also* Parker, *supra* note 9, at 168 (noting that while the public policy reasons behind the doctrine remain important, "[t]he doctrine's necessity may have passed. The doctrine is riddled with exceptions; many states ignore the doctrine and some outrightly have refused to enforce the doctrine. Changes in the health care industry have also contributed to the demise of the corporate practice prohibition, including the evolution of HMOs and the continuing rise in health care costs.").

n15 Health Care Fraud Prevention and Paperwork Reduction Act of 1995, H.R. 1912, 104th Cong. § 141 (1995) ("No provision of State or local law shall apply that prohibits a corporation from practicing medicine.").

HMO legislation is only one of the signs that state restrictions on corporate practice and lay ownership should be fading. By 1971, all states had enacted statutes allowing physicians to practice through professional corporations, n16 although such laws generally restrict share ownership to licensed professionals. Courts in jurisdictions with corporate practice bars have long taken judicial notice of the fact that hospitals and their affiliates employ physicians, n17 and enforcement of restrictive doctrines in some of these jurisdictions is notoriously lax. n18 In some jurisdictions, courts have gone out of their way to infer exceptions for specific practices, such as employment of physicians by teaching hospitals, private hospitals, federal military hospitals, and employers engaging "company doctors" for employees. n19

n16 *See* Robert W. Hamilton, *Professional Partnerships in the United States*, 26 J. CORP. L. 1045, 1048 (2001); Richard O. Jacobs & Elizabeth Goodman, *Splitting Fees or Splitting Hairs? Fee Splitting and Health Care--The Florida Experience*, 8 ANNALS HEALTH L. 239, 246 (1999); Patricia F. Jacobson, *Prohibition Against Corporate Practice of Medicine: Dinosaur or Dynamic Doctrine?*, in 1993 HEALTH LAW HANDBOOK 67, 67 (Alice G. Gosfield ed., 1993).

n17 *See, e.g.*, *Bing v. Thunig*, 143 N.E.2d 3, 8 (N.Y. 1957) (Hospitals "regularly employ on a salary basis a large staff of physicians, nurses and interns, as well as administrative and manual workers, and they charge patients for medical care and treatment, collecting for such services, if necessary, by legal action.").

n18 MARK A. HALL & JUSTIN G. VAUGHN, *The Corporate Practice of Medicine*, in HEALTH CARE CORPORATE LAW: FORMATION AND REGULATION § 3.4, at 3-13 to -14 (Mark A. Hall ed. 1999).

n19 *Id.* at 3-14.

Under the circumstances, doctrinal restrictions on commercialism in medical practice should by now have become an historical footnote. n20 And with the lowered legal and policy bars to lay equity participation in healthcare enterprises that should have resulted, there should now be a greater variety of arrangements than currently exist, under which healthcare providers could find employment, share enterprise ownership, access debt and equity financing, shift management responsibilities, create personal mobility and practice exit plans, and so forth. But the corporate practice doctrine and related impediments to lay ownership have proven remarkably resilient. As evidence, consider the following catalogue of concerns addressed in the Management Discussion and Analysis sections of Annual Reports filed by **companies** providing practice management services to physicians throughout the United States: n21

- . State corporate practice laws, variously prohibiting the acquisition and ownership of healthcare provider entities and the employment of professionals by nonprofessionals or corporations;
- . State laws prohibiting the practice of medicine without a license;
- . State licensure, registration, and minimum net worth requirements for insurance **companies** (a concern for risk-bearing PPMCs);
- . State fee-splitting laws (whether aimed at kickbacks, improper practice development incentives, or quasi-owner-ship arrangements), especially where a management fee is based on a percentage of revenues or profits; n22
- . State and federal antikickback regulations and self-referral prohibitions, especially when a management fee is based on a percentage of revenues or profits;
- . Various payor restrictions on the assignment of professional receivables;
- . Public policy restrictions on the enforcement of non-competition covenants against professionals;
- . Federal and state antitrust regulations (especially price-fixing regulations and, if applicable, regulations triggered by market share);
- . State certificate of need statutes and regulations controlling the development of new facilities and expansion of existing ones n23; and
- . Requirements of various payor programs for certification for reimbursement.

n20 See OFF. INSPECTOR GEN. (OIG), DEPT OF HEALTH & HUMAN SERVS. (HHS), REP. NO. OEI-01-91-00770, STATE PROHIBITIONS ON HOSPITAL EMPLOYMENT OF PHYSICIANS at i (1991), *available at* <http://oig.hhs.gov/oei/reports/oei-01-91-00770.pdf> (last visited Jan. 3, 2006) (noting that only California, Colorado, Iowa, Ohio, and Texas then enforced prohibitions against employment of physicians by hospital corporations).

n21 *E.g.*, Amsurg Corp., Annual Report (Form 10-K), at 9 (Mar. 30, 2000) [hereinafter Amsurg], *available at* <http://investors.amsurg.com/phoenix.zhtml?c=83089&p=irol-SECCat> (last visited Dec. 21, 2005); PhyCor, Inc., Annual Report (Form 10-K), at 10-11 (Mar. 30, 2000) [hereinafter PhyCor], *available at* www.sec.gov/Archives/edgar/data/881400/0000950144-00-002291.txt (last visited Dec. 21, 2005).

n22 Federal laws, and often state laws, carry civil and criminal penalties, together with the threat of expulsion from payment programs. Conduct raising the concern includes not only exclusivity and referral arrangements, but also physician practice acquisition, since physicians would remain under contract after the purchase and no "safe harbor" or Stark "exception" would exist. Amsurg, *supra* note 21, at 9-10;

PhyCor, *supra* note 21, at 12-13.

n23 *E.g.*, *Women's Med. Ctr. v. Finley*, 469 A.2d 65 (N.J. Super. Ct. App. Div. 1983) (discussing physician-owned medical practices who contract with privately owned management **companies**, and whether these physician groups forfeited their private practice status and were therefore subject to New Jersey's certificate of need requirements).

Why are the legal and policy barriers to lay ownership of healthcare enterprises so resilient? n24 To the extent the answer is simply political expedience, n25 legislative inertia, or the intransigence of professional interest groups, n26 there is perhaps little of interest to be said on the subject. But to the extent that the legal barriers purport to stand on their merits and to serve public policy principles, other questions come to mind: Do the laws properly and effectively serve those principles? Why, as we shall see is the case, are the applicable laws so multiform, so porous, and so erratically enforced? n27 Are they informed by a single coherent underlying principle, or several? Why are some entities (notably HMOs, stand-alone emergency care clinics, ambulatory surgical centers, and hospitals) treated differently from others in which nonprofessionals have equity interests? These are the questions that have prompted this Article, and that presumably have tormented many a business person, lawyer, physician, and investor contemplating a healthcare business plan affected by this doctrine. If there are to be changes in legislation and common law with respect to the issue of lay ownership, such changes should be informed by the answers to these questions.

n24 For more on the continued vitality of the corporate practice of medicine doctrine, see John Wiorek, *The Corporate Practice of Medicine Doctrine: An Outmoded Theory in Need of Modification*, 8 J. LEGAL MED. 465, 470-90 (1987).

n25 *See, e.g.*, Russell C. Coile, Jr., *Health Care Trends 1997: Top 10 Trends for "Health Reform Debate II"*, reprinted in HEALTH CARE M&A: HOW TO STRUCTURE THE TRANSACTION 357 (1998); Russell C. Coile, Jr., *Top 10 Health Care Trends for 1998: Tomorrow's Trends Will be Consumerism, Cyberhealth, and Co-Opetition*, reprinted in HEALTH CARE M&A: HOW TO STRUCTURE THE TRANSACTION 367 (1998). Coile notes that state attorneys general have discovered the publicity value of opposing for-profit takeovers of nonprofit providers. *Id.* at 374.

n26 Rosoff, *supra* note 8, at 492 (noting the pressures brought to bear on legislatures by the AMA).

n27 Jacobson, *supra* note 16, at 75. *See also*, *Garcia v. Tex. State Bd. of Med. Exam'rs*, 384 F. Supp. 434 (W.D. Tex. 1974) (raising equal protection implications of corporate practice bars and licensure statutes).

This Article proposes an analytic approach to the body of law affecting lay ownership of healthcare enterprises. The history of the applicable doctrines is already well documented. n28 More useful now is an understanding of their logic and the effect they are having on contemporary business planning. With an analytic framework with which to evaluate the various existing legal restraints, courts, agencies, and legislators should be more open to innovation that rationally protects the legitimate concerns and advances the legitimate interests of all groups involved. Progress toward that objective will involve discarding some venerable but unsound articulations of principle and creating new licensure authority for state or federal agencies.

n28 *E.g.*, Chase-Lubitz, *supra* note 5.

II. The Physician Practice Management **Company**: An Experiment in Lay-Professional Partnering

The physician practice management **company** (PPMC) as it emerged and then declined in the 1990s was one such innovation. n29 Once the darlings of Wall Street, n30 the most ambitious of such **companies** have by now gone under or reconceived themselves. n31 If their demise was in part due to the discovery that the exuberance with which they were initially greeted by investors was generally unjustified, n32 the strain of complying with a multitude of state and federal regulations could not have helped. Regulation not only increased start-up and compliance costs, but provided

disgruntled physicians with a ready store of legal claims and defenses when they sought to terminate their affiliations with PPMCs. n33

n29 For a chart showing the precipitous decline of the stock prices of the ten largest publicly traded physician practice management **companies** (PPMC) as of December 1999, see Stanley G. Andeel, *Representing Physicians in Buying Back Practices in Failed PPM Relationships*, SE66 A.L.I.-A.B.A. 265, 268 (2000). See also Nancy A. Peterman & Joshua W. Dobin, *State Regulators Order Financially Distressed Health Care Businesses to Cease and Desist!*, AM. BANKR. INST. J., June 1999, at 27.

n30 John R. Hayes & Howard Rudnitsky, *M.D., Inc.*, FORBES, Sept. 11, 1995, at 222, 227. In 1998, Medpartners, Inc. ("Medpartners"), one of the larger PPMCs, was reported to have a market capitalization of \$ 4.78 billion and its stock traded with a P/E ratio of 38.69. Healthcare Financial Partners, *The Physician Practice Management Company: Alternative to the Solo Practice*, HEALTH CARE PERSP., Winter 1998, at 1, 19, available at www.hfseurope.com/europe/perspectives/39240.pdf (last visited Dec. 22, 2005). In 1997, another PPMC, Phycor, Inc., agreed to buy Medpartners for \$ 6.98 billion in stock. Richard L. Reece, *PhyCor-MedPartners Deal Raises Questions for Physicians Considering PPMCs*, PHYSICIAN PRAC. OPTIONS, Dec. 1997, at 3, 4, available at www.arthritis-options.com/common/pdfs/PPO1297.pdf (last visited Dec. 22, 2005). Medpartners was among the PPMCs subject to a 1999 cease-and-desist order issued by the California Department of Corporations based on reports of insolvency. Peterman & Dobin, *supra* note 29, at 27.

n31 Jeffrey L. Cohen, *PPMCs: A Perspective*, 7 U. MIAMI BUS. L. REV. 495, 495 (1999) (noting the "mad rush by [PPMCs] to leave the business" after the failed Med-partners/PhyCor merger in January, 1998).

n32 *Id.* at 500.

n33 See generally Robert P. Borsody, *Practice Management Contracts: State of the Law*, 6 N.Y. CITY L. REV. 11 (2003). Borsody discusses several cases, but focuses particularly on *Mainline Med. Services, Inc., v. Teyibo*, Index No. 602614/00 (N.Y. Sup. Ct. 2000), in which the court denied the management **company's** motion for summary judgment against a physician-owned professional corporation seeking to void management contracts as violating the corporate practice prohibition.

Very generally, PPMCs are lay-owned **companies** that provide management services to physicians. Such management services generally consist of billing, practice development, negotiating professional services and other contracts, providing non-professional personnel services, office space and equipment, insurance, accounting and legal services, and similar administrative support.

A. The Promise

The potential advantages of the PPMC arrangement to physicians were considerable. n34 If the arrangement involved the sale and purchase of the physician's practice, the physician immediately realized full value for her practice. Purchase prices often included value for goodwill as well as assets and receivables, even when the selling physician remained in practice with the purchaser, n35 which option was frequently not available in sales of practices to hospitals or other doctors. n36 In any event, immediate realization of equity in a practice solved what many physicians had begun to appreciate could be a significant problem, the practice exit strategy. At a time when it had begun to appear that sales of practices by retiring physicians to younger physicians would become more rare, when state and federal regulations had begun to impact the form of such transactions adversely, when the flurry of acquisitions by hospitals and HMOs had begun to show signs of slowing, PPMCs were there to secure a selling physician's retirement in advance, often with a combination of cash and stock in **companies** then heralded by Wall Street.

n34 Borsody, *supra* note 33, at 11.

n35 Theodore N. McDowell & Martin D. Brown, *Physician Management Companies: Just What the Doctor Ordered?*, in 1996 HEALTH LAW HANDBOOK 11 (Alice G. Gosfield ed., 3d ed. 1996); Cohen, *supra* note 31, at 496-98.

n36 Because no "exception" existed for such transactions under the Stark Law, 42 U.S.C. § 1395nn (2005), and no "safe harbor" under the Federal Fraud and Abuse Act § 1128B, commonly known as the Antikickback Statute, 42 U.S.C. § 1320a-7(b) (2005), such transactions risked civil and criminal prosecution. The risk related not only to the payment for goodwill (potentially a payment for a stream of referrals), but also to subsequent incentive compensation arrangements. See OIG, HHS, Advisory Op. No. 10 (Aug. 31, 1998), available at www.oig.hhs.gov/fraud/docs/advisoryopinions/1998/ao98_10.htm (last visited Dec. 22, 2005).

In addition to the personal exit strategy, PPMCs provided selling physicians with other advantages. n37 Doctors could be freed from administrative headaches to concentrate on providing medical care. Salaried doctors were promised income security. PPMCs could offer revenue enhancement through ancillary medical services and access to clinical trials. PPMC doctors were afforded personal mobility and crisis support where the PPMC could help arrange professional or nonprofessional staff coverage. Where not prohibited by self-referral prohibitions, other PPMC-affiliated doctors constituted a pool of reliably-credentialed professionals to which to refer and from which they might receive referrals. Enhanced access to private and public capital markets often meant additional cash was available for practice development and capital projects, such as office and equipment upgrades or expansions. Overhead could be reduced through economies of scale and with the implementation of software solutions that had previously been out of the reach of individual practitioners. PPMC billing expertise could result in higher profits and fewer errors. PPMC clout could result in more favorable terms under managed care agreements or office and equipment leases. PPMC development resources could lead to new business. To the extent permitted by applicable employment or professional services contracts, doctors were sometimes afforded opportunities to relocate, which was mobility they often could not have hoped for as independent practitioners financially tied to a particular practice locale. Stock ownership in publicly traded PPMCs or options therefor seemed for a while to be excellent investments, and certainly offered more liquidity than did ownership of the assets of a typical medical practice.

n37 See Cohen, *supra* note 31, at 496; McDowell & Brown, *supra* note 35. See also Rosoff, *supra* note 8, at 496 (noting the growing trend toward use of lay-owned management **companies** in the operation and financial support of physician practices in the late 1980s). See generally Respondents' Brief at 2-10, Moore v. Orthodontic Centers of America, Inc., No. D0358082002, WL 32351 (Cal. Dist. Ct. App., Jan. 11, 2002) (arguing that benefits provided to physician by PPMC included working capital loan, living allowance, office, equipment, staff, payroll, employee benefits, inventory management, accounting, billing, purchasing, marketing, insurance claim processing and enhanced practice mobility in relocating physician from a failing practice in Virginia to a successful one in California).

Besides the advantages to physicians, the PPMC had potential benefits for consumers in terms of better facilities, more efficiently managed professional time, and even lower cost.

B. Form and Substance Struggles

In the earliest stage of their development, where permitted by law, n38 many PPMCs experimented with business models involving direct purchase of physician practices and subsequent employment of the selling physician, since this format had the highest appeal to investors. n39 The attractions for investors were (i) the value of the acquired practices could immediately be reflected on the **companies'** balance sheets, and (ii) as owner/employer, the PPMCs retained full ownership and control of all practice revenues. To the extent that practice acquisitions could be made with PPMC stock, more capital remained available for operations and expansion. Publicly-traded PPMCs could pay physicians a price in the neighborhood of five to eight times the practice's annual management fee with the proceeds of stock that often traded at twenty to thirty times price-to-earnings ratios. n40

n38 Borsody, *supra* note 33, at 11-12.

n39 Cohen, *supra* note 31, at 495.

n40 Michael W. Hubbard, *Physician Practice Management Companies* 1 (1999) (unpublished manuscript), available at www.smithlaw.com/misc/47387_1.pdf (last visited Dec. 22, 2005).

As PPMCs moved across jurisdictions, they encountered a variety of state laws affecting lay ownership and were eventually forced to adjust their business models. For reasons that will become evident in a moment, most PPMCs eventually settled on a pure management model in which no equity interest in the physicians' practices was held directly by the PPMC.ⁿ⁴¹ The relationship between the professional practice and the PPMC was that of independent contractors rather than employer/employee. This was necessary in states with law or other authority to the effect that corporations (other than professional corporations) could not employ physicians,ⁿ⁴² and useful in any state to shield the PPMC from liability for professional negligence on a *respondeat superior* theory.ⁿ⁴³

ⁿ⁴¹ Cohen *supra* note 31, at 495.

ⁿ⁴² Such restrictions exist in Arkansas, California, Colorado, Connecticut, Delaware, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Massachusetts, Minnesota, Montana, Nevada, New Jersey, New York, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Washington, West Virginia and Wisconsin. AM. ACAD. OF EMERGENCY MED. (AAEM), CORPORATE PRACTICE OF MEDICINE: STATE BY STATE LISTING OF RELEVANT STATUTES, CASES, AND OPINIONS [hereinafter AAEM], available at www.aaem.org/corporatepractice/states.shtml (last visited Dec. 22, 2005). For a shorter list of those states in which Appellate Courts have recently applied or reaffirmed the doctrine, see Andeel, *supra* note 29, at 275 (identifying Texas, California, Illinois, Iowa, Georgia, and Kansas).

ⁿ⁴³ *But see, e.g.,* Wadsworth v. McRae Drug Co., 28 S.E.2d 417, 419 (S. Carolina 1943) (stating that a corporation may not avoid the professional negligence liability of its licensed employees even though corporations may not legally employ professionals to practice medicine).

Viewed from the perspective of a hypothetical multi-state PPMC, the regulatory landscape is extremely challenging.ⁿ⁴⁴ Assuming the business plan was to acquire physician practices and subsequently employ those physicians, the PPMC could conceivably proceed to do so in Louisiana,ⁿ⁴⁵ Mississippi,ⁿ⁴⁶ New Mexico,ⁿ⁴⁷ and Virginia,ⁿ⁴⁸ but not in California,ⁿ⁴⁹ Colorado,ⁿ⁵⁰ or Illinois,ⁿ⁵¹ and only at significant risk in Pennsylvania. Pennsylvania illustrates the ambivalence found in several states that may ultimately lead the PPMC decisionmaker to take an indirect approach to practice acquisition in order to avoid potential hazards. Pennsylvania repealed a regulation, based solely on common law, which stated that nonprofit corporations may not employ physicians to practice medicine, but the repeal left open whether the legislative intent was to overrule the common law corporate practice prohibition altogether and allow for-profit corporations to employ physicians, or merely to remove the codification of common law and allow the underlying case law precedent to continue, in which case presumably neither for-profit nor nonprofit corporations could employ physicians.ⁿ⁵² Even in states without an express prohibition against corporate employment of physicians, however, the PPMC could run afoul of prohibitions against excessive controls of physician conduct.ⁿ⁵³ As an added complication, state licensure statutes limit incorporated professionals to practicing in the state of incorporation, so a multi-state enterprise using a corporate format would have to link horizontally professional corporations licensed in separate states.

ⁿ⁴⁴ For a survey of state corporate practice of medicine laws, see AAEM, *supra* note 42.

ⁿ⁴⁵ A Statement of Position by the Board of Medical Examiners dated August 20, 1992, provides that employment of a physician by a corporation is not *per se* unlawful under the Louisiana Medical Practice Act, as long as the physician is free to exercise "independent medical judgment in the diagnosing, treating, curing or relieving" of physical conditions. *Id.*

ⁿ⁴⁶ The Mississippi State Board of Medical Licensure does not concern itself with the form of business arrangements entered into by a physician, provided that the physician is licensed, has discretion over the method and manner of patient treatment and billing, and receives no inducement for referrals. *Id.*

ⁿ⁴⁷ 1987 N.M. Op. Att'y Gen. 39, 1987 WL 270340 (concluding that a lay-controlled corporation may employ physicians to provide

medical services if control of medical decisions is allocated to the physicians).

n48 1992 Va. Op. Att'y Gen. 147, 1992 WL 526777 (concluding that the corporate practice of medicine doctrine has not been adopted in Virginia).

n49 83 Op. Cal. Atty. Gen. 170 (2000), 2000 Cal. AG LEXIS 28, *citing* CAL. BUS. & PROF. § 2400 (2005) ("Corporations and other artificial entities shall have no professional rights, privileges, or powers."); 57 Op. Cal. Att'y Gen. 231 (1974) 1974 Cal. AG LEXIS 57; 55 Op. Cal. Att'y Gen. 103 (1972) 1972 Cal. AG LEXIS 28, *citing* CAL. BUS. & PROF. CODE § 650 (2005) (prohibiting inducement for referrals).

n50 COLO. REV. STAT. ANN. § 12-36-117(1)(m) (West 2005) (Physicians may not practice medicine as the employee or in joint venture with any corporation other than a professional services corporation (§ 12-36-134), or any other entity, or as the partner, agent, employee or in joint venture with any lay person. Only a professional services corporation may practice medicine.); *id.* § 12-36-134(1) ("[C]orporations shall not practice medicine" except professional service corporations and except as provided in 25-3-103.2).

n51 2002 Ill. Att'y Gen. Op. 005, 2002 WL 377669, *citing* 225 ILL. COMP. STAT. 60/22(A) (West 2000) (prohibiting fee-splitting).

n52 In 1998 Pennsylvania repealed 19 PA. CODE § 41.4(d), providing that "[a] nonprofit corporation may not conduct professional services. Only a professional corporation may render professional services." Notices, Independent Regulatory Review Commission, Actions Taken by the Commission, Department of State--Nonprofit Corporations; Doc. No. 16-16, 28 Pa. Bull. 588 (Jan. 13, 1998). Underlying case law in Pennsylvania held that corporations could not practice medicine because they could not satisfy the licensure requirements. *Neill v. Gimble Brothers, Inc.*, 199 A. 178, 182 (Pa. 1938).

n53 For example, a 1992 declaratory ruling by the Alabama Board of Medical Examiners effectively stated that "[p]hysicians are free to enter into contracts of employment for their professional services with professional corporations, nonprofit corporations, business corporations, partnerships, joint ventures or other entities, *provided however*, that the physician must exercise independent judgment in the matters related to the practice of medicine." AAEM, *supra* note 42 (emphasis in original). Similar agency positions were taken in Mississippi, Utah, and Virginia. *Id.* South Dakota permits corporate employment of physicians by statute, as long as the physician's independent judgment is preserved, the corporation does not mark up the physician's fees, and the arrangement is renewed every three years. S.D. CODIFIED LAWS § 36-4-8.1 (2005).

State laws that narrowly prohibit lay-owned corporations from employing physicians could be accommodated (circumvented) in various ways. One method was to employ what is called a "captive PC," or a professional corporation whose stock is owned entirely by one or more professionals contractually bound to the lay-owned entity in a manner assuring control by the lay-owned entity. n54 The lay-owned entity, for instance, might have a professional services agreement or an employment agreement with the shareholder(s) of the professional corporation requiring the shareholder(s) to act within certain parameters with respect to the professional corporation (e.g., cause the professional corporation to enforce productivity standards for professional employees, to employ professionals on terms mandated by the PPMC, with compensation and incentive packages designed by the PPMC, and generally to comply with the provisions of the PPMC's management agreement). n55 The "friendly" or "captive" PC could then in turn employ individual physicians. As a result, the PPMC would have indirectly what it could not achieve directly in an employer-employee relationship with the doctors. Control provisions could be inserted not only into employment agreements between the PC and the individual physicians, but also in the charter documents of the PC, in the management agreement between the PC and the PPMC, and in the employment agreement (usually a medical director agreement) between the PC's shareholder(s) and the PPMC. As added security, the "friendly" shareholder(s) of the PC were sometimes required to execute an option agreement, pursuant to which the PPMC could unilaterally require the shareholder(s) to sell their shares in the PC to a successor physician designated by the PPMC (since the PPMC could not own the shares itself). n56 This would insure a management-friendly successor, and effectively placed into the hands of the PPMC another stick from the bundle of ownership rights.

n54 Hubbard, *supra* note 40, at III-14.

n55 *Id.* at III-12 to -14.

n56 *Id.* at III-14.

The captive PC arrangement solved certain problems, but continued to face problems of revenue control, in that all revenue from professional services would belong to the PC rather than the management **company**. This weak link in the control of cash flow made lenders, investors, and underwriters nervous. In some jurisdictions, and with respect to some sources of revenue, this problem could be addressed by allocating to the management **company** a percentage of practice revenues equal to what would otherwise have been the lay entity's share of equity in the PC as compensation for management services. n57 That is, by having a right to a percentage of revenue net of expenses (profits), the management **company** would have the functional equivalent of an equity interest in practice revenues. In many cases, however, state statutory or common law doctrines, n58 as well as principles of medical association ethics codes, n59 prohibit such "fee splitting" with nonprofessionals. In such cases, a key attribute of ownership is effectively denied to the management **company**.

n57 The Second District Court of Appeal in Florida, for instance, has held that a percentage-based management fee does not violate Florida's fee-splitting prohibition as long as no inducement for referrals is implicated. *Practice Mgmt. Assocs. v. Orman*, 614 So. 2d 1135, 1138-39 (Fla. Dist. Ct. App. 1993). California allows percentage-based management fees when based on gross rather than net practice income. CAL. BUS. & PROF. CODE § 650 (West 2005) ("The payment or receipt of consideration for services other than the referral of patients which is based on a percentage of gross revenue or similar type of contractual arrangement shall not be unlawful if the consideration is commensurate with the value of services furnished . . .").

n58 FLA. STAT. § 458.331(1)(i)(2005); *In re* Petition for Declaratory Statement of Dr. Magan L. Bakaranian, M.D., 20 F.A.L.R. 395 (1997), *aff'd*, *PhyMatrix Management, Inc. v. Bakaranian*, 737 So. 2d 588, 588 (Fla. Cir. Ct. 1999). *See* *TLC The Laser Ctr., Inc. v. Midwest Eye Inst. II, Ltd.*, 714 N.E.2d 45, 55-56 (Ill. App. Ct. 1999).

n59 AM. MED. ASS'N (AMA), CODE OF MEDICAL ETHICS 6.02 (1994), *available at* www.ama-assn.org/ama/pub/category/8365.html (last visited Dec. 22, 2005).

There are solutions even in jurisdictions with fee-splitting prohibitions, however. For one thing, as we shall see, some such jurisdictions frame fee-splitting rules to prohibit revenue-sharing only when the lay-owned entity is in a position to refer patients to the practice entity. n60 For another, the management **company** can achieve something like the targeted percentage interest by contractually setting a flat fee in an amount estimated to equal or exceed the amount the percentage arrangement would have yielded. n61 To protect the interest of the independent contractor physician in a negotiated minimum base income, such income could be guaranteed and would thereby come to resemble an employee's base salary more than an independent contractor's earnings. n62 To assure that it would retain all but the revenues allocated to the physician income guarantee, the PPMC could supplement its fee with claims on practice revenue for performance bonuses, for debt repayment (from loans for start-up, upgrade, or operating costs), and for equipment and space leases. n63 To achieve the maximum level of control over the revenue stream, the management **company** could undertake to bill and collect for the practitioner, then deduct fees and expenses from the proceeds. In addition, some PPMCs secured debt repayment obligations by factoring receivables. n64 Such arrangements could in turn be further frustrated by regulatory provisions such as Medicare's anti-reassignment rule, which prohibits reassignment of Medicare receivables from the provider to a third-party except under certain circumstances. n65

n60 *See Orman*, 614 So. 2d at 1138.

n61 Hubbard, *supra* note 40, at III-23. *But see* *Vine St. Clinic v. HealthLink Inc.*, 819 N.E.2d 363, 370-71 (Ill. App. Ct. 2004) (fixed flat fee violated fee-splitting statute when fee varied from physician to physician).

n62 *See, e.g.*, The arrangement described in Respondent's Brief at 2-3, *Moore v. Orthodontic Ctrs. of America, Inc.*, 2002 WL 32351 (Cal. Dist. Ct. App., July 11, 2001), and Appellant's Opening Brief at 12, *Moore*, 2001 WL 34156899 (Mar. 30, 2001).

n63 Use of a lease as an implement of lay control is an old device. *See State v. Kindly Optical Co.*, 248 N.W. 332, 335 (Iowa 1933):

The execution of the so-called lease between the defendant and its employee Jensen, in connection with the contract of employment between the same parties, was also a sham and fraud and a too evident plan, purpose, and intent to evade the provisions of the statutes herein referred to. It is true that the name of the defendant did not appear publicly in connection with the business, but the record shows without controversy that the business was in fact owned and operated by the defendant **company**. The defendant **company** controlled the conduct and policies of the business. Jensen was simply its employee on a stipulated salary. The so-called lease between Jensen and the defendant, under the terms of which the defendant, as lessor, was to pay Jensen, as lessee, \$ 281 per month, was only a clever attempt to change the character of Jensen from an employee to a lessee, and does not change the fact that Jensen was an employee of the defendant **company**.

n64 PhyCor used this approach, as evidenced by its annual statement and contracts attached as exhibits thereto. *Phycor*, *supra* note 21.

n65 42 U.S.C. §§ 1395g(c), 1396a(a)(32) (2005); 42 C.F.R. §§ 424.73(a), 447.10(a) (2005). CTRS. FOR MEDICARE & MEDICAID SERVS., CARRIERS MANUAL PART III, ch. 3, § 3060 (July 1999), *available at* <http://www.cms.hhs.gov/Manuals/PBM/list.asp> (last visited Jan. 4, 2006). While direct payment of Medicare/Medicaid receivables can generally not be made to a third-party creditor, the provider may pledge them as long as payment is first made to the provider, who then pays the third-party. PPMCs typically use a "lockbox" arrangement to satisfy this requirement: receivables are deposited into the provider's account and the PPMC "sweeps" the account on a daily basis. A lender's security interest in Medicare/Medicaid receivables must be nonpossessory. *See* Michael M. Schmidt, *Physician Management Service Agreements*, at III(B)(7) (unpublished seminar outline), *available at* <http://tinyurl.com/gpcb8> (last visited Mar. 5, 2006).

In the game of imbuing a (permissible) independent contractor arrangement with the control attributes of an (impermissible) employer-employee arrangement between a lay-owned PPMC and a professional, there are many stratagems in addition to the captive PC arrangement: n66 To assure control a variety of mechanisms may be used: the PC or individual practitioner, as the case may be, agrees that the PPMC is the exclusive provider of management services, and the management agreement may have a very long term; the PPMC owns or controls all hard assets (equipment, space, nonprofessional staff), which it then leases to the practice; the practice may be obligated to buy the assets back from the PPMC, with physician guarantees secured by personal and practice assets; the PPMC may control managed care contracting, sometimes through a PPMC-owned provider group; where permitted, lay managers may hold offices in the PC, including directorships; n67 the PPMC may control receivables, if not with a factoring arrangement, then through a billing services agreement under which practice receivables are applied to management services before being deposited to the practice's account, or the account itself, if in the name of the practice, is subject to withdrawal restrictions protective of the PPMC; physician employment agreements, whether directly with the PPMC or with the friendly PC, contains restrictive covenants prohibiting the physician from competing with any practice controlled by the PPMC; any financing arrangements provided by the PPMC may be further secured by practice and personal physician assets; any practice acquisition consideration in the form of stock or options in the PPMC may be conditioned on continued physician compliance and performance goals; where the transaction began with a practice sale and purchase acquisition, subject to any applicable antikickback regulations, n68 physicians may be further controlled by terms providing for deferred payment based on practice performance. As a further control device, some PPMCs established joint policy boards with practitioners to establish productivity goals and generally supervise actions taken to achieve them. The joint policy board could deadlock a PC in the event it sought to take a direction deemed by the PPMC to be inimical to business purposes. n69

n66 Hubbard, *supra* note 40, at III-4, -7.

n67 Connecticut permits three-fourths of the members of the board of directors of a healthcare center to be lay persons. CONN. GEN.

STAT. § 38a-179(a) (2005).

n68 Besides those contained in the Stark Law, 42 U.S.C. § 1395nn (2005), and the Federal Fraud and Abuse Act § 1128B, 42 U.S.C. § 1320a-7b (2005), various similar state antikickback regulations may be implicated by earn-out provisions.

n69 Hubbard, *supra* note 40, at III-16.

With respect to the joint policy board and every other control mechanism used by PPMCs, it was always important to make it explicit that professionals would remain solely in charge of medical decisions. This was important not only, as previously noted, as a defense against any claims for professional negligence that might be brought against the PPMC itself, but also because no PPMC would wish to be deemed to be practicing medicine in violation of the medical practices or licensure act of any given state.

And so it goes, at virtually every point in the business plan of the PPMC, another regulatory hurdle, and with each such hurdle, another brilliant legal solution. Ultimately, rather than use one business model in some states and another in others (with the inevitable further state-to-state customization for still other reasons), most PPMCs chose a model that accommodated the largest number of regulatory circumstances with the least amount of state-to-state adjustment. For the most part, this meant a pure management model. But this choice was only the starting point on a path with many more choice points to follow involving control through captive PCs, management agreement terms, financing arrangements, joint policy boards, and so forth.

The example of the PPMC yields two observations of immediate relevance here. The first concerns the fact that the architects of PPMCs were forced to alter their business model to accommodate the vagaries of different state laws, and the second concerns the fact that the PPMC designers were able to do so. Let it first be acknowledged that the multitude of state laws in our federalist system had the effect of forcing PPMC planners to ring changes on the initial model involving direct employment of physicians. Even the least obstructive of the state rules in question n70 would have this effect, because lawyers knowing they would be required to give an enforceability opinion to a PPMC lender would not readily gamble on a direct employment arrangement that might be held to violate a corporate practice doctrine or a licensure statute when a management agreement would achieve the same result. The same lawyers opining as to the due organization and valid existence of a PPMC entity in a prospectus would have similar feelings where state rules on ownership of professional corporations by professionals are concerned.

n70 Commentators have occasionally observed that the corporate practice doctrine, for instance, is moribund, and that enforcement would be unlikely. Jacobson, *supra* note 16, at 67. Some reputable hospital systems, however, calculated and then took the enforcement risk when they initiated programs in the 1990s to acquire physician practices in states with common law corporate practice doctrines. The Hospital of the University of Pennsylvania, for instance, established a subsidiary nonprofit, Clinical Health Care Associates, through which to acquire practices and employ the selling physicians, as did Wilkes-Barre General Hospital in the same state, at a time when counsel for Pennsylvania's Corporation Bureau generally took the position that nonprofit corporations could not employ physicians. See Letter from John T. Henderson, Jr., Assistant Counsel, to Melinda J. Roberts (May 3, 1994) (on file with the Secretary of the Commonwealth of Pennsylvania); 19 PA. CODE § 41.4(d) (repealed 1998).

Without a doubt state laws had an adverse impact on transactional, compliance, and operations costs of PPMCs; but did the laws have the effect of **protecting** the interests for which they were intended? Admittedly this question cannot be answered until we can better understand the purpose(s) of those laws; but we can at least acknowledge here that the PPMCs went forward and became, at least for a time, darlings of Wall Street. The legal architects of PPMCs, that is, were successful enough to create something of value to the public financial markets, as well as to the participating physicians. Put in the most cynical terms, they circumvented state prohibitions, and did so well enough to satisfy the national equity markets and a number of physicians hoping, among other things, to rid themselves of administrative and financial distractions in order to concentrate more exclusively on the application of their professional skills. The PPMC could be structured as a relative of the HMO, the credentials of which had already passed the scrutiny of public policy, except that a PPMC is arguably less intrusive than the HMO where such principles as physician autonomy, quality

assurance, and the physician-patient relationship are concerned. At any rate, the relative success of the adaptive strategies of PPMCs in circumventing state laws forces us to ask whether any of those laws served other than a temporarily obstructive purpose. Advocates of lay-owned healthcare enterprises may lament the compliance costs and the litigation risks necessitated by the applicable regulations, all of which inevitably add to the cost of capital. Anyone not inclined to cheer the advance of lay ownership of healthcare enterprises may applaud their demise, but nonetheless wish to reflect on the lost opportunities to physicians in terms of access to capital markets, mobility, retirement strategies, cost-effective administrative services, avoidance of management responsibilities, bargaining leverage with managed care and other payors, and so forth. But anyone, even someone not wishing well to lay-controlled healthcare, may feel discomfort at the picture of a regulatory environment whose objectives could apparently be fully circumvented, n71 albeit at the costs detailed above.

n71 On circumvention, see Rosoff, *supra* note 8, at 499.

III. State Law: Rules and Rationales

Did state laws succeed in **protecting** challenged values in the case of the PPMC? Was the underlying regulatory rationale served, for instance, by compelling the shift from a model in which a lay entity directly employed physicians to one in which the lay entity provided management services? If the purpose of the doctrine was to prevent unlicensed persons from practicing medicine, it could be said that at least there was no failure on the part of the doctrine. PPMCs, like HMOs, are scrupulous (at least on paper) in the observance of the principle that the physician is solely responsible and has sole authority with respect to medical conduct. After all, liability for professional negligence is at stake. But then again, this objective could have been met within a direct employment arrangement if all that is required is a straightforward stipulation to the effect that the physician is autonomous within the scope of her professional practice. If on the other hand the purpose of the doctrine is to assure that financial control of the practice is retained by the professional, or that the professional determines who may succeed to practice ownership, or where he may practice, or with what equipment, or even how the line between professional and commercial conduct is to be drawn, the doctrine appears to have fallen short of its objective. As evidenced by the PPMC, these elements can be controlled by lay persons even when there is no direct employer-employee relationship.

A. Introduction

1. The Corporate Practice Doctrine

One of the principal mechanisms by which states restrain lay ownership of medical practices is a collection of rules and statutes generally known as the "corporate practice doctrine." This doctrine includes prohibitions against corporate employment of physicians and against the unlicensed corporate practice of medicine. To know definitively whether the doctrine has succeeded, we need a better understanding of its rationale. For its part, the corporate practice doctrine has been said to serve the following purposes (1) preventing lay control of physician practices; (2) preventing commercialization of the profession; (3) **protecting** the physician-patient relationship from interference by lay interests; n72 and it has sometimes been added that (4) enforcement of the doctrine restrains impermissible fee-splitting. n73 Items (1) and (3) are sometimes expressed in terms of the conflict of interest that may arise when a physician owes one duty of loyalty to an employer and another to his patient. n74 This list is a good start at understanding the doctrine, with the admission that there is some overlap and some commingling of causes and results. In the last analysis, it is hard to say why there should be three or four such categories. The objection against lay control, for instance, presumably arises from the concern that a lay-owned enterprise would elevate profit motive above the best interests of the patient, and this is presumably also the concern underlying the commercialism objection, and to some extent the objection based on **protecting** the physician-patient relationship. Put another way, lay control of physician practices is the enabling and causal condition, commercialism the effect, and unjustified interference the means thereto; but it is hard to escape the feeling that with some effort the entire list of could have been expressed as one objection.

n72 Chase-Lubitz, *supra* note 5, at 467.

n73 Parker, *supra* note 9, at 161.

n74 HALL & VAUGHN, *supra* note 18, at 3-11.

2. Other Legal Restraints

It should be noted at the outset of this discussion that the corporate practice doctrine is but one subclass of the larger class of laws affecting lay ownership of the healthcare enterprise. Others include the various state medical practice acts, which universally prohibit anyone from practicing medicine without a license; laws against physician self-referrals; laws prohibiting fee-splitting; laws against restraints of trade or business; professional corporation statutes, generally requiring all owners to be licensed; and laws prohibiting the assignment of professional receivables to anyone other than the professional who performed the underlying services. The corporate practice doctrine itself consists of several variants from jurisdiction to jurisdiction, including those that admit exceptions for nonprofits, or for hospitals, whether or not organized as nonprofits, community health centers, and fraternal organizations; those that emphasize form (no employment of physicians, but control of independent contractors can be made acceptable); and those that emphasize substance (no control of physician practices, even in an independent contractor arrangement).

If the corporate practice doctrine is only a subclass of the larger body of laws that affect lay ownership, this Article is concerned with that larger body of laws. All belong to the same general class in that they impinge upon one or another aspect of ownership. The bundle of rights that would comprise lay ownership of a healthcare enterprise would include not only the rights of an employer that are directly implicated by the corporate practice doctrine, but also, and more particularly, rights to the revenue from the employee's services and command and control rights over the delivery of medical services. Some states prohibit corporations, other than professional corporations, from employing physicians to provide healthcare services, but do not separately restrict the sharing of fees, n75 with the effect that lay interests may participate in healthcare revenue as long as they do so by means of an independent contractor rather than an employment arrangement. Other states prohibit fee-splitting, but arguably do not prohibit lay-owned corporations from employing physicians. n76

n75 *E.g.*, Arkansas, Connecticut, Indiana, Iowa, Kansas, Massachusetts, Missouri, Montana, Pennsylvania, Washington, and West Virginia. *See* AAEM, *supra* note 42.

n76 Florida takes this approach. *See* Jacobs & Goodman, *supra* note 16, at 246.

For purposes of analysis, the universe of laws affecting lay ownership can be grouped according to the interests they serve rather than the various aspects of objectionable results they seek to prevent (e.g., lay control, commercialism, conflicted conduct). A given law, that is, may be oriented towards one of the three component members of the healthcare triad of interests, the physician, the patient, or the payor. There is, for instance, a body of rules whose stated objective is to preserve physician autonomy; another aimed at quality assurance; and a third focused on cost control. In the first group, which includes certain types of corporate practice prohibitions, the implicit assumption is that to the extent practice control is left to the physician, quality of care will be best served and everything else will fall into place. The prime objective is to restrain commercialism or lay control. At the other extreme are rules arising from a concern with possible adverse results from excessive physician control, including runaway costs. From this perspective rules restraining overutilization of healthcare goods and services are necessary, and physician autonomy is a subordinate value. Rules in this group attempt to remove incentives for overutilization by regulating fee-splitting, kickbacks, and the like; or they attempt to remove restraints on competition, such as professional association advertising restrictions and antitrust laws; or they attempt to improve resource allocation, as with certificate of need laws requiring economic justification and regulatory approval for deployment of new facilities. And not fully accommodated by either the

physician autonomy or the payor-oriented rules is the quality assurance perspective, which seeks to serve the interest of the patient by assuring that practice standards are met. Licensure laws are the preferred method of advancing this interest--both the autonomy of the physician and the interest of the payor are subordinate to objective practice qualifications and standards. Within jurisdictions that emphasize this rationale, the corporate practice doctrine may exist, but exceptions are made for licensed corporate healthcare providers such as hospitals.

The foregoing regulatory orientations may be represented schematically as follows:

Orientation	Provider	Patient	Payor
			Utilization/cost
Regulatory Objective	Provider autonomy	Patient Welfare; Quality assurance	control; Rational resource allocation; Competition
Objectionable Conduct	Lay control; Commercialism; Provider conflict of interest; Certain commercial advertising practices	Unlicensed practice of medicine	Overutilization; Runaway costs; Certain professional advertising restrictions
Regulatory Methods	Professional corporation statutes; "Corporate practice of medicine" doctrine, as derived from concerns about commercialism	Licensure laws; "Corporate practice of medicine" doctrine, as derived from licensure laws	Antickickback, self-referral, fee-splitting laws; Antitrust laws; Certificate of need laws; Anti-assignment of receivable rules
Exceptions	May exempt nonprofits from the corporate practice bar	May exempt licensed corporate entities from the corporate practice bar	May exempt transactions within networks and groups, or allow fee splitting if no referral

motive

This Article will ultimately urge that all such regulatory schemes, whether oriented towards provider autonomy, quality assurance, or utilization and cost control, are ultimately parts of a single whole, and that a fully articulated and integrated regulatory system needs to accommodate all three perspectives (as to a large extent HMO regulation has done). When all three perspectives are accommodated, a proper place can be found for lay involvement, even lay equity participation in the healthcare enterprise. On the other hand, when regulatory approaches to the issue of owning and controlling healthcare enterprises fail to acknowledge all three perspectives, we find regulatory schemes that seem to invite circumvention or disregard. As a class, existing statutes, regulations and common law rules aimed at lay ownership of healthcare enterprises are too often reflexively proscriptive, formalistic, and fragmentary. As a result they have, ironically, proved to be relatively easy to circumvent. Faced with a ban against corporate employment of a physician, lawyers have not found it difficult to effectively duplicate an employment arrangement through a professional services agreement. Confronted with a ban on lay ownership, lawyers have responded with the near economic equivalent in the form of a management agreement.

If they are sieves on the one hand, these laws are traps for the unwary on the other; they are too frequently invoked collaterally, in contexts that do not even implicate the core rationale of the particular regulation in question. n77 Prohibitions against corporate employment of physicians, for instance, are regularly employed as defenses by physicians seeking, for reasons unrelated to clinical autonomy, to avoid an employment agreement and, often, its restrictive covenant. n78 They thus become, as one commentator has eloquently put it, "'legal landmines,' remnants of an old and nearly forgotten war, half-buried on a field fast being built up with new forms of health care organizations." n79

n77 For arguments against a breaching party defensively invoking the corporate practice doctrine, in dicta, see *TLC The Laser Ctr., Inc. v. Midwest Eye Inst. II, Ltd.*, 714 N.E.2d 45, 55 (Ill. App. Ct. 1999) ("The contention could be made that the doctrine is intended to protect the public, not to allow medical professionals to avoid contractual obligations into which they have voluntarily entered.").

n78 A typical situation involves a court's refusal to enforce a non-competition clause in an employment agreement with a corporation on the grounds that the agreement is void as against public policy. *See, e.g., Carter-Shields, M.D. v. Alton Health Inst.*, 777 N.E.2d 948, 960 (Ill. 2002); *Early Detection Ctr. v. Wilson*, 811 P.2d 860, 868 (Kan. 1991). *See also HALL & VAUGHN, supra* note 18, at 3-5 (citing *Bartron v. Codington County*, 2 N.W.2d 337 (S.D. 1942) (allowing county to refuse payment to a physician clinic under a contract it had negotiated for indigent care services, even though the services had already been rendered)).

n79 Rosoff, *supra* note 8, at 499.

That a regulatory relic of one jurisdiction resists integration with an orientation adopted by another is perhaps understandable when the inherent antagonisms among the various systems are considered. A system focused on preserving provider autonomy, for instance, naturally resists imperatives framed in terms of cost control or quality of care (particularly when administered by an administrative agency or other lay person). But it should be obvious that any responsible regulatory system needs to accommodate such needs.

B. Autonomy: The Provider Orientation

The body of law principally aimed at preserving provider autonomy against interference by lay or commercial influences comes with a lot of history, most of which will not be recited here. The history of such law, however, helps explain its bias. These are laws, statutory and court-made, that emerged during the 1920s and 1930s in the context of the medical profession's struggle against "contract practice" medicine, healthcare purchased by industry for its employees. As Paul Starr describes the period, physicians had reason to resist the growth of contract practice:

Employers had a practical interest in using medical services for recruiting and selecting workers,

maintaining their capacity and motivation to work, keeping down liability and insurance costs, and gaining good will from their employees and the public. But they did not want to pay for medical services or the hidden costs of disease that their workers or the community would otherwise bear. n80

n80 STARR, *supra* note 7, at 200.

Some courts of the period envisioned the irresistible decline of the medical profession with the introduction of lay ownership. Witness the following fearful syllogism, offered by a court tracing the process by which lay ownership gives rise to a conflict of interest in the professional that ultimately leads to the commercialization and thus the corruption of the profession:

Because of the rights with which the law invests a stockholder in a corporation for profit, recognition of such a means of conducting a professional business involves yielding the right of participation in control of its policies and in its earnings to lay persons. A share in the fees of professional men would come to the owners of capital stock as a matter of right in the form of dividends. The stockholder's right to vote his stock would provide him with an instrumentality to be used for shaping policy. Ownership of stock would ordinarily qualify him to serve as a director or officer of the **company**. Lay ownership of stock would be ultimately assured by the incidental rights of transfer and succession. The object of such a **company** would be to produce an earning on its fixed capital. Its trade commodity would be the professional services of its employees. Constant pressure would be exerted by the investor to promote such a volume of sales of that commodity as would produce an ever increasing return on his investment. To promote such sales it is to be presumed that the layman would apply the methods and practices in which he had been schooled in the market place. The end result seems inevitable to us, viz., undue emphasis on mere money making, and commercial exploitation of professional services. To universalize the use of this method of organizing the professions, or to permit such a use to become general, would ultimately wipe out or blight those characteristics which distinguish the business practices of the professions from those of the market place. Such an ethical, trustworthy and unselfish professionalism as the community needs and wants cannot survive in a purely commercial atmosphere. n81

n81 *Bartron v. Codrington County*, 2 N.W.2d 337, 346 (S.D. 1942).

That is stock ownership would be a corrupting economic interest and the power to do something about it, leading inevitably to the downfall of the medical profession. n82

n82 By way of contrast with this broadly conceived notion of professional autonomy, consider the position articulated by the U.S. Supreme Court in *Liggett Co. v. Baldridge*, 278 U.S. 105 (1928), in declaring unconstitutional on due process and equal protection grounds a Pennsylvania law providing that only licensed pharmacists may own pharmacies. With Justices Holmes and Brandeis dissenting, the Court noted legislative intent to the effect that a lay-owner might give more credit to the price than to the quality of drugs required to be stocked in the stores, but then observed that "mere stock ownership in a corporation, owning and operation a drug store, can have no real or substantial relation to the public health," thereby rejecting the logic that compels the conclusion that lay-ownership would inevitably taint a professional enterprise. *Id.* at 113. *Liggett* was subsequently overruled, and the position of Justices Holmes and Brandeis adopted in an opinion by Justice Douglas in *North Dakota State Bd. of Pharmacy v. Snyder's Drugstores, Inc.*, 414 U.S. 156, 167 (1973).

Recognizing a divergence of the interests of the profession and those of the corporate purchasers of medical services, physicians resisted as "commercialism" the two most salient features of contract practice: (i) employment of

physicians by business concerns, and (ii) the advertising of professional services. n83 If corporate employment of physicians threatened professional autonomy by subjecting the physician to a duty of loyalty to his employer that often conflicted with the physician's duty to his patient, advertising was equally a threat to autonomy because the resulting competition forced underbidding. n84 Much of the applicable common law developed during the 1930s from cases like the "Painless Parker" cases. n85 These were cases instituted by boards of medicine in states such as Colorado n86 and California n87 against a California business corporation owned by a dentist who had had his name legally changed to Painless Parker so that the word "painless," otherwise impermissible in the marketing of professional services, could be used on practice signage. Painless Parker, or rather Painless Parker Dentist, the California corporation controlled by him, attracted the prosecutorial attention not only by breaching advertising ethics, but also by employing dentists in various states. n88

n83 Starr notes that physicians "had no more desire to be dominated by private corporations than by agencies of government, and consequently resisted the two forms in which business corporations threatened to move into medical services--the provision of treatment for their own employees through 'company doctors' and the marketing of services to the public." STARR, *supra* note 7, at 200.

n84 HALL & VAUGHN, *supra* note 18, at 3-7.

n85 Rosoff, *supra* note 8, at 491, n.14.

n86 State Bd. of Dental Exam'rs v. Savelle, 8 P.2d 693 (Colo. 1932); People v. Painless Parker Dentist, 275 P. 928 (Colo. 1929).

n87 Parker v. Bd. of Dental Exam'rs, 14 P.2d 67 (Cal. 1932).

n88 There were as yet no professional corporation statutes, and therefore no format in which Painless Parker Dentist could legally employ professionals. *See id.*

The concept of professional autonomy as it emerged in California from the Painless Parker cases cut a wide path, in part due to court construction of statutory language defining the practice of dentistry. A person practices dentistry within the meaning of applicable California licensure statute if he "[m]anages or conducts as manager, proprietor, conductor, lessor, or otherwise, a place where dental operations are performed." n89 This definition leaves little room for involvement by anyone but a licensed practitioner in a dental practice. There is no room for an ownership interest, even a minority one, even if the lay partner acts in a purely administrative capacity. The principle continues to apply in contemporary cases, n90 and applies in the context of medical as well as dental practices. Thus, in a recent case in California's First District, the Court of Appeal upheld a Medical Board disciplinary ruling against a physician on the grounds that a minority interest in the clinic that employed him was owned by two persons not licensed in California, even though the majority owner physician worked with what he deemed to be complete clinical autonomy. n91

n89 CAL. BUS. & PROF. CODE § 1625(e) (West 2005).

n90 Moore v. Orthodontic Ctrs. of Am., Inc., No. D035808, 2002 WL 32351, at *7 (Cal. Ct. App., Jan. 11, 2002).

n91 Steinsmith v. Med. Bd. of Cal., 85 Cal. App. 4th 458, 461, 465 (2000).

As it has evolved in California, the principle of professional autonomy amounts to an insistence that licensed professionals have authority over all aspects of their practices, including management. The alternative is seen as an incursion of commercialism offensive to both statutory law and public policy. The notion that clinical and administrative conduct cannot be separated becomes fundamental to the analysis of lay ownership cases in California,

independent of any statutory justification. Thus in *Marik v. Superior Court*, to illustrate the impossibility of drawing a line between the "business" side of a professional medical corporation and the part that renders professional services, the court cited the example of a medical corporation's decision to purchase new equipment:

the prospective purchase of a piece of radiological equipment could be impacted by business considerations (cost, gross billings to be generated, space and employee needs), medical considerations (type of equipment needed, scope of practice, skill levels required by operators of the equipment, medical ethics), or by an amalgam of factors emanating from both business and medical areas. The interfacing of these variables may also require medical training, experience, and judgment. n92

n92 *Marik v. Superior Court*, 191 Cal. App. 3d 1136, 1140 n.4 (1987), *quoted in* *Duel v. Latino Health Servs. Med. Group, Inc.*, No. G029298, 2002 WL 31630893, at *4 (Cal. Ct. App., Nov. 21, 2002) (voiding the issuance of stock in a professional medical corporation to a non-physician).

The physician must retain control over both clinical and administrative aspects of the practice, because the two cannot be divided. Moreover, the source of the physician's authority over his practice (both its clinical and administrative aspects) must be structural, not merely contractual. That is, licensed persons must hold all equity interests in the practice; it would not suffice for physicians to be employed by lay persons, even under contracts stipulating that all aspects of the practice remain within the control of licensed physicians. An employer-employee relationship between laity and professionals would create an impermissible division of loyalties, as the professionals "would owe their first duty of loyalty to the corporation based on the employer-employee relationship and a 'secondary and divided loyalty to the patient,' jeopardizing the health and safety of the patients." n93

n93 *Moore*, 2002 WL 32351, at *5 (quoting *Parker v. Bd. of Dental Exam'rs*, 14 P.2d 67, 72 (Cal. 1932)).

California's commitment to a concept of physician autonomy that requires physician ownership and control of healthcare enterprises and refuses to indulge line-drawing between clinical and administrative conduct raises obvious difficulties for any business plan contemplating a division of labor between professionals and administrative participants. n94 Consider *Moore v. Orthodontic Centers of America, Inc.*, n95 in which an orthodontist sought to avoid a Business Services Agreement (BSA) with a subsidiary of Orthodontic Centers of America, Inc. (OCA), a physician practice management **company** with practices in forty-two states, on the grounds that the BSA illegally gave OCA the right to manage and control the orthodontic practice. n96 Dr. Moore, a Virginia orthodontist, had retained OCA to help him establish a new orthodontic practice in Southern California. Pursuant to the BSA, OCA established Dr. Moore in new offices in California, loaned him several hundred thousand dollars, provided him with a six-figure living allowance, assisted with equipping and staffing the new offices, provided administrative services (including marketing, patient scheduling, inventory, personnel, billing, accounting, and legal services), and provided financial assistance that allowed Dr. Moore to accept patients with no down payment for services to be rendered. In return, besides repaying the loans, the BSA stipulated that Dr. Moore would practice exclusively with OCA-affiliated dental practices in California. Dr. Moore breached the exclusivity covenant within two years after relocating to California and allegedly diverted patients from OCA practices to his own. n97 Dr. Moore, at all times an independent contractor with OCA, alleged that OCA had "lured" him into the BSA with an empty promise that he would eventually be located in San Diego, and then proceeded to pressure Dr. Moore into increasing his practice load to an unmanageable volume. n98 When OCA proved unwilling or unable to relocate Dr. Moore to San Diego, he took the offensive in litigation (after allegedly breaching the BSA himself), suing for a declaration that the BSA was illegal and therefore unenforceable. n99 The trial court held for OCA and awarded nearly \$ 600,000 in damages, approximately \$ 400,000 for loan repayment and \$ 200,000 for lost profits and expenses. n100 The Fourth District Court of Appeal reversed in part, holding that certain provisions of the BSA violated the corporate practice of medicine doctrine and were thus unenforceable. n101

n94 By way of comparison, a distinction between clinical and administrative conduct seems well within the limits of acceptability in other jurisdictions. *See, e.g.*, Arizona, Arkansas, Colorado, Georgia, Indiana, Iowa, Louisiana, Maine, Michigan, Minnesota, Mississippi, Montana, North Dakota, Oklahoma, South Dakota, Utah and Virginia, all of which have statutory provisions erected on the assumption that clinical and administrative conduct can be segregated, or opinions of attorneys general to this effect. *See* AAEM, *supra* note 42.

n95 *Moore*, 2002 WL 32351.

n96 Dr. Moore relied on Sections 1625 and 1626 of California's Business & Professions Code, the statute construed in the Painless Parker case. *Parker*, 14 P.2d at 67; *Moore*, 2002 WL 32351, at *4-5. Section 1626 provides "[i]t is unlawful for any person to engage in the practice of dentistry in the state . . . unless the person has a valid, unexpired license or special permit." CAL. BUS. & PROF. CODE § 1626 (West 2005). Section 1625 states "a person practices dentistry within the meaning of this chapter who does any one or more of the following: . . . [m]anages or conducts as manager, proprietor, conductor, lessor, or otherwise, a place where dental operations are performed." *Id.* at § 1625 (emphasis added).

n97 Respondents' Brief at *2-3, *Moore*, 2001 WL 32351 (No. D035808).

n98 Appellant's Opening Brief at 2-3, 18, *Moore*, 2002 WL 32351 (No. D035808).

n99 *Moore*, 2002 WL 32351, at *2.

n100 *Id.* at *3.

n101 *Id.* at *8.

Although Dr. Moore was an independent contractor, not an employee of OCA or any affiliate, the Court of Appeal found objectionable those provisions of the BSA requiring Dr. Moore to practice exclusively at OCA-affiliated practice sites on a full-time basis. After struggling briefly with "the modern realities of medical/dental practices which often require a health care professional to obtain expert business assistance to exist in today's increasingly competitive medical environment," n102 the Court held that under the BSA, OCA, an unlicensed entity, was effectively practicing dentistry within the meaning of the Business & Professions Code, because OCA effectively controlled the orthodontist's hours and patient load. n103 The Court acknowledged that the BSA was "carefully drafted . . . with the intent to comply with California's ban on an unlicensed entity managing a dental business":

The BSA's first operative paragraph states "it is expressly agreed that the Orthodontic Entity shall retain ultimate responsibility for the management of its orthodontic practice at the Center (including all business aspects of the practice), and nothing in the Agreement is intended to transfer such ultimate responsibility from the Orthodontic Entity to [OCA]." . . . Section 3.2 likewise provides "The Orthodontic Entity shall be solely responsible for the business management of the Center (including all business functions), and all business services provided by the Orthodontic Entity to [OCA] hereunder are at the discretion and subject to the control of the Orthodontic Entity." n104

n102 *Id.* at *6.

n103 *Id.* at *7-8.

n104 *Moore*, 2002 WL 32351, at *6 (emphasis in original).

Nonetheless, by requiring Dr. Moore to deal exclusively with OCA, and then requiring him to work at hours established by OCA at a particular location, the BSA effectively gave OCA impermissible control over a clinical issue, the amount of time Dr. Moore could spend with patients. n105 In singling out the exclusivity provisions of the BSA in finding it to have violated California's licensure statute and corporate practice doctrine, and because the Court severed the loan provisions of the BSA and found them to be enforceable, the Court theoretically left open the possibility of a management services agreement that could comply with the Business and Professions Code. Presumably a dentist or physician in California can legally contract for administrative services. Decisions like *Moore*, however, must inevitably have an effect on the availability of the full range of benefits offered by OCA. It is hard to imagine a **company** willing to extend credit to the degree it had been extended by OCA in *Moore* without the security of a restrictive covenant. n106

n105 *Id.* at 7.

n106

In exchange for the PPMC's obligations to (i) exclusively contract with the PPMC in a defined area, (ii) commit to loan and fund capital expenditures, operating and working capital needs, and possibly to purchase practice assets and goodwill of the Physician Group . . . , the PPMC will require several exclusivity covenants from the Physician Group.

Schmidt, *supra* note 65.

At the very least, a decision like *Moore* increases the risk, and therefore the cost, of providing capital to professionals through a turnkey practice management format in California. Had Dr. Moore been fully successful with his claims, he would have been able to retain nearly \$ 400,000 provided to him by OCA in loans and would have been able to walk away from over \$ 200,000 in lost profits and expenses payable had the BSA been enforceable. As it was, only the loan portion of his obligation to OCA was affirmed by the Court of Appeal. From OCA's vantage, Dr. Moore's claim amounted to an assault "brought *in terrorem* because of its potential to declare OCA's core business--in fact the entire industry--illegal." n107 Where an agreement between lay persons and professionals is held illegal, it is not unusual for the court to leave the parties as it found them, which is often with the professional holding practice assets acquired with lay capital and the lay person holding an unenforceable debt obligation. n108 If the result seems inequitable, it is nonetheless an affirmation of the principle of professional autonomy.

n107 Respondent's Brief, at *3, *Moore*, 2002 WL 32351 (No. D035808).

n108 *Morelli v. Ehsan*, 756 P.2d 129, 133 (Wash. 1988) (denying an accounting of an illegal partnership between a physician and a nonphysician to operate a medical clinic that had been funded in part by the nonphysician).

Moore confirms the propositions that commercialism and the prospect of divided physician loyalty are perceived under California law to be the chief threats to professional autonomy, and that the protection of professional autonomy is the prime objective of California public policy. Given the historical origins of the state's efforts in this area, this is not surprising, as an autonomous profession is well suited to restrain the harms that can be inflicted when industry controls medicine. Although things have changed since the days when railroad and lumber **companies** employed physicians for the limited purposes of making the labor force maximally productive and minimizing liability, the rationales forged to support those holdings continue in effect. From these historical origins derives the argument that the medical profession can best be protected using "a structural safeguard which prohibits economic or clinical control over a physician, to ensure that a physician's medical decisions are not based on commercial interests, but rather on professional medical judgment." n109 Left in control, the argument goes, physicians will do what is best for patients. If physician autonomy

is assured, everything else will fall into place. The greatest threat to patient welfare arises from sources of interference with the physician's primary obligation to the patient, such as a conflicting legal duty to a lay employer, or cost constraints imposed by payors (indeed, the cost-control perspective is sometimes identified in California jurisprudence as an adverse influence in the context of apologies for provider autonomy, as cost concerns may corrupt medical judgment). n110

n109 Opposition Brief of Plaintiff and Appellee California Medical Association at 1-2, Cal. Med. Ass'n v. Regents of the Univ. of Cal., 79 Cal. App. 4th 542 (2000) (No. B135833).

n110 "In order to bring soaring health care costs under control, health coverage has [sic] shifted from traditional unmanaged, fee-for-service ('indemnity') insurance to prepaid managed care coverage. Under this managed costs system, cost-containment mechanisms under which physicians provide medical services have the potential for corrupting medical judgment." *Id.* at 2 (citing Wickline v. State, 192 Cal. App. 3d 1630 (1987)).

The most vociferous proponents of this position, not surprisingly, have been professional associations--the AMA and various state medical associations. The position was recently articulated by the California Medical Association (CMA) in an appellate brief. The CMA described the rationale behind the corporate practice bar as protection against "(1) a division of the physician's loyalty between a lay entity and the patient; (2) the dangers of commercial exploitation of the medical profession; and (3) lay control over the physician's professional judgment." n111 The CMA continued in language typical of proponents of professional autonomy:

All of these threats to a physician's professional autonomy undermine the profound public policy that physicians, who deal with the most intimate bodily functions, the most personal mental processes, and most profound life and death issues, will devote their entire professional judgment and training to the furtherance of their patients' best interests. n112

n111 *Id.* at 1.

n112 *Id.*

Exceptions can be quite illuminating when it comes to understanding legal doctrines like the corporate practice of medicine bar. Illinois, as we shall see, allows licensed hospitals, whether profit or nonprofit, to employ physicians despite a general prohibition against corporate employment of professionals. California courts, on the other hand, may contemplate an exception for nonprofits, but not for-profit corporate entities, whether or not they are independently licensed hospitals, allowing the reasonable inference that it is the profit motive that California finds objectionable when it comes to lay ownership. In *California Medical Association v. Regents* ("*CMA v. Regents*"), the court referred to commercialism as one of the "principal evils attendant upon the corporate practice of medicine." n113

n113 79 Cal. App. 4th 542, 550 (2000) (citing *People v. Pacific Health Corp.*, 82 P.2d 429, 431 (Cal. 1938)). For other states making an exception to corporate practice doctrines for nonprofits, see *Minn. Op. Att'y Gen.* 92-B-11, Oct. 5, 1955 (excluding nonprofit corporations from the prohibition on the assumption that they do not generally abuse corporate control and dominion); 1989 Va. Op. Atty. Gen. 283, 1989 WL 433173 (deciding that nonprofit foundation of medical college may employ physicians where there is no exercise of control over professional judgment).

CMA v. Regents involved an attempt by an anesthesiology group to block the UCLA Medical School from establishing a closed anesthesia service, which would have precluded any anesthesiologist in the area unwilling to practice as an employee and member of the Medical School faculty from practicing in the UCLA hospital system. The

case arose from UCLA's purchase of Santa Monica Hospital, where the plaintiff anesthesiologists had practiced. After the purchase, the Medical School offered the anesthesiologists an exclusive contract, but when they declined the Medical School staffed the anesthesiology department with Medical School employee physicians. The plaintiff anesthesiologists alleged not only breaches of California's corporate practice doctrine, but also that the arrangement would have entailed illegal fee-splitting and kickback arrangements. n114 The anesthesiologists were joined in their suit against the Medical School by the CMA, eager to defend California's corporate practice bar. The Court of Appeals for the Second District, however, held that UCLA Medical School, as a publicly-funded nonprofit, was exempted from the corporate practice bar. The rationale for the corporate practice doctrine, the Court said, is to curb potential corruption of professional judgment by the profit motive: "Concerns about for-profit corporations have nothing to do with non-profit teaching hospitals." n115 In addition, or perhaps as an alternative justification for its holding, the Court noted that the UCLA Medical School, as an instrumentality of the state, is exempted from the corporate practice doctrine because application of the corporate practice bar would effectively defeat the state's purpose in granting the University of California a charter to operate its medical center as a teaching and research institute. n116

n114 *CMA*, 79 Cal. App. 4th at 546. See CAL. BUS. & PROF. CODE §§ 650, 2400 (West 2005). Applicable California law would have permitted the Medical School to employ physician staff members in a teaching facility, but the plaintiffs contended that the clinic in question was not yet sufficiently integrated into the Medical School to qualify for such treatment. *CMA*, 79 Cal. App. 4th at 546-48.

n115 *CMA*, 79 Cal. App. 4th at 550.

n116 *Id.* at 548.

It does not appear to be settled that nonprofits may be exempted from the corporate practice bar in California. When the Fifth District Court of Appeal addressed the issue in *San Joaquin Community Hospital v. San Joaquin Valley Medical Group*, the court determined that no such exemption exists and that the only valid basis for the *CMA v. Regents* decision was that application of the ban to the UCLA Medical School would infringe on the powers granted to it as an instrumentality of the state. n117 *San Joaquin* involved, among other things, a "friendly" or "captive" PC arrangement between San Joaquin Community Hospital, a charitable nonprofit (Hospital) and a professional corporation originally owned by Dr. Carlos Alvarez, a physician serving a poor Hispanic community the Hospital wished to support as part of its charitable mission. The Hospital initially supported Dr. Alvarez directly with loans, and then agreed to forgive a portion of the loans and to acquire the practice. Because the Hospital could not directly purchase the practice under California law, n118 the acquisition was to take place in stages, the first of which involved converting the loans to options for stock in Dr. Alvarez's professional corporation, which would be held by licensed physicians designated by the Hospital, and the second of which involved the conversion of the practice entity into a management services organization (MSO), which could legally be owned by the Hospital. The MSO would then provide management services to Dr. Alvarez (or rather a new professional corporation established for his practice) in exchange for a percentage of practice revenues. n119 Cross-complainants in the dispute n120 alleged, and the court agreed, that the "friendly PC" arrangement constituted a violation of California's corporate practice bar, even when (i) holders of the stock in the professional corporation were licensed physicians, and (ii) the ultimate corporate entity in interest was a charitable nonprofit. Having determined that there is no exemption to the corporate practice bar for nonprofits, the court held that the Hospital could not do indirectly, through a professional corporation, what the law prohibited it to do directly, namely, exercise an owner's control over a medical practice: "We cannot imagine any consideration of public policy that would cause us to impute to the Legislature the intent to, on the one hand, ban corporate ownership of medical practices and, on the other, permit such ownership through mere 'straw men' acting on behalf of the corporation." n121

n117 *San Joaquin Cmty. Hospital v. San Joaquin Valley Med. Group*, Nos. F039938, F040280 & F041430, 2004 WL 1398551, at *17 (Cal. Ct. App., Jun. 23, 2004). The argument is deemed a "stretch" by a BNA commentator:

The California Education Code grants the University of California the authority to engage in instruction . . . at its medical schools, but that does not include providing, and collecting fees for, direct medical care to patients. The argument [advanced by the Medical School] that every patient is "potentially" a teaching case is a real stretch. The court was determined to carve out an exception from the corporate practice prohibition for the university, and did so using a combination of the "state sovereignty" doctrine and a broad interpretation of California's otherwise strict corporate practice prohibition to get that result.

See *The Corporate Practice of Medicine Prohibition in the Modern Era of Health Care*, Health Law & Business Library (BNA) No. 2800, § 2800.06.F (Dec. 2003) [hereinafter BNA Report].

n118 CAL. BUS. & PROF. CODE § 2400.

n119 California fee-splitting rules permit payment for management services based on a percentage of gross, but not net practice revenue. *Id.* § 650; see *supra* note 57 and accompanying text.

n120 Cross-complainants include Heritage Provider Network, Inc., a healthcare service plan challenging the Hospital's arrangement with Dr. Alvarez in connection with a dispute involving payments allegedly owed to the Hospital by the health plan. *San Joaquin*, 2004 WL 1398551, at *4-5.

n121 *Id.* at *18.

For the moment, then, California districts are arguably split as to whether there is an exemption from the corporate practice ban if sufficient absence of a profit motive can be established. Even if it is not clear whether California has settled the question of a corporate practice exemption for nonprofits, the fact that this is where California courts have considered the possibility of an exemption is diagnostic. It confirms the centrality of the profit motive to the analysis of questions of lay ownership of healthcare enterprises in California. If, as the court noted in *CMA v. Regents*, the "principal evils attendant upon the corporate practice of medicine spring from the conflict between the professional standards and obligations of the doctors and the profit motive of the corporate employer," n122 then there is no need to apply the doctrine when a profit motive does not exist.

n122 *CMA v. Regents*, 79 Cal. App. 4th 542, 550 (2000).

That there may be no *per se* exemption for nonprofits does not mean there can be no lay equity interest in healthcare enterprises in California. The *San Joaquin* court did not consider whether the proposed management agreement between the MSO and the new medical practice would have passed muster, but a management services agreement that could avoid the control pitfalls of that in *Moore* could conceivably succeed. California's fee-splitting statute, which expressly permits fee-sharing arrangements based on gross practice revenue, would seem to be conducive to management services arrangements. At last check, affiliates of Orthodontic Centers of America (the practice management entity involved in the *Moore* case) were still operating in California. And with respect to corporate employer or "friendly PC" arrangements, perhaps it should be noted here that even if the exemption applies only for state, teaching, nonprofit hospitals, as the *San Joaquin* court seems prepared to admit, that is a significant exception as both a theoretical and a practical matter. It is an exemption, even if so narrowed, that implicitly acknowledges that the California legislature does not perceive corporate practice to be an absolute evil, since it is willing to carve out the extremely large state medical school system.

Clearly, however, the corporate practice doctrine as established in California is quite restrictive. Neither *CMA v. Regents* nor *San Joaquin* involved any lay conduct of the sort the doctrine is intended to curtail, n123 and yet the doctrine was successfully invoked to prohibit the business arrangements in question. But then a substantive finding of harm is not an element necessary to stating a claim for violation of the corporate practice doctrine in California. As the CMA has been consistent in arguing in its various *amicus* briefs filed on behalf of practitioners in California, the protections afforded by California's corporate practice and fee-splitting prohibitions are "structural safeguards." n124 It

is a point well taken. Under California law certain arrangements, such as employment agreements between for-profit entities and professionals, are structurally illegal, and "[a]ctual 'medical' control need not occur for a violation of these Californian laws to be shown." n125 California appears to proceed from the assumption that if a structure that assures physician autonomy is in place, the concerns of public policy for patient care will be served, and if this structure is not in place, the arrangement is inherently flawed no matter what conduct ensues. In California, taken here as an example of a jurisdiction whose regulation of lay ownership proceeds from the principle of physician autonomy, it is evidently sufficient to considerations of quality of care to address the structural issue, and it is evidently less than critical to address cost issues when considering lay ownership of the healthcare enterprise.

n123 Regarding *San Joaquin*, "[t]here was no evidence in the present case that agents of Hospital actually interfered in Alvarez's medical decisionmaking." *San Joaquin*, 2004 WL 1398551, at *18. Regarding *CMA*, "[n]one of the abuses or practices that the prohibition was intended to prevent are [sic] present in the facts of this case (e.g., interference with the anesthesiologists' professional medical judgment, etc.)." BNA Report, *supra* note 117.

n124 *See, e.g.*, Opposition Brief of Plaintiff and Appellee California Medical Association at *1, *CMA v. Regents*, 79 Cal. App. 4th 542 (2000) (No. B135863), 1999 WL 33738691 [hereinafter Opposition Brief]; Brief for the California Medical Association as Amici Curiae Supporting Petitioners, at Introduction, *Affiliated Catholic Healthcare Physicians v. Emergency Physicians Med. Group*, (Cal. App. Dep't Super. Ct., Mar. 27, 1998) (No. C993954) [hereinafter Amici Curiae Brief], at www.aem.org/corporatepractice/amicus.html (last visited Dec. 27 2005).

n125 Amici Curiae Brief, *supra* note 124, at Introduction.

C. Licensure/Quality Assurance: The Patient Orientation

Illinois, like California, regulates the lay ownership of healthcare practices with both a corporate practice doctrine n126 and a fee-splitting n127 prohibition, but each is conceived in a significantly different manner from its counterpart in California. The argument of the discussion to follow is that the differences between the two state regulatory schemes reveal fundamentally different orientations. Whereas California courts may entertain exceptions to the corporate practice doctrine where there is demonstrable absence of a profit motive, Illinois courts tend to base any exception on the issue of licensure, n128 and in any event not solely on nonprofit status. n129 Any Illinois exceptions to the corporate practice ban for hospitals are premised not the hospital being a nonprofit, but on its licensure as a healthcare provider. In the alternative to a licensure exception, an Illinois court may find no violation of the state's corporate practice bar where responsibility for clinical and administrative conduct are respectively delegated to licensed and lay personnel. n130 California courts, by contrast, are generally unwilling to undertake to draw lines between clinical and administrative conduct. n131 Whereas in California a "captive PC" arrangement has been categorically dismissed by one court as an effort to achieve indirectly what is impermissible if attempted directly, n132 in Illinois such arrangements may be acceptable, as long as they properly delegate clinical responsibilities to duly licensed professionals. n133 Ultimately it is probably this willingness to entertain the possibility of segregating clinical and administrative conduct that distinguishes Illinois from California. Regulation in California proceeds from an expansive concept of physician autonomy, one that insists on the professional's ultimate control of all aspects of the practice, whether clinical or administrative. Illinois courts, on the other hand, proceeding from a narrower focus on clinical conduct alone, are willing to sanction arrangements in which physicians cede or delegate control over administrative aspects of the business of healthcare, as long as a licensed individual continues to be in charge of the delivery of healthcare. Depending on one's bias, Illinois could be said either to have a more restricted view of professional autonomy than California, or an inclination to focus more directly on the matters that fall within the purview of licensure and impact quality of care. This is not to say that Illinois is ultimately more concerned with quality assurance than California, but rather that the Illinois approach to preserving quality is more functional than structural. With respect to lay ownership, and solely with respect to the corporate practice doctrine, Illinois is, by virtue of its willingness to delineate and segregate licensure issues, more amenable to lay involvement with a healthcare enterprise. (The result with respect to fee-splitting regulations in the two jurisdictions is, as we shall see, somewhat different.)

n126 Based on the Illinois Medical Practice Act of 1987, 225 ILL. COMP. STAT. ANN. 60/3 (West 2005).

n127 225 ILL. COMP. STAT. ANN. 60/22-(A)(14) (West 2005).

n128 See *Berlin v. Sarah Bush Lincoln Health Ctr.*, 688 N.E.2d 106 (Ill. 1997).

n129 *Carter-Shields, M.D. v. Alton Health Inst.*, 777 N.E.2d 948, 958 (Ill. 2002).

n130 *Id.* at 957; *TLC Laser Ctr., Inc. v. Midwest Eye Inst. II, Ltd.*, 714 N.E.2d 45, 54 (Ill. App.Ct. 1999).

n131 See *supra* note 93 and accompanying text.

n132 *San Joaquin Cmty. Hospital v. San Joaquin Valley Med. Group*, 2004 WL 1398551, at *18 (Cal. Ct. App., Jun. 23, 2004). But for a court-tested arrangement in California that meets many of the criteria of a captive PC arrangement, including mandated exclusivity between the professional corporation and hospital, see *Mateo-Woodburn v. Fresno Cmty. Hospital & Med. Ctr.*, 270 Cal. Rptr. 894 (Ct. App. 1990).

n133 See *Cleveland HairClinic, Inc. v. Puig*, 968 F. Supp. 1227 (N.D. Ill. 1996) (professional services corporation had exclusive contract to perform hair transplant procedures at lay-owned clinic, which had exclusive right to provide management services to professional corporation); *TLC*, 714 N.E.2d at 54 ("We see no basis to conclude that a **company** which solely provides administrative services to a physician or group of physicians is thereby engaging in the corporate practice of medicine.").

At any rate, Illinois is among a group of states that infer a prohibition against the corporate practice of medicine from licensure statutes. Corporations cannot practice medicine, the reasoning goes, because they cannot be licensed to do so. Some such states, Illinois among them, go further and assert that the reason corporations cannot be licensed is that they cannot pass the exam, or satisfy certain of the other requirements for licensure, such as being twenty-one years old and of good moral character. For the limited purpose of medical licensure analysis, in other words, the legal fiction of personality otherwise generally attributed to corporations is withheld:

[The Medical Practice Act] prohibits the issuance of a license to any person unless he passes an examination of the qualifications therefor by and satisfactory to the Department of Registration and Education. The next section declares that each applicant for such examination shall, among other things, submit evidence under oath satisfactory to the department that he has attained the age of twenty-one years, that he is of good moral character, and that he has the preliminary and professional education required by the Medical Practice Act. . . . The legislative intent manifest from a view of the entire law is that only individuals may obtain a license thereunder. No corporation can meet the requirements of the statute essential to the issuance of a license. n134

n134 *People ex rel. Kerner v. United Med. Serv., Inc.*, 200 N.E. 157, 162-63 (Ill. 1936), *quoted in Berlin v. Sarah Bush Lincoln Health Ctr.*, 688 N.E.2d 106, 111 (Ill. 1997). The *Kerner* case suggests the reason Illinois goes to such lengths in claiming corporations cannot be licensed, as the respondent corporation accused of unlicensed practice of medicine in that case claimed that the applicable Medical Practice Act did not state what acts could be regarded as constituting the practice of medicine. 200 N.E. at 162. Accordingly, the court was forced to focus on the examination and other listed qualifications for licensure in order to uphold the doctrine.

Taken at face value, this reasoning seems disingenuous. If this court's argument were applied universally, it would compel the prohibition of hiring of pilots by airline **companies** on the grounds that the corporation, physically unable to

pass the exam to obtain a pilot's license, would be operating planes without a license. But clearly there is more behind the corporate practice doctrine than is explicit in this literalist argument. Illinois has centered its position regarding lay ownership of healthcare enterprises on the issue of licensure. The effect of this orientation can be seen by comparing the way the two jurisdictions deal with the issue of hospitals.

In the *CMA v. Regents* case discussed above, a California Court of Appeals exempted a hospital-based arrangement from the application of the corporate practice doctrine on the grounds that the "principal evil" with which the doctrine is concerned derives from the profit motive of lay owners, and there was no profit motive where a nonprofit teaching hospital was concerned. n135 In *Berlin v. Sarah Bush Lincoln Health Center*, the Illinois Supreme Court found the problem of lay control to have been alleviated where the lay entity in question was a licensed hospital that had taken steps to preserve physician control over medical services. The Illinois Supreme Court reviewed a decision by a county circuit court (subsequently affirmed by the appellate court) to grant summary judgment in favor of a plaintiff physician who sought to nullify his employment agreement with the medical center, and thus its noncompetition covenant, on the grounds that the employment agreement violated the prohibition on the corporate practice of medicine. n136 Dr. Berlin, a general surgeon, had been specifically recruited by the Health Center, at its expense, to relocate to its service area from New York. Initially Dr. Berlin operated as an independent contractor, but when he became dissatisfied with the development of his practice, he requested the employment arrangement that he later sued to nullify. n137 His employment agreement with the Health Center specified a five-year term with a two-year restrictive covenant prohibiting him from practicing medicine within a fifty-mile radius of the Health Center. Under the terms of the agreement, the Health Center collected fees for Dr. Berlin's services and paid him a salary. Barely over a year into the agreement, Dr. Berlin gave his notice and accepted employment from the Carle Clinic, a competing hospital, at a facility located approximately one mile from the Health Center. n138

n135 *CMA v. Regents*, 79 Cal. App. 4th 542, 550 (2000).

n136 *Berlin*, 688 N.E.2d at 107.

n137 Brief of Defendant-Appellant at *12-13, *Berlin* (No. 81059), 1996 WL 33468391.

n138 *Berlin*, 688 N.E.2d at 107-08.

The *Berlin* case was one of first impression in Illinois in deciding whether hospitals could employ physicians. Such employment practices were not novel, however, either in Illinois or in other jurisdictions throughout the United States, and accordingly the stakes were high. The court was called upon to determine whether the widespread practice of employing physicians and residents in hospital and clinic settings was legal. The case attracted significant attention from interested parties. n139 Amicus briefs were filed in support of Dr. Berlin by the Illinois State Medical Society, the Illinois State Dental Society, numerous local and county medical societies, physician associations, and physician networks, and in support of the Health Center by the Illinois Hospital and Healthsystems Association, the Chicago Health Care Council, the American Hospital Association, and Cook County. In the end, the Illinois Supreme Court declined to follow the lower courts in declaring Dr. Berlin's employment agreement and restrictive covenant to be void for violating the corporate practice doctrine, choosing instead to carve an exception for licensed hospitals:

[W]e find the public policy concerns, which support the corporate practice doctrine[,] inapplicable to a licensed hospital in the modern health care industry. The concern for lay control over professional judgment is alleviated in a licensed hospital, where generally a separate professional medical staff is responsible for the quality of medical service rendered in the facility. n140

n139 Including, one imagines, Dr. Berlin's new employer, the Carle Clinic.

n140 *Berlin*, 688 N.E.2d at 113-14.

The *Berlin* court grounded its holding on the notice it took of the effectiveness of separations observed between professional and lay conduct. Evidence of the deliberate delineation of clinical and administrative authority was abundant. It was evident in the very structure of the hospital, the court noted, where there was a separate medical staff organization charged with quality assurance. n141 There was also a provision in Dr. Berlin's employment agreement stipulating that the medical center could exercise no control over Dr. Berlin's medical judgment. n142 The court further noted that that "Dr. Berlin . . . never contended that the Health Center's lay management attempted to control his practice of medicine." n143 The implicit logic underpinning this analysis is that if there can be meaningful segregation of clinical and administrative conduct, the conduct with which licensure is concerned, and which has a direct impact on the quality of patient care, need not be compromised by lay influences. The *Berlin* court expressly declined to follow precedent in other jurisdictions basing a hospital exception from the corporate practice doctrine on the theory that hospitals employing physicians are "not practicing medicine, but rather . . . merely making medical treatment available." n144 That is, in searching for the theoretical basis upon which to pin its justification for a new corporate practice exception for hospitals, the court reviewed theories prevalent in other jurisdictions and expressly declined to take the "not practicing medicine" approach. The court declined, moreover, to anchor its exception on the fact that the Sarah Bush Lincoln Health Center was a nonprofit entity, and in this the *Berlin* court distinguishes itself from those in California that focus on commercialism as the "principal evil" to be guarded against: "We . . . see no justification," the court observed, "for distinguishing between non-profit and for-profit hospitals in this regard. The authorities and duties of licensed hospitals are conferred equally upon both entities." n145 Given the court's rationale for the corporate practice doctrine, the holding makes sense. An emphasis on the distinction between nonprofit and for-profit entities would perhaps have been more appropriate were the corporate practice doctrine logically grounded on concerns of commercialism, but in *Berlin*, the issue was licensure. For the same reason, in order to center on licensure, the court did not wish to dodge the issue by taking the "not practicing medicine" approach. n146

n141 *Id.*

n142 The employment agreement "expressly provided that the Health Center had no control or direction over Dr. Berlin's medical judgment and practice, other than that control exercised by the professional medical staff." *Id.* at 114 n.5.

n143 *Id.*

n144 *Id.* at 112.

n145 *Id.* at 113.

n146 *See id.* at 112. Illinois hospitals might well have wished the court had taken the "not practicing medicine" approach, given the liability problems attending a holding that they were in fact practicing medicine, but with a proper license.

Five years after *Berlin*, in *Carter-Shields v. Alton Health Institute*, the Illinois Supreme Court remained faithful to its focus on the state's licensure statute when asked to decide whether the exception to the corporate practice bar could be extended to an unlicensed, nonprofit organization, itself controlled by a licensed healthcare facility and a partnership of physician groups. n147 Dr. Carter-Shields had entered into an employment agreement containing a restrictive covenant with an unlicensed for-profit subsidiary of St. Anthony's Health Systems, itself a nonprofit organization. n148 Almost immediately, Dr. Carter-Shields expressed dissatisfaction with her employment arrangement, specifically with interference in the conduct of her professional practice from lay administrators. n149 Eventually she sought a

declaratory judgment to void the agreement and its restrictive covenant. The trial court denied her request and the Illinois Appellate Court for the Fifth District reversed. For its part, the Illinois Supreme Court refused to extend the exception created in the *Berlin* case for licensed entities to all nonprofit or charitable organizations and continued to apply the corporate practice prohibition to unlicensed corporations, whether profit or nonprofit. n150 Noting that the dispute between the doctor and the corporate employer centered on issues of professional conduct, n151 the court reasoned that the case exemplified "the pitfalls of corporations practicing medicine." n152 (Anyone having read a large number of corporate practice cases would be tempted to add that in this respect the case was unusual). *Carter-Shields* establishes that the hospital exception to Illinois's corporate practice doctrine may be somewhat circumscribed. It applies to licensed hospitals, but not their unlicensed affiliates. *Carter-Shields* confirms that for Illinois, unlike California, it is licensure, not nonprofit status that is critical to the analysis.

n147 777 N.E.2d 948 (Ill. 2002). The hospital's partner in the Institute consisted of a partnership of medical groups--one of whom had a nonphysician therapist as a partner. *Id.* at 950.

n148 The employment agreement was subsequently assigned by the employer to an Illinois medical services corporation whose sole shareholder was a doctor presumably having contractual ties to the hospital, as the doctor-shareholder appointed the hospital's president as the executive director of the medical services corporation. The medical services corporation appears to have been what is commonly known in practice as a "captive PC." *Id.* at 952.

n149 "Plaintiff complained repeatedly about the lay persons who were directing her practice and interfering with the treatment of her patients." *Carter-Shields v. Alton Health Inst.*, 739 N.E.2d 569, 575 (Ill. App. Ct. 2000).

n150 *Carter-Shields*, 777 N.E.2d at 958.

n151

The agreement outlined plaintiff's duties as a physician in AHI's employ. For example, the agreement set forth AHI's expectations with respect to the productivity of plaintiff's practice, including the number of weekly patient appointments plaintiff was required to schedule, as well as guidelines plaintiff was expected to follow in requesting time off. The agreement also outlined the obligations of AHI as plaintiff's employer. For example, the agreement stated that AHI was to provide plaintiff with office space and was to furnish plaintiff with the equipment, services, supplies, and personnel that AHI 'reasonably determines necessary' for the operation of plaintiff's medical practice.

...

... [And], (1) that, contrary to earlier assurances made by AHI that plaintiff would be able to fulfill her obligations to perform Army reserve duty without negative repercussions, she was subsequently informed that she would be forced to use vacation time or take unpaid leave; (2) that plaintiff's attendance at mandatory meetings set up by AHI reduced the amount of office time she could spend with patients; (3) that AHI failed to provide plaintiff with adequate staffing to set up and operate her medical practice; (4) that plaintiff had a dispute with AHI as to whether AHI had the right to compensation received by plaintiff as a result of her outside activity as a **nursing home** medical director; and (5) that although plaintiff had been assured by AHI that it would establish a retirement plan, she was concerned that AHI had taken no action to set up such a plan. In her letter, plaintiff stated that AHI's interpretation of her employment contract was "vastly different from the understanding I reached with AHI for the job of which I was recruited," and she requested that she be "involved in issues and decisions involving my office that relate to the practice."

Id. at 950-51.

n152 *Id.* at 954.

Based on *Berlin* and *Carter-Shields*, then, it would appear that Illinois may be willing to go only so far with respect to direct employment of physicians. For lay persons hoping to hold at least some of the sticks in the bundle of property rights that constitutes ownership, however, there continues to be hope in Illinois because of its licensure orientation. As far as the Illinois corporate practice doctrine goes (and without reference, for the moment, to its fee-splitting doctrine),

the focus on licensure, and the concomitant willingness of Illinois courts to take into account the facts as to whether there is or could be actual lay interference with professional judgment, has meant that certain management services arrangements are permissible. In *Cleveland Hair Clinic, Inc. v. Puig*,ⁿ¹⁵³ for instance, the lay owner of a hair transplant clinic was permitted to proceed with a suit against independent contractor physicians for breaching their professional services contract and the exclusivity covenant therein. The agreement was typical of PPMC arrangements, a long term (ten year) contract with reciprocal exclusivity covenants (the physician group had the exclusive right to provide professional hair transplant services and the clinic had the exclusive right to manage the professional group). The lay-owned clinic provided space, equipment, marketing and advertising, nonprofessional staff (and even employed nurses, surgical assistants and professional consultants), and general management services. All scheduling of the procedures was carried out solely by the clinic. The physician would have little if any contact with the typical patient beyond designing the treatment plan (usually in tandem with the clinic's employee consultant) and performing the actual surgery. Even then, of the three to eight hours a typical procedure would take, the doctor may have been present for only half an hour. Post-operative interviews, bandage changing and suture removals were performed by clinic employees.ⁿ¹⁵⁴

ⁿ¹⁵³ *Cleveland Hair Clinic, Inc. v. Puig*, 968 F. Supp. 1227 (N.D. Ill. 1996).

ⁿ¹⁵⁴ *Cleveland Hair Clinic, Inc. v. Puig*, 968 F. Supp. 1227, 1231-32 (N.D. Ill. 1996).

The court found no licensure or corporate practice violations with this arrangement. Litigation was initiated in response to conduct of Dr. Puig, who had conceived what the court determined to be "an opportunistic plan to ambush Cleveland Hair and to leave it in a position in which it would have no viable alternative other than to turn over its . . . operations 'lock, stock, and barrel' to Puig Group."ⁿ¹⁵⁵ Dr. Puig had solicited the clinic's employees, secretly obtained financing for the project, and commenced devastating the clinic's business. The U.S. District Court for the Northern District of Illinois found that the clinic had a protectable interest in its business sufficient to warrant injunctive relief.

ⁿ¹⁵⁵ *Id.* at 1243.

The *Cleveland Hair* decision was followed in *TLC The Laser Center, Inc. v. Midwest Eye Institute II, Ltd.*, which recognized the protectable interest of the lay purchaser of nonmedical assets of an ophthalmologic practice against corporate practice allegations leveled by ophthalmologists: "We see no basis to conclude that a **company** which solely provides administrative services to a physician or group of physicians is thereby engaging in the corporate practice of medicine."ⁿ¹⁵⁶ *TLC* involved a (familiar) dispute between a lay-owned management **company** seeking to enforce an exclusive management services agreement and non-competition and confidentiality covenants against physicians from whom the management **company** had purchased assets. The management **company** had sought to preserve its interest in what it maintained were commercial assets, including its trade name, marketing and sales information, pricing formulae, contracts, and other business practices. The agreement provided that the physicians would maintain control over "all aspects of their practice of medicine and the delivery of medical service at the TLC Facilities," but also that they would work no fewer than twenty-five hours per week at TLC.ⁿ¹⁵⁷ *TLC*'s complaint alleged that defendant surgeons conspired to "break away" from TLC, use TLC's trade name and confidential information, and divert patients to a new facility owned by the surgeons.ⁿ¹⁵⁸ The defendant physicians raised corporate practice and fee-splitting bars in their defense, and were unsuccessful with respect to the former.ⁿ¹⁵⁹ With respect to the corporate practice doctrine, the court held for the plaintiff management **company**, noting that applicable Illinois law was not simply the *Berlin* holding to the effect that only licensed entities could participate in medical enterprises, but rather that a lay entity could acquire a business interest in a medical enterprise cognizable at law, as long as the boundaries between lay and professional conduct are properly observed.ⁿ¹⁶⁰ In *dicta* the court noted, with detectable levels of sarcasm, that "[t]he contention could be made that the [corporate practice] doctrine is intended to protect the public, not to allow medical professionals to avoid contractual obligations."ⁿ¹⁶¹

n156 714 N.E.2d 45, 54 (Ill. App. Ct. 1999).

n157 *Id.* at 48.

n158 *Id.*

n159 *Id.* at 52. The fee-splitting issue, on which the defendants prevailed, will be considered below.

n160 *Id.* at 54-55.

n161 *Id.* at 55.

Thus far this Article has drawn a distinction between a regulatory orientation that asserts the preeminence of the principle of physician autonomy and one that proceeds to educe its principles from licensure regulations. Admittedly for convenience, and perhaps with some unfairness, the autonomy orientation has been attributed to California and the licensure orientation to Illinois. Both jurisdictions, of course, ultimately seek to ensure quality of care for patients by minimizing commercial interference with professional judgment; but there are nonetheless discernible differences in regulatory theory and application. The regulatory approach herein attributed to California has been termed "structural" by those intending to convey the fact that the court's inquiry can begin and end with questions of ownership and contractual control; n162 "[a]ctual 'medical' control need not occur for a violation of these [Californian] laws to be shown." n163 If California courts are reluctant to undertake line-drawing exercises to determine the boundaries between lay and professional conduct, Illinois courts have tended to venture there and consequently to inquire as to the existence of actual interference with professional conduct. n164 Structure can apparently be subordinated to function. From the vantage of the licensure orientation, autonomy is a principle that can be overvalued, with the effect that legitimate business interests may be sacrificed. From the vantage of the autonomy orientation, on the other hand, the licensure rationale may undervalue the threat of commercialism, the principal source of professional corruption.

n162 See Opposition Brief, *supra* note 124, at *1-2.

n163 *Id.* at *4.

n164 See *People ex rel. Illinois Soc'y of Orthodontists v. U.S. Dental Inst., Inc.*, 373 N.E.2d 635 (Ill. App. Ct. 1978) (inquiring as to whether a training school charged with corporate practice of medicine was diagnosing patients or performing other services covered by the licensure statute).

The respective positions of California and Illinois on the corporate practice issue, however, are not sufficient as explanations of their respective positions on the lay ownership of healthcare enterprises. While the *TLC* court, for instance, exonerated the lay-owned management **company** on the corporate practice issue, it ultimately held that the arrangement with physicians in question violated Illinois rules on fee-splitting. n165 Among the bundles of rights comprising property or ownership interests in medical enterprises, the division of revenue is clearly one of the most important, and the methods of its regulation must therefore now be addressed.

n165 *TLC*, 714 N.E.2d at 55, 57.

D. Cost: The Payor Orientation

In *TLC*, the lay-owned management **company** prevailed on its argument that it did not violate the Illinois corporate practice doctrine, but lost on the issue of fee-splitting. The court found that its compensation arrangement, in which the management **company** received a fee based on practice revenues in addition to its fee for services rendered, was illegal under Illinois law. n166 225 ILCS 60/22 makes the following illegal:

Dividing with anyone other than physicians with whom the licensee practices in a partnership, Professional Association, limited liability **company** or Medical or Professional Corporation any fee, commission, rebate or other form of compensation for any professional services not actually and personally rendered. n167

n166 *Id.* at 57.

n167 225 ILL. COMP. STAT. ANN. 60/22-(A)(14) (West 2005).

The management fee in question was not calculated as a percentage of revenue, but clearly increased as revenues increased, and this, the court held, was enough to violate not only the literal language of the statute but also the underlying public policy:

The policy reasons behind the prohibition are the danger that such an arrangement might motivate a non-professional to recommend a particular professional out of self-interest, rather than the professional's competence. In addition, the judgment of the professional might be compromised, because the awareness that he would have to split fees might make him reluctant to provide proper (but unprofitable) services to a patient, or, conversely, to provide unneeded (but profitable) treatment. n168

n168 *TLC*, 714 N.E.2d at 56.

The purpose of the Illinois statute, at least as recited by the *TLC* court, is to prevent improper lay referrals and the ill effects of provider underpayment. Presumably the legislature had envisioned, and wished to prevent, medical "mills," grinding out high-volume, low-quality medical services.

The teleology of Illinois' fee-splitting statute matches that of its corporate practice doctrine fairly well. Both emphasize quality of care. Working together, these two regulatory principles permit some variations on lay involvement with healthcare: a lay-owned entity may employ physicians, provided the lay entity is independently and appropriately licensed (*Berlin*); it may establish and enforce rights to a business plan involving the delivery of healthcare services, so long as the line between business and professional conduct is duly observed (*Cleveland Hair, TLC*); and it may simply provide management services to licensed healthcare providers, provided the compensation arrangement is neither a percentage of revenues nor an amount whose increases are too closely tied to increases in revenues (*TLC*). Given a situation for which a judicial consensus is relatively easy to reach, such as the medical "mill," these laws can be applied in confidence that public policy is being served. The corporate practice doctrine and fee-splitting statutes are simply complementary means of enforcing a licensure-based, quality-oriented public policy.

The problem is that it becomes increasingly difficult to discern the meaning, predict the effect, or articulate the rationale of fee-splitting rules the more one drifts from the consensus target situation like the medical "mill," and the target situation, it should be acknowledged, is often buried in history, like one of Professor Rosoff's legal landmines from a forgotten war. n169 Consider, for instance, that with relatively manageable adjustments the medical "mill" of

one era becomes the policy objective of another, a strategy for increasing access to healthcare while controlling cost. The AMA's stance against fee-splitting evolved in response to the late nineteenth century practice of surgeons paying family practice doctors for patient referrals, but eventually broadened to the point where the AMA opposed profit sharing plans that included lay employees. n170 The expressions of policy that fee-splitting prohibitions are intended to serve tend to change at a much faster pace than the literal language of the rules can accommodate. A rule that may have originated to restrain surgeons from paying family practice physicians for referrals has more recently been pressed into the service of the corporate practice bar, prohibiting nonprofessionals from sharing in practice revenue. n171

n169 Rosoff, *supra* note 8, at 499.

n170 Jacobs & Goodman, *supra* note 16, at 241; *see* STARR, *supra* note 7, at 136; MARC A. RODWIN, *MEDICINE, MONEY & MORALS: PHYSICIANS' CONFLICTS OF INTEREST* 23-31 (1993) (noting that historically fee-splitting rules were aimed at curbing the practice of dividing fees between professionals).

n171 *In re: Petition for Declaratory Statement of Magan L. Bakarania, M.D.*, 20 F.A.L.R. 395 (1997).

At their best, fee-splitting statutes may work together with corporate practice doctrines and other rules within a given jurisdiction to produce a harmonious regulatory effect. In California, for instance, the fee-splitting rule, which permits the division of gross but not net practice revenue, n172 is arguably consistent with the state's opposition to lay ownership generally, since the division of gross revenue would be consistent with payment of an expense to an independent contractor or employee, whereas division of net (profit) is the treatment a partner or co-shareholder could expect. In at least some jurisdictions in Florida, fee-splitting rules have been construed narrowly to apply only as a restraint on kickbacks and self-referrals, in part because it would be inconsistent with the fact that Florida has no corporate practice prohibition to apply the fee-splitting rules to prohibit lay ownership outright. n173 But the fact is that fee-splitting rules and corporate practice rules regulate entirely different aspects of the healthcare business, its organization and its economy, its structure and its revenue, respectively. The two regulatory systems are not necessarily linked. Accordingly, one will sometimes operate at odds with the other. Thus the court in *TLC*, after reproaching the professional who would invoke the corporate practice doctrine to avoid his contractual obligation, n174 was forced to reach that very result in its analysis of the fee-splitting issue.

n172 CAL. BUS. & PROF. CODE § 650 (West 2005) ("The payment or receipt of consideration for services other than the referral of patients which is based on a percentage of gross revenue or similar type of contractual arrangement shall not be unlawful if the consideration is commensurate with the value of the services furnished . . .").

n173 *See generally* Practice Mgmt. Assocs. v. Orman, 614 So. 2d 1135 (Fla. Dist. Ct. App. 1993).

n174 *See* *TLC The Laser Ctr., Inc. v. Midwest Eye Inst. II, Ltd.*, 714 N.E.2d 45, 55 (Ill. App. Ct. 1999).

Few jurisdictions have joined the fee-splitting issue more hotly than Florida. In *Orman*, Florida's Second District Court of Appeals applied Illinois law in a dispute between a practice management **company** and individual chiropractors who had defaulted under agreements to pay the **company**, Practice Management Associates, Inc. ("PMA"), a fee for practice development services. n175 *Orman* was a case of first impression for the appellate court, and will serve as a good introduction to the murky business of fee splitting rule construction. Faced with Illinois' simple proscription against "dividing" fees and lacking any statutory definition of the term, n176 the court looked to dictionary definitions, all of which suggested that "fee-splitting" was objectionable only to the extent that it was a method of payment for referrals. n177 As the Second District Court of Appeals was later to assert, fee-splitting statutes have to be narrowed, because taken literally they have the potential of making it illegal for doctors to pay their utility bills:

The contrary interpretation, if carried to its logical conclusion, would lead to absurd results. Presumably[,] all of [the physician's] gross income consists of "fees for services." If he were not permitted to "divide" those fees to pay such necessary expenses as secretarial salaries, office rent, and telephone charges, his practice would not long survive. n178

n175 Practice Mgmt. Assocs. v. Orman, 614 So. 2d 1135, 1136 (Fla. Dist. Ct. App. 1993).

n176 See 225 ILL. COMP. STAT. ANN. 60/20-(A)(14) (West 2005).

n177 Orman, 614 So. 2d at 1137.

n178 Practice Mgmt. Assocs., Inc. v. Blickensderfer, 630 So. 2d 1147, 1148 (Fla. Dist. Ct. App. 1993) (construing New York's law, which defines impermissible fee splitting in terms of "[p]ermitting any person to share in the fees for professional services." N.Y. EDUC. LAW § 6530.19 (McKinney 2005)).

To be sure no court has applied a fee-splitting rule to prohibit a professional from spending his income, but the Second District's point may be taken to show the need for judicial clarification of exceedingly vague language. The *Orman* court thus applied its referral-based definition to uphold a Practice Starter Agreement, which provided for chiropractors to pay the greater of 10% of weekly gross income or \$ 75 per week to PMA for counseling services intended to promote the growth of the chiropractic practices. Although the services rendered by PMA related to practice development, there was no direct payment for referrals and therefore, in the view of the court, no offense to the Illinois statute.

For its part, Illinois has consistently rejected the interpretation of its fee-splitting law propounded by Florida's Second District Court of Appeals. n179 For Illinois courts, a fee division may be impermissible even where there is no question of patient solicitation; perhaps because to hold otherwise would open a back door by which lay management **companies** could pass through the state's corporate practice bar and acquire the equivalent of an equity interest in professional practices. To permit lay managers to take a percentage of practice income simply by avoiding the referral issue would be to allow unlicensed persons to enjoy an ownership interest otherwise prohibited by the corporate practice bar. But in Florida, where there is no corporate practice bar, the *Orman* decision has progeny, at least in the Second Appellate District. In *Practice Management Associates, Inc. v. Gulley*, the Second District Court of Appeals held that substantially the same agreement at issue in *Orman* did not violate Florida's fee-splitting law applicable to chiropractors. n180

n179 See *TLC*, 714 N.E.2d at 45; *Lieberman & Kraff, M.D., S.C. v. Desnick*, 244 Ill. App. 3d 341, 346 (1993); *Licensed Occupations: Prohibited Fee-Splitting in Preferred Provider Contract*, 2002 Ill. Op. Att'y Gen. 005 (Mar. 5, 2002), available at www.ag.state.il.us/opinions/2002/02-005.html (last visited Dec. 20, 2005).

n180 Practice Mgmt. Assocs. v. Gulley, 618 So. 2d 259, 261 (Fla. Dist. Ct. App. 1993).

There is much to be said for the relatively restrained approach taken by the Second District in the early 1990s, limiting the fee-splitting statute to referral situations. For one thing, it was consistent with Florida's statutory language, and arguably much more obviously applicable there than to Illinois law, which prohibited any "dividing" of fees, or New York law, which similarly prohibited fee "sharing." The applicable Florida statute, by contrast to Illinois and New York, embedded the operative term "split-fee arrangement" in a referral or antikickback context, prohibiting "[p]aying or receiving any unearned commission, bonus, kickback, or rebate or engaging in any split-fee arrangement in any form whatsoever with a physician, organization, agency, or person, either directly or indirectly, for patients referred to

providers of healthcare goods and services." n181 Part of the attraction of limiting this law's application to referral situations is, as has already been mentioned, that this application is consistent with Florida's regulatory approach to the lay ownership issue generally. Florida law contained no express corporate practice bar, n182 and to the extent that this constituted a legislative policy to permit lay ownership, it would have appeared to some to be judicial overreaching to effectively bar lay ownership by prohibiting an arrangement where the lay owner could receive his share of the profits. n183 Put another way, a fee-splitting rule, in its narrowest configuration, regulates revenue, not organizational structure. It focuses on the revenue stream because its prime objective is to control cost, to restrain overutilization of medical goods and professional services, not to restrict the field of participants. The most direct effect of any restraint on improper referrals is to remove an incentive for revenue-generating conduct, to slow down the referral engine that otherwise drives the healthcare economy.

n181 *Id.* (quoting FLA. STAT. ANN. § 460.413 (1)(k) (West 1985)).

n182 FLA. BAR AD HOC LEGISLATION COMM., HEALTH L. SECTION, FINAL REPORT 38, available at www.flabarhls.org/hls/whatsnew/adhoc.pdf (last visited Dec. 21, 2005) [hereinafter FLA. BAR] (citing *In re: The Petition for Declaratory Statement of John W. Lister*) ("Florida law does not prohibit a duly licensed medical doctor from practicing as an employee of a corporation").

n183 See Brief for Appellee, *PhyMatrix Mgmt., Inc. v. Magan L. Bakaranian, M.D.*, No. 97-4543 (Fla. Dist. Ct. App., Apr. 17, 1998), cited in FLA. BAR, *supra* note 182, at 38.

But fee-splitting regulation can be so much more, as Florida discovered along with the rest of the country in the early 1990s. In 1991, the Office of the Inspector General promulgated the first eleven of several "safe harbors" from the Medicare/ Medicaid antikickback rules, n184 making it evident by inference that regulators might prosecute conduct that only indirectly stimulated referrals, such as below-market leases or practice acquisition transactions with payment provisions contingent on subsequent productivity. No longer would the federal government be bound to find a *quid pro quo* arrangement for compensating referrals before deeming conduct to violate Medicare's fraud and abuse regulations. n185 The effect of this approach, it was hoped, would be to magnify the effect of laws that restrained overutilization by restricting referrals. In this spirit, Florida enacted its Patient Self-Referral Act of 1992, n186 and its patient brokering statute, n187 which joined its antikickback n188 and fee-splitting n189 laws.

n184 OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952 (July 29, 1991) (codified at 42 C.F.R.pt. 1001).

n185

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by Federal health care programs. The statute has been interpreted to cover any arrangement where *one* purpose of the remuneration is to obtain money for referral of services or to induce further referrals.

OIG, HHS, Advisory Op. No. 10 (Aug. 31, 1998), available at www.oig.hhs.gov/fraud/docs/advisoryopinions/1998/ao98_10.htm (last visited Dec. 22, 2005).

n186 FLA. STAT. § 456.053 (2005).

n187 *Id.* § 817.505.

n188 *Id.* § 456.054.

n189 *Id.* § 458.331(1)(i).

Additionally, Florida's Board of Medicine initiated a series of rulings that departed from one of the fundamental assumptions of *Orman* and its progeny in the Second District. Whereas *Orman* had held that the inclusion of practice-enhancing services in a Practice Starter Agreement did not implicate antikickback regulations, the Board of Medicine initiated a series of rulings leading to another conclusion. The *Orman* court had distinguished compensation paid for management services, acceptable even if calculated as a portion of professional fees, from compensation paid solely for referrals, which the court deemed improper and illegal. The court observed that payment for management services could be consistent with the "complexities of marketing and management of professional services in today's competitive business environment without compromising the public policy behind legislation prohibiting or regulating the division of professional fees." n190 Payment for certain services on a percentage-of-revenue basis, the court implicitly acknowledges, may be appropriate, as with billing services, where the management activity necessarily varies in accordance with revenue; and rewards commensurate with productivity, as in the case of compensation for marketing services based on practice growth, are reasonable in an era that had relaxed its earlier abhorrence of professional advertising. n191

n190 Practice Mgmt. Assocs. v. Orman, 614 So. 2d 1135, 1138-39 (Fla. Dist. Ct. App. 1993).

n191 *See, e.g.*, Urowsky v. Bd. of Regents of the Univ. of New York, 362 N.Y.S.2d 46, 47 (1974) (upholding Board of Pharmacy regulations against advertising).

In 1995, in holding an employment compensation arrangement to involve illegal fee-splitting, the Florida Board of Medicine (Board) began expanding the reach of Florida's fee-splitting prohibition. The Board held a compensation arrangement to be illegal to the extent a physician was to receive, in addition to a base salary and a percentage of practice revenues generated by or under him, a percentage of all practice revenues in excess of a target level. This would have included revenues from ancillary services not performed by the physician (e.g., laboratory, radiology, diagnostic testing, and out-patient surgery fees) and to which the physician may have referred his patients. The Fifth District Court of Appeals affirmed over the objection of the physician that all ancillary services were performed "in house" within facilities owned or controlled by his employer and therefore did not constitute referrals subject to the fee-splitting prohibition. n192 The court noted that "the Board was concerned with the possibility that an employee physician's medical judgment might be skewed where that physician benefits financially from overutilization of ancillary tests and services even if performed by [his employer]." n193 Percentage-based productivity compensation was acceptable, but only to the extent of a division of the fees generated directly by or under the applicable physician. This, in the view of at least one commentator, represented a materially new gloss on Florida's fee-splitting statute, which "does not define fee splitting, and particularly, does not distinguish between fees earned from ancillary services and personal services." n194 The effect of the ruling, the commentator urges, n195 is to make a new distinction between employee physicians, who may not share in the fees from ancillary services, from owners (whether or not they may be physicians), who may participate in revenues from ancillary goods and services by virtue of their equity interest in the provider. n196 If Florida's fee-splitting statute had been conceived as a revenue-oriented regulatory scheme to curtail overutilization, with the Board's rulings it began to have an effect on the ownership of affected entities.

n192 Crow v. Agency for Health Care Admin., 669 So. 2d 1160, 1162 (Fla. Dist. Ct. App. 1996).

n193 *Id.* at 1162.

n194 Jacobs & Goodman, *supra* note 16, at 255-56.

n195 Jacobs and Goodman argue that the Board's holding constitutes unauthorized rulemaking, and that in this respect the state agency borrows from federal agencies in their promulgation of Stark II regulations that effectively "preclude group practice physicians from being compensated for designated [ancillary] self-referred health services." *Id.* at 256-57.

n196 *But see In re: Petition for Declaratory Statement of George G. Levy, cited in FLA. BAR, supra* note 182, at 37 (holding that the employer physician may not share in fees of employee radiologist where employer physician did not actually perform or supervise performance of radiologist services). Other commentators have noted that Board's rulings are inconsistent. *FLA. BAR, supra* note 182.

Consistent with its undertaking to expand the reach of Florida's fee-splitting sanctions, the Board scrutinized independent contractor compensation arrangements for evidence of fee-sharing based on referrals rather than services. As a general proposition, the Board accepted arrangements in which the professional's fees were paid directly to management corporations that retained a percentage for providing office space, advertising, billing, and administrative services. n197 But where a clinic and an independent contractor physician divided on a percentage basis fees from the physician's services to clinic patients both within and outside the clinic, the Board found a fee-splitting violation, as some of the revenue thus retained by the clinic would not have related to services or overhead provided by it and would thus have been attributable to payment by the physician for referring the patient. n198

n197 *See In re: The Petition for Declaratory Statement of Edmund G. Lundy, M.D., cited in FLA. BAR, supra* note 182, at 38.

n198 *See In re: The Petition for Declaratory Statement of Gary R. Johnson M.D. and the Green Clinic, cited in FLA. BAR, supra* note 182, at 39; *In re: The Petition for Declaratory Statement of Paul B. Speiller, M.D., cited in FLA. BAR, supra* note 182, at 39.

The Board rulings of perhaps the greatest consequence to practice management **companies** were those circumscribing the kinds of services that could be compensated on a percentage basis. Whereas the *Orman* court had held that payment for management services, even practice enhancement services such as marketing and advertising, could be structured as a percentage of revenues "without compromising the public policy behind legislation prohibiting or regulating the division of professional fees," n199 the Board, perhaps again following the lead of federal regulatory agencies, n200 began to view practice enhancement services as a species of referral to which the fee-splitting prohibition might apply. Thus, in *In re: Petition for Declaratory Statement of Joseph M. Zeterberg, M.D.*, the Board objected to a fee-share arrangement that included "'the activities of the [management] **company** going out and marketing allergy care services.'" n201 The Board's approach culminated in *In re: Petition for Declaratory Statement of Magan L. Bakarania, M.D.*, in which the Board rejected a proposed management agreement between Dr. Bakarania and a PPMC called PhyMatrix. n202 Under the agreement PhyMatrix would have provided "practice expansion" services, such as access to a provider network, providing ancillary services and negotiating managed care contracts, and would have received, among other forms of compensation, a performance fee equal to thirty percent of practice net income. The Board concluded that the practice expansion services helped generate referrals upon which its compensation would ultimately be based, and was therefore illegal as a fee split tied to referrals. The Board's decision was affirmed by the First District Court of Appeals in 1999 in a one-paragraph per curiam opinion to the effect that the Board's interpretation of the law was not clearly erroneous. n203

n199 *Practice Mgmt. Assocs. v. Orman*, 614 So. 2d 1135, 1139 (Fla. Dist. Ct. App. 1993)

n200 *See* OIG, HHS Advisory Op. No. 4 (1998), *cited in FLA. BAR, supra* note 182, at 44 (concluding that a PPMC agreement including passive marketing responsibilities for which the PPMC was paid on a percentage basis implicated the anti-kickback statute since the arrangement could encourage overutilization and upcoding).

n201 *FLA. BAR, supra* note 182, at 41 (quoting Board of Medicine).

n202 *In re*: Petition for Declaratory Statement of Dr. Magan L. Bakarania, *M.D.*, 20 F.A.L.R. 395 (1997), *cited in* FLA. BAR, *supra* note 182, at 41-42.

n203 PhyMatrix Mgmt. Co. v. Bakarania, 737 So. 2d 588 (Fla. Dist. Ct. App. 1999).

Although the *Bakarania* decision may be limited to contracts in which the management **company** is *obligated* to generate referrals, n204 it had a chilling effect on PPMC operations in Florida, n205 and was widely received as a ban on percentage-based management fees generally. n206 Whatever the final position in Florida on percentage payment for practice enhancement services, *Bakarania* evidences the potential of a fee-splitting statute to have a very broad effect. *Bakarania* has been perceived in some quarters as a *de facto* corporate practice bar, making it difficult for anyone but another licensed professional to hold an equity interest in a practice that in turn would constitute a claim against profits and thus violate the fee-splitting bar.

n204 *See In re*: Petition for Declaratory Statement of Rew, Rogers & Silver, M.D.s, P.A., *cited in* FLA. BAR, note 180, at 54 (providing that a percentage management fee did not necessarily violate the statute if the management **company** was not responsible for generating referrals).

n205 *See* Marshall R. Burack, *Florida Board of Medicine Resists Change*, 7 U. MIAMI BUS. L. REV. 485, 489 (1999).

n206 *See* Jacobs & Goodman, *supra* note 16, at 240.

Florida has witnessed other applications of the fee-splitting rule to restrict lay ownership. In *Medical Management Group of Orlando, Inc. v. State Farm Mut. Auto. Ins. Co.*, the court held the re-assignment of practice receivables from the provider to a manager constituted an improper fee-splitting arrangement. Here a lay-owned medical management entity took assignment of patients' rights to insurance reimbursement from an MRI facility. The management **company** did not, strictly speaking, share the professional fee, but the court noted the management **company's** role in attracting business to the MRI facility and accordingly held the practice a violation of Florida's antikickback fee-splitting prohibition. n207 The resulting anti-reassignment rule has a counterpart in Medicare rules, which prohibit re-assignment of the patient's assignment to his physician of the patient's right to reimbursement under the Medicare program. n208 The effect is to solidify the provider's control of a fundamental attribute of ownership, the revenue stream.

n207 *Med. Mgmt. Group of Orlando, Inc. v. State Farm Mut. Auto. Ins. Co.*, 811 So. 2d 705, 706 (Fla. Dist. Ct. App. 2002).

n208 *See supra* note 65.

However close Florida courts may come to a position similar to the corporate practice bar in Illinois or California, Florida proceeds from a very different premise. Florida courts are consistent in viewing improper incentives for *referrals* as the principal evil to be guarded against, and the rationale underlying this is the concern that improperly motivated referrals lead to overutilization of medical goods and services. To the extent that this regulatory perspective focuses on restraining improper professional conduct and controlling healthcare costs, it is manifestly different from California's focus on provider autonomy or Illinois's focus on licensure. California appears tolerant of some exceptions to its rather broad fee-splitting prohibition, but in a manner that evidences its differences with Illinois and Florida on policy with respect to lay participation in healthcare enterprises. California, as mentioned above, n209 permits fee-sharing as a division of gross but not net revenue, the net number being that which partners would presumably share, whereas a division of gross revenue would be consistent with the manner in which some businesses would pay for services (commissions, for example). California's position on fee-splitting is thus consistent with its approach to regulating lay ownership of healthcare enterprises generally, approaching the issue in structural and organizational terms. As in California (but unlike Florida), under Illinois law the policy against fee-splitting can be violated whether or

not a physician referral is at issue, and regardless of whether the fee is split on a percentage or flat fee basis. n210 Thus, in *The Laser Center, Inc. v. Midwest Eye Institute II, Ltd.*, the management services contract in question was held to violate Illinois' fee-splitting rule n211 because the management fee was based directly on professional revenues, although not on a percentage basis, and without the necessity of a showing that the arrangement might have influenced the professional's referral practices. n212 The arrangement offended the same policy that stands behind the Illinois corporate practice rules, namely, that only licensed individuals should be in the business of providing professional services. This is a concern that Florida does not share.

n209 CAL. BUS. & PROF. CODE § 650 (West 2005) ("The payment or receipt of consideration for services other than the referral of patients which is based on a percentage of gross revenue or similar type of contractual arrangement shall not be unlawful if the consideration is commensurate with the value of the services furnished . . .").

n210 Practice Management, Ltd. v. Schwartz, 628 N.E.2d 656 (Ill. App. Ct. 1993) (rejecting fee based on percentage of net).

n211 225 ILL. COMP. STAT. ANN. 60/22-(A)(14) (West 2005).

n212 TLC The Laser Ctr., Inc. v. Midwest Eye Inst. II, Ltd., 714 N.E.2d 45, 56 (Ill. App. Ct. 1999).

IV. Shortcomings of State Regulatory Programs

This section provides a few general observations on the various state programs affecting lay ownership, starting with some relating to matters of form.

A. Formal Characteristics

First, these laws are multifarious. They vary from state to state; they are susceptible to rapid transformation over time; and they are statutory, common law doctrine, and in at least one case codified common law. n213 They may regulate organizational structure, as in the case of the corporate practice doctrine expressed as a prohibition against lay ownership of a healthcare entity; professional conduct, as with statutes and common law doctrines prohibiting the unlicensed practice of medicine; or receipts, as with fee-splitting and anti-assignment restrictions. Our federalist system is costly and risky for those seeking to do business with healthcare professionals on a national scale.

n213 See *supra* notes 42, 52.

Second, these laws tend to be reflexively and excessively proscriptive, and, as a related observation, protectionist. Where commercial conduct has been perceived to have a potential to corrupt professional judgment, the regulatory response has historically been to prohibit, if not criminalize, everything that would make the conduct possible. n214 Where the prospect of department stores providing medical services was offensive, the response has been to make it illegal, not just for retail commercial enterprises but for any corporation to employ healthcare professionals. n215 The history of such regulation has often included a subsequent staged retreat from a radically proscriptive position as needed to make it accord with reality. Thus, while many states initially reacted to the perceived or real excesses of corporate medicine in the early part of the last century by prohibiting corporate practice altogether, by 1971 all states had created statutory exceptions to the ban on practicing medicine in a corporate format by authorizing the formation of professional corporations, generally with the stipulations that (i) no lay persons could own shares or hold offices and (ii) no professional could thereby limit liability for professional negligence. n216 Likewise, where it has been perceived that the duty of loyalty of a physician to her patient would be divided if the physician simultaneously owed a duty of loyalty to an employer, the response has been to prohibit all business corporations from employing physicians. In jurisdictions where this extreme position was adopted, retreats have been ordered for various employment practices,

including employment by professional corporations, by hospitals, by certain nonprofits, or by licensed entities. Where it has been perceived that physicians are more likely to refer their patients for MRI testing when the physician owns an interest in the MRI facility, the response has been to prohibit physicians from referring to facilities in which they have a financial interest, or from sharing fees, or from assigning receivables; and reasonable exceptions have been carved for referrals and fee divisions within a network, a partnership, or between employer and employee. From a regulatory viewpoint, the advantage of a radically proscriptive approach with extreme sanctions is that it can be effectively and efficiently administered on a wide scale. It is much easier to identify misconduct that has been defined structurally (Doctor X referred her patient to an MRI facility in which she held an ownership interest) than to evaluate individual conduct (did Doctor X's referral of her patient to her own MRI facility constitute overutilization of medical services?).

n214 Federal Medicare/Medicaid payment regulations, which as a practical matter drive most healthcare business arrangements, carry criminal sanctions. See Federal Fraud and Abuse Act § 1128B, 42 U.S.C. § 1320a-7(b) (2005); Stark Law, 42 U.S.C. § 1395nn (2005).

n215 See *Neill v. Gimbel Bros., Inc.*, 330 Pa. 213, 221-22 (1938).

n216 See *supra* note 16; Rosoff, *supra* note 8, at 495 (noting the dual characteristics of professional corporations in most states).

Such regulation is conceived with the virtuous intention of **protecting** all persons involved in transactions in which one or more participants are often disadvantaged. The physician, history had shown, could be disadvantaged by a corporate employer to whom a legal duty was owed; n217 but the professional is not the only member of the triad of the healthcare economy that gets protection. Both the patient and the payor are also perceived as needing protection under one or another regulatory program. As professionals may need protection from the often rather vaguely conceived threat of commercialism, patients and payors need protection from professionals. Clearly a patient can be disadvantaged by the disequilibrium of knowledge and information existing between herself and her physician when it comes to medical matters. n218 Where the patient is not the payor, and indeed may be insensitive to issues of cost because the payor is a third-party insurer, the payor is at a clear disadvantage when it comes time for the practitioner and the patient to agree upon course of action and price. n219 Something in this perceived need for mutual protection, however, suggests a regrettable lack of faith in the integrity of persons otherwise engaged in a fiduciary relationship. Perhaps because of the magnitude of the healthcare portion of the national economy, n220 or the portion thereof sustained by public funds, n221 or because of the difficulty in regulating such an economy without the use of *in terrorem* measures, relatively little is left to trust when it comes to regulating the business of healthcare. Thus to protect the autonomy of professionals, states have implemented various aspects of the corporate practice of medicine doctrine. To protect the interests of patients and payors, the federal and various state governments have implemented antikickback, self-referral, and fee-splitting rules to eliminate inducements for the overutilization of medical services.

n217 See generally STARR, *supra* note 7, at 198-232.

n218 See Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941, 951 (1963).

n219 See *id.* at 962.

n220 \$ 1.6 trillion, or nearly 15% of the gross national product in 2002. BARRY R. FURROW ET AL., HEALTH LAW: CASES, MATERIALS AND PROBLEMS 497 (5th ed. 2004).

n221 Approximately 45% of all healthcare expenditures. See Earl Dirk Hoffman, Jr. et al., *Overview of the Medicare and Medicaid Programs*, in CMS, HHS, HEALTH CARE FINANCING REVIEW, 2003 STATISTICAL SUPPLEMENT 2, available at www.cms.hhs.gov/apps/review/supp/2003/overview.pdf (last visited Jan. 4, 2006).

Although regrettable, and although it may be fair to say that the protectionism of state healthcare regulation undervalues the integrity of the medical professional (notably to a degree the legal profession has not had to suffer), the impetus is nonetheless understandable. There is simply too much of what Kenneth Arrow termed "moral hazard" in the fabric of the healthcare profession to permit us to allow it to self-regulate, to find its own ethical level. n222 Normal market forces cannot work unassisted to protect the interests of professionals, patients, and payors. To a large extent, the patient must rely upon the doctor not only to diagnose the condition and prescribe the treatment, but also to inform the patient of the extent to which the physician was successful in both undertakings. The payor, often absent at all relevant times, must trust both other parties, each with an interest adverse to its own, to negotiate cost. This is not a market that readily corrects itself. Information about the costs and benefits of services is not fully transmitted among the provider and consumer of and the payor for the services. n223

n222 Arrow, *supra* note 218, at 961; see JOSEPH FLETCHER, MORALS AND MEDICINE: THE MORAL PROBLEMS OF: THE PATIENT'S RIGHT TO KNOW THE TRUTH, CONTRACEPTION, ARTIFICIAL INSEMINATION, STERILIZATION, EUTHANASIA at viii-ix (1954).

n223 Arrow's point about what he calls "informational inequality" is not that the typical patient did not go to medical school, but that unlike the purchaser of a car, who can determine the effectiveness of what he has purchased, the typical patient does not know how to determine whether the service provided by the physician is optimal, or even effective.

To avoid misunderstanding, observe that the difference in information relevant here is a difference in information as to the consequence of a purchase of medical care. There is always an inequality of information as the production methods between the producer and the purchaser of any commodity, but in most cases the customer may well have as good or nearly as good an understanding of the utility of the product as the producer.

Arrow, *supra* note 218, at 951-52.

It is also important to note in connection with this catalog of formalist characteristics of the subject body of laws, rules, and regulations that they are fragmentary. They tend to regulate fewer than all aspects of the conduct they seek to control, and as a result they have been relatively ineffective, taken individually. Thus a rule against the employment of professionals can be circumvented by replicating the terms of an employment agreement within the context of an independent contractor arrangement, and a rule against dividing fees on a percentage basis can be circumvented by dividing them on some other basis, or resorting to flat fees subject to adjustments, and so forth.

Put another way, each of the regulatory subclasses identified in the foregoing discussion--those respectively oriented towards the provider, the patient, and the payor--is deficient in its own way when viewed from a perspective that accommodates all three orientations. The provider orientation overvalues physician autonomy and undervalues cost issues. The payor perspective is the reverse; it overvalues economic incentives (the danger that a profit motivation will lead professionals to overutilize healthcare goods and services) and correspondingly undervalues professional integrity. For its part, the patient orientation arguably overvalues regulation itself in the pursuit of quality assurance through licensure.

One problem with such rulemaking is the problem of the baby and the bath water. Blanket restrictions on physician self-referrals may inhibit the commercial development of innovative technology. Doctors, who may be in the best position to evaluate the utility of new technology, could be a valuable source of financing, were it not for the moral hazard. So too, general structural prohibitions on lay ownership are not properly targeted to the "evils" at issue.

As a final and related observation about matters of form, the laws, rules, and regulations in question are Protean. They begin as one thing and rapidly become another. Thus fee-splitting statutes, as we have seen, can evolve to the point where they effectively achieve what corporate practice prohibitions are intended to do, prohibiting lay ownership of healthcare enterprises. Similarly, licensure statutes may be interpreted to prohibit corporations from practicing medicine. The rules in this class have a tendency to become unruly, to serve new masters, new rationales, as shifts in the perception of public policy from time to time require. Thus a rule that may have originated in response to pressures of

medical societies to restrict professional advertising can become state versions of federal Medicare/Medicaid fraud and abuse regulations, restraining kickbacks and physician self-referrals. n224

n224 The point was made in the context of Florida's fee-splitting rules; but evidence of the federalization of state healthcare regulation is widespread. Pennsylvania's Workers' Compensation regulations, for instance, simply incorporate by reference the federal Stark exceptions to transactions that would otherwise constitute prohibited self-referrals. 34 PA. CODE § 127.301(c) (2005).

B. Application

Reflection on the application of state laws, rules, and regulations affecting lay ownership provokes another set of observations. First, as mentioned above, they have historically been less than effective, at least to the extent that they have been circumvented by sufficiently determined and resourceful parties. Secondly, they have too frequently been invoked disingenuously by practitioners seeking to unwind bargains voluntarily entered into, often from which the defaulting party has already disproportionately reaped the benefit. n225

n225 See *TLC The Laser Ctr., Inc. v. Midwest Eye Inst. II, Ltd.*, 714 N.E.2d 45, 55 (Ill. App. Ct. 1999) (The applicable doctrine "is intended to protect the public, not to allow medical professionals to avoid contractual obligations.").

It may also be added in this connection that in their application these laws often appear to have an unequal impact on the parties. Witness the equal protection argument historically advanced to challenge state statutes restricting the practice of medicine to professional corporations. n226 Whatever the merits of the assertion in that case, it seems clear that what may, as a practical matter, constitute a relatively immaterial formal difference can produce a materially different legal result. Thus where a hospital can employ a physician, a wholly-owned subsidiary of the same hospital may not; or where a hospital may not employ a physician, a captive professional corporation wholly owned by a physician controlled by the hospital may do so.

n226 See generally *Garcia v. Texas State Bd. of Med. Exam'rs*, 384 F. Supp. 434 (W.D. Tex. 1974).

C. Doctrinal Shortcomings

It is not news that the various rationales traditionally invoked to support doctrines restraining lay ownership of healthcare enterprises are logically flawed. n227 A more compelling question is, given their flaws, why have these rationales not been finally and definitively discarded? What is the source of their resilience?

n227 See generally HALL & VAUGHN, *supra* note 18, at 3-19 to -23.

1. The Autonomy Orientation

Those jurisdictions that, like California, tend to resist lay ownership on the theory it would damage professional autonomy generally point to the dangers of "commercialism," lay control over professional judgment, and division of the physician's loyalty between a lay employer and the patient. n228 In the application of its protective doctrines, such a jurisdiction abhors lay employment of physicians, but may create an exception for nonprofits, and generally tolerates independent contractor arrangements between lay managers and physicians. Employment arrangements are suspect chiefly because the employed physician is thought thereby to have potentially conflicting duties of loyalty to the employer (presumably to maximize profits and minimize expenses) and the patient; but an exception may be contemplated for nonprofits, presumably because they lack the profit motive of a commercial enterprise. Independent contractor arrangements are presumably tolerated because the physician retains autonomy over professional matters,

and in any event has no duty of loyalty corresponding to that owed to an employer. Where the same jurisdiction has a fee-splitting prohibition, it can be made consistent with the foregoing position on employment and independent contractor arrangements by permitting a division of fees on a basis that accommodates the latter but not the former. That is, the fee-splitting rule may permit a division of gross but not net revenue, since the former is consistent with payment for independent contractor services (such as billing or marketing services, which reasonably relate to revenue generated), while the latter implies a business partnership, a forbidden equity arrangement.

n228 For a list of reasons for resisting lay-ownership of healthcare enterprises, including commercialism, lay control of professional judgment, and division of the physician's loyalty, see Chase-Lubitz, *supra* note 5, at 467-70.

Very little of the foregoing withstands scrutiny. First of all, with respect to "commercialism," it should be acknowledged from the outset that economic motivation exists regardless of the practice format, even where the physician's employer is not a business corporation--even, one might add, where the employer is a professional corporation, or, for that matter, where there is no employer. If the problem were simply that economic motives can divert the professional from acting in the best interests of the patient or the payor, it would have to be acknowledged that a doctor would be faced with that conflict whether she worked independently, for a nonprofit hospital, a for-profit hospital, or for a public **company**. Charitable institutions have revenue needs as palpable as those of commercial enterprises, and can as easily exert economic pressure on their professional employees. It would make little difference in an analysis focused wholly on the problem of economic coercion of professional conduct whether the coercive pressure were to come from shareholders, an employer, or creditors--or whether the employer were a lay entity, a professional corporation, or a nonprofit.

It seems hardly worth the effort to point out that what defines a nonprofit corporation is not a lack of interest in making a profit from operations; but having done so, we may also note the fallacy in the argument that nonprofits, as such, deserve an exemption from the corporate practice bar when "commercialism" is the "principal evil" to be guarded against. n229

n229 See *CMA v. Regents*, 79 Cal. App. 4th 542, 550 (2000) (The profit motive is one of the "principal evils attendant upon the corporate practice of medicine.").

But in fairness to proponents of the "commercialism" rationale for the corporate practice and fee-splitting doctrines, the real objection must arise when the physician employee is subject not to conflicting economic temptations or coercions, but to conflicting legal duties. The physician employee, that is, has a legal duty to her employer and a professional duty to her patient, and the two duties could conceivably diverge. Those jurisdictions advocating the "commercialism" rationale are perhaps contemplating the situation in which the employer demands higher productivity at the expense of good medical practice. n230

n230 See generally *Moore v. Orthodontic Ctrs. of Am., Inc.*, No. N080601, 2002 WL 32351 (Cal. Ct. App., Jan 11, 2002); *Carter-Shields v. Alton Health Inst.*, 777 N.E.2d 948, 950 (Ill. 2002).

Yet the "divided loyalty" argument is also flawed. Legislative responses to the objection already exist both federally and in many states, chiefly in the context of HMO legislation. HMO enabling legislation provides in one way or another that the business arrangement may not interfere with the independent professional judgment of the clinician. It may be fairly argued that this solution is in many ways inadequate, and that as a practical matter it is often impossible to distinguish clinical and administrative matters; n231 but this argument is of necessity made in the face of legislation that, if nothing else, makes it clear that public policy does not prohibit an enterprise from proceeding under the promise of undertaking to observe the distinction. n232 There would seem to be no compelling public policy rationale, then, to preclude other healthcare delivery enterprises from attempting the same thing contractually. It is unlikely that the duty

owed to an employer by a physician employee is nonwaivable in any jurisdiction, and if it were, there is no reason it could not be made waivable by legislative act within the context of healthcare contracts, so that the employer could agree to subordinate to clinical matters.

n231 Witness the court's rejection of line-drawing solutions in *Moore*, 2002 WL 32351 at *5, (following *Parker v. Bd. of Dental Exam'rs*, 14 P.2d 67, 71-72 (Cal. 1932)).

n232 See *supra* note 53.

State laws permitting professionals to incorporate illustrate another flaw in the "division of loyalty" argument. The reasoning behind exempting professional corporations from the corporate practice bar is somewhat tenuous, as it would seem to depend on the dubious proposition that a physician, *qua* shareholder or employee of a professional corporation, does not have interests or duties that conflict with her duty of loyalty to patients. Nothing in the fact that only licensed professionals may own shares of a professional corporation compels the conclusion that as such they have a duty to patients. Certainly physician shareholders may not raise their duty to patients as a legal defense against corporate obligations to trade creditors, or even other shareholders. Why then should legislatures that otherwise seek to promote physician autonomy, exempt professional corporations from the corporate practice bar? One conclusion from the fact that they do so is that there may in fact be no logically compelling public policy against the corporate practice of medicine.

One further important, if somewhat provocative, argument against the "division of loyalty" justification for physician autonomy regulation is that in certain respects perhaps the physician's loyalties *should* be divided. Perhaps at some point the physician should be required to respond to an obligation to the public at large to exercise reasonable restraint in the application of resources to a particular patient. Like managed care organizations, society may have a legitimate right to redirect the professional from the single-minded pursuit of the best interests of her patient.

Another fallacy among laws restricting lay ownership of health-care entities is the apparent assumption that, from the perspective of the patient, employment arrangements are necessarily worse than independent contractor arrangements. Is the duty a professional owes to her employer essentially more detrimental to the patient than a duty the same professional may incur through another form of contract? True, the extensive body of employment case law may help define the duty when nothing is expressed in an employment contract; but there is no reason that equally conflict-burdened stipulations could not be expressed in a carefully designed professional services agreement. It is unclear why the corporate practice of medicine doctrine should apply to employment of physicians, but not to provider contracts with physicians. By the same token, since any potential conflict of duty in an employment agreement is presumably waivable by the parties, an employment arrangement would seem as susceptible to redemption as an independent contractor arrangement with respect to establishing the priorities of the professional. From this perspective it is unclear why the corporate practice of medicine doctrine should apply to either an employment or an independent contractor arrangement. In any event, it is an evident weakness of the doctrine that under rules currently in effect it can be effectively circumvented with form over substance subterfuge, by substituting for an employment agreement a substantially equivalent independent contractor provider agreement.

2. Patient Orientation

The "licensure" rationale for the corporate practice doctrine has its own difficulties with logic. As developed in the Illinois line of cases following *Berlin*, the licensure rationale states that only individuals, not corporations, are capable of meeting the requirements established by licensure laws for the practice of medicine. This rationale involves construction of statutes and regulations, and in this activity it is generous with respect to hospital licensure regulations and stingy with respect to business corporations. The *Berlin* court, for instance, generously construes the Illinois Hospital Licensing Act to infer legislative authorization to employ physicians from its definition of a "hospital" as: "any institution . . . devoted primarily to the maintenance and operation of facilities for the diagnosis and treatment or care of

. . . persons admitted for overnight stay or longer in order to obtain medical . . . care." n233 From this language and language in Illinois' Hospital Lien Act and Hospital Emergency Service Act referencing the provision of medical services by hospitals, the court concludes that the licensure statute implicitly authorized the employment of physicians, because how else could hospitals provide the services contemplated? n234

n233 210 ILL. COMP. STAT. ANN. 85/3-(A) (West 1995).

n234 The court reasoned as follows:

In addition, the Hospital Lien Act provides "[e]very hospital *rendering service in the treatment, care and maintenance, of such injured person*" a lien upon a patient's personal injury cause of action. Moreover, the Hospital Emergency Service Act requires "[e]very hospital . . . *which provides general medical and surgical hospital services*" to also provide emergency services.

The foregoing statutes clearly authorize, and at times mandate, licensed hospital corporations to provide medical services. We believe that the authority to employ duly-licensed physicians for that purpose is reasonably implied from these legislative enactments.

Berlin v. Sarah Bush Lincoln Health Ctr., 688 N.E.2d 106, 113 (Ill. 1997) (alteration in the original) (citations omitted).

One answer to this last question, conveniently overlooked by the court, is that hospitals could engage physicians on an independent contractor basis to provide the services, or admit them through the hospital's medical staff to do so without any professional services contract, thus avoiding the corporate practice prohibition on employment of physicians. Another answer involves recognizing that when the drafters of the Hospital Lien Act and the Hospital Emergency Service Act referred to the *provision* of medical services, it was not critical for them to distinguish between providing and arranging for the provision of the services. The most compelling objection to the court's construction of legislative and regulatory language was voiced by Justice Harrison in dissent, observing that in the sixty years since the Illinois Supreme Court had established its prohibition on corporate employment of healthcare professionals, the legislature had not taken action to change course, in whole or in part, even to clarify that hospitals may employ physicians. "To the contrary, it has continued to adhere to the requirement that medicine can only be practiced by those who hold valid licenses from the state" n235 The court-made licensure rationale is in the nearly untenable position of having to accomplish a legislative task in creating a licensing rule.

n235 *Id.* at 115 (Harrison, J., dissenting) (citations omitted).

While the Illinois Supreme Court's construction of the license statute is generous to hospitals, its construction of corporate law is rather stingy. As mentioned above, this licensure rationale is essentially a selective refusal to extend to certain corporations (healthcare organizations, as opposed to, say, airline **companies**) the corporate attribute of legal personality. n236 The application of this argument to healthcare is inconsistent with licensure principles as applied in other contexts in which corporations employ licensed individuals, such as airline **companies**.

n236 The refusal is express in California law; CAL. BUS. & PROF. CODE § 2400 provides: "Corporations and other artificial legal entities shall have no professional rights, privileges, or powers." *See also* Pediatric Neurosurgery v. Russell, 44 P.3d 1063 (Colo. 2002); *State ex rel. Loser v. Nat'l Optical Stores Co.*, 225 S.W.2d 263 (Tenn. 1949).

Ultimately, the *Berlin* court justifies its conclusion not with regulatory parsing, but with its observation that the arrangement between Dr. Berlin and the medical center properly drew a line between professional and lay conduct and thereby maintained the requisite degree of professional autonomy, but in this, too, a trap awaits. As developed by the *Berlin* court, the licensure rationale may also be an indirect route to taking a position on corporate liability for professional negligence. The *Berlin* court expressly declined to follow the argument advanced in some jurisdictions to

the effect that corporations do not themselves practice medicine so much as merely make medical practitioners available. The advantage of such an argument, from the point of view of the hospital, is that it creates a logical gap between providing and arranging for the provision of healthcare, in which a legal barrier to hospital tort liability can be erected. Indeed, it has historically been argued that the corporate practice doctrine protects not only physicians but also the hospitals that would employ them by establishing that hospitals do not practice medicine. It is the defense often erected for HMOs as they seek to avert tort liability by standing behind their function as mere insurers rather than providers. By declining to follow precedent that held hospitals could not employ physicians because they are not providers of services, n237 the *Berlin* court arguably left the door open for hospital tort liability, and thus handed the Sarah Bush Lincoln Health Center a victory on terms which may well have given the facility deep concern.

n237 *Berlin*, 688 N.E.2d at 112.

3. Payor Orientation

When fee-splitting laws fail to provide a coherent definition of the term "fee-splitting," n238 the task is left to courts, at which point it becomes apparent that the possibilities and their implications are endless. A court starting with the observation that the rule cannot mean professionals may not pay their bills n239 may proceed, as in the *TLC* case, to draw upon historical expressions of public policy to help narrow the range of possible meanings. It is no mean feat to select an expression of public policy that does not pertain to a bygone business practice or a dated issue; but assuming the court avoids this pitfall, it faces the danger of articulating a policy position that may stifle a development the healthcare community would have accepted at the next opportunity. Thus, the *TLC* court, as noted above, focused on a policy against medical "mills", or high-volume, low-paying service delivery arrangements, inevitably forging a rule that could clash with contemporary endeavors to lower medical costs and increase access.

n238 See FLA BAR, *supra* note 182, at 8. Minnesota is a notable exception. See MINN. STAT. ANN. § 147.091(p) (West 2005).

n239 *Practice Mgmt. Assocs. v. Blickensderfer*, 630 So. 2d 1147, 1148 (Fla. Dist. Ct. App. 1993).

To continue with the *TLC* decision as further evidence of the difficulties of statutory construction in this area, recall the court's rationale for holding that a management fee violated the applicable fee-splitting statute: "The policy reasons behind the prohibition are the danger that such an arrangement might motivate a non-professional to recommend a particular professional out of self-interest, rather than the professional's competence." n240 Perhaps the first question this statement provokes is why should a statute whose policy purpose is to discourage specified lay conduct, a recommendation made by a nonprofessional, appear in a licensure statute, with sanctions against only the professional? This question may quickly be followed by asking whether there is any rational purpose in seeking to preserve the integrity of a lay recommendation for professional services. Does anyone justifiably rely on such a thing?

n240 *TLC The Laser Ctr., Inc. v. Midwest Eye Inst. II, Ltd.*, 714N.E.2d 45, 56 (Ill. App. Ct. 1999).

The Illinois statute, like several other state fee-splitting statutes, states its prohibition in terms of "dividing" professional fees. n241 This language raises another definitional issue characteristic of states with fee-splitting rules. Illinois courts have drawn the reasonable conclusion that the legislative intent in using the word "dividing" was to prohibit *percentage* allocations of fees (thereby avoiding the interpretation that would have prohibited any use of a portion of fees to pay practice bills). But many subsequent decision points remain. Unless, as in California, n242 the statute specifies that its target is net revenue, or profit, there is the possibility that an arrangement whereby a billing **company** would receive a percentage of billings as its fee would be illegal. The problem with this conclusion, as the California legislature has evidently recognized, is that such an arrangement, common in other areas of the economy,

makes perfect sense with respect to matters such as billing, where the work involved increases proportionally with revenue generated. And where the legislative purpose is to preserve physician autonomy from lay persons who would become their partners, that purpose is served as long as any division of fees relates to gross and not net revenue. But in Illinois, where the legislative purpose is less tightly focused on the preservation of physician autonomy through the avoidance of equity-sharing arrangements, it is harder to direct the application of the statutory bar against dividing fees. If it simply meant that there can be no division based strictly on percentages, the statute could be circumvented with a modified percentage arrangement, such as one where a management fee is based on a percentage of revenue but subject to a cap. At some point, however, there must be a recognition that the process will lead to the equally untenable conclusion that a fixed, flat management fee cannot be related to the results achieved for the practice, or even the amount of effort expended by the management **company**, and at that point the purpose of the statute has to be revisited. In many jurisdictions, business persons and professionals alike are already facing the illogical effect of laws which apparently require that the management **company** agree in advance to a flat fee, which may or may not properly relate to either the results to be achieved or the efforts to be expended by the manager. n243

n241 225 ILL. COMP. STAT. ANN. 60/22-(A)(14).

n242 See CAL. BUS. & PROF. CODE § 650 (West 2005).

n243 See OIG, HHS Advisory Op. No. 4 (1998), cited in FLA. BAR, *supra* note 182, at 44.

V. Conclusion

Given the logical, pragmatic, and other deficiencies of laws restricting lay ownership of healthcare enterprises, why do they endure? Because each is a manifestation of an abiding concern, if only partially conceived and partially expressed. It is the fragmentary nature of each of the regulatory perspectives that gives rise to problems. There is nothing wrong in and of itself with a public policy to protect the autonomy of professionals, or to guard against the unlicensed practice of medicine, as long as the policy finds room reasonably to recognize the interests of those with whom professionals interact, the patient and the payor; just as there is nothing wrong with a policy against overutilization of professional goods and services as long it properly observes professional autonomy and quality assurance concerns. What the various regulatory approaches throughout our federalist system clearly reveal is that there are ultimately three interdependent components to any fully-realized healthcare policy on lay ownership. The professional, the patient, and the payor each deserves protection, but not at the expense of the others.

What would a regulatory program that accommodated all three perspectives look like? To begin with, it should not be excessively formalistic or reflexively proscriptive. Simple prohibitions of selected behavior, as we have seen, invite circumvention, and as the rules evolve to thwart circumvention, they become unruly; they obstruct more conduct than originally intended. Narrowly conceived proscriptive regulation tends to leave underserved the interest of one of the members of the healthcare triad, professional, patient, and payor, and often it is the interest of the party the rule seeks to protect. Thus, rules against lay participation in healthcare enterprises have the effect of unnecessarily limiting professionals' access to capital and administrative services.

Any regulatory program should be coherent, and in this regard the provider-patient-payor matrix should prove a useful assessment tool. It is a reminder that regulatory systems should not overvalue one perceived virtue, such as provider autonomy, at the expense of another, such as utilization control. By viewing the various methods of restraining lay ownership as interrelated, the matrix should promote consistency within a given regulatory system. Thus, a jurisdiction that gives with one hand by permitting lay corporate ownership of healthcare enterprises should not then take away with the other by prohibiting fee-sharing so broadly as to deprive the concept of ownership of a fundamental attribute. A jurisdiction that seeks to restrain lay control should rationalize its rules with respect to both ownership and fee-sharing through independent contracting to be sure it has not barred the unwelcome conduct at the front door and

invited it in through the back door.

A coherent regulatory system can take many forms. A minimally invasive program might accommodate (i) the need for provider autonomy simply by mandating that any lay-professional venture observe the authority of the professional with regard to clinical matters, (ii) the quality assurance objective by establishing and enforcing practice standards, and (iii) the payor perspective by simply recognizing a fiduciary obligation of professionals to payors to the extent they are not, in a given circumstance, in a position to negotiate and police utilization and other cost matters. Alternatively, a state could follow the HMO economic model by determining that the interests of the payor are properly accommodated when the provider has accepted sufficient risk.

While regulatory systems could continue to vary from state to state (and some jurisdictions could of course elect to continue as now without regulation), it is to be hoped that the regulatory landscape would ultimately be less Balkanized than is currently the case. It would be good if regulatory programs were sufficiently similar that multistate organizations with useful business solutions for healthcare providers and patients were not unnecessarily impeded. Our federalist system has performed its initial task in identifying the universe of regulatory concerns where lay and professional healthcare providers are involved. The time is ripe for the lawmakers of all jurisdictions to compare notes and share the best of their solutions to common problems. At a minimum, regulatory programs should consider licensing arrangements having certain qualifications in order to remove the uncertainty that currently plagues many enterprises and stultifies the development of others. Licensure would remove some of the "legal landmines" that are too often used simply as defenses by the breaching party against contractual obligations. A licensed PPMC, operating under state-sanctioned management agreements, would not have to worry that a disputing physician could bring down the whole operation by prevailing in a claim that the management contract is void as against public policy.

What would a regulatory program look like if it were to take into account all three components of the provider, patient, payor triad? HMO enabling legislation is an example. It authorizes a variety of legal relationships between laymen and professionals, including both employment and independent contractor arrangements. The legislation contemplates different ways of allocating income from services, as long as the professionals and lay administrators stipulate that the professionals will have ultimate authority with respect to clinical matters, that certain minimal contract and statutory rights of patients will be observed, and that certain quality of care and level of service obligations are met. A PPMC licensure law could be another example, and other examples would undoubtedly follow, given the evidence of mutual lay and professional interest provided by PPMCs. To be sure, there would be litigation as to where the line between clinical and administrative conduct should be drawn and what should be the respective obligations of the lay and the professional parties, just as there is now in the managed care context; n244 but the existence of such litigation cannot be taken as evidence of a public policy objection to lay ownership of all healthcare enterprises. Public policy has moved beyond the strictures sometimes attributed to it in the context of state doctrines restricting lay ownership of healthcare enterprises.

n244 *E.g.*, Whether the term "medically necessary" is a medical term or an insurance contract coverage term. *See generally* Pegram v. Herdrich, 530 U.S. 211 (2000).

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LENGTH: 4596 words**TITLE:** **Protecting** Employees Against Hepatitis B**AUTHOR:** Beatrice K. Bleicher *

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TEXT:

INTRODUCTION

The transmission of hepatitis B virus (HBV) in the workplace is a problem facing employers in many occupational settings, especially in various health care occupations. [n1] Over the last few years several governmental agencies have issued recommendations aimed at addressing this health risk. The Centers for Disease Control (CDC) issued guidelines for minimizing the risk of workers' contracting HBV and human immunodeficiency virus (HIV), [n2] the virus associated with Acquired Immune Deficiency Syndrome (AIDS). The United States Department of Labor and the Department of Health and Human Services issued a Joint Advisory Notice (JAN), [n3] incorporating the CDC's guidelines, which encouraged health care employers to adopt precautions on a voluntary basis. In addition, in 1983 the Occupational Safety and Health Administration (OSHA) issued a Field Instruction recommending vaccination and certain work practices as methods of preventing HBV infection. [n4] In 1988 OSHA issued a Compliance Instruction (Instruction) to guide OSHA personnel during the inspection of employer practices in health care facilities. [n5] Finally, in 1989 OSHA published a proposed standard, which will obligate employers to implement specific mandatory requirements aimed at reducing occupational exposure to all bloodborne diseases. [n6] This proposed standard is currently undergoing the public comment and review process in accordance with normal OSHA rulemaking procedures. [n7]

The differences among these documents often create confusion for the employer who wants to protect employee health and avoid liability. Although the relevant documents deal with both HBV and HIV, this Article will focus on hepatitis B prevention by discussing: (1) an employer's current legal obligation to minimize occupational exposure to HBV; (2) OSHA's proposed bloodborne disease standard as it will modify an employer's obligations in the future; and (3) recommendations for reducing an employer's potential legal exposure regarding HBV pending promulgation of OSHA's final standard.

THE EMPLOYER'S LEGAL OBLIGATIONS REGARDING HEPATITIS B PREVENTION

Sources of Obligations

Common law. Courts have generally held that an employer may be held liable for occupational diseases resulting from the employer's negligence. [n8] This liability is based on the principle that an employer must warn its employees

of conditions of employment which may engender disease, and the employer must furnish protection from such a danger if the employer has greater knowledge of that danger than the employees. [n9] Cases have also held that the employer may be under a duty to become informed of hazards involved in the work place; and, thus, the employer may acquire greater knowledge than employees. [n10] Liability is based on an employer's duty to exercise ordinary or reasonable care to protect employees from hazards in the workplace. [n11] The standard of care required by the law under these circumstances is the standard of care which would be exercised by the average prudent individual in similar circumstances. [n12] Because of workers' compensation statutes, [n13] an employer is unlikely to face a common law suit from an employee. Under workers' compensation, employer liability for an employee's injuries is eliminated in exchange for payment of a certain amount of compensation to an injured employee regardless of fault. [n14]

Federal statutory law. The primary basis for an employer's current legal obligation for hepatitis B prevention is found in the Occupational Safety and Health Act of 1970 (OSH Act), [n15] which was established to "assure as far as possible every working man and woman in the nation safe and healthful working conditions." [n16] The OSH Act authorizes OSHA to issue specific standards for employers to follow in the development of safe and healthful working conditions; and, as indicated above, OSHA is in the process of issuing a standard relating to all bloodborne diseases.

Until the final standard is promulgated, OSHA is enforcing its HBV requirements under the general duty clause of the OSH Act, [n17] a provision that covers situations not otherwise governed by specific regulatory or statutory directives. The general duty clause requires that an employer: "furnish to each of his [or her] employees employment and a place of employment which are free from recognized hazards that are causing or likely to cause death or serious physical harm to his [or her] employees." [n18] This clause "enable[s] the Secretary [of Labor] to insure the protection of employees who are working under special circumstances for which no standard has yet been adopted." [n19] This clause also imposes an obligation on employers to take all feasible measures necessary to eradicate a recognized hazard or alleviate the danger it presents.

In addition to the general duty clause, OSHA has relied on four standards which have already been promulgated as the legal basis for its current HBV prevention. These standards deal with the use of personal protective equipment, [n20] housekeeping operations, [n21] methods of waste disposal, [n22] and labeling procedures. [n23]

Nature of Current Obligations

Pursuant to the legal authority mentioned above, the practices an employer must follow currently to reduce occupational exposure to hepatitis B are contained in the JAN [n24] and the Instruction. [n25] These documents represent OSHA's first efforts at regulation of HBV in the health care industry.

Joint Advisory Notice

The Department of Labor developed voluntary guidelines on the occupational hazards of bloodborne pathogens as early as 1983. [n26] In September 1986, petitions were filed by the American Federation of State, County, and Municipal Employees and by the Service Employees International Union, requesting OSHA to issue an emergency temporary standard and to initiate rulemaking to promulgate a permanent standard to protect health care workers from HBV and HIV. [n27] These petitions were the main impetus behind the issuance of the JAN. The petitions included a request that OSHA immediately require employers to provide the HBV vaccine free of charge to high risk health care workers. [n28]

In October 1987, OSHA denied both petitions, but announced it would: 1) immediately initiate an educational campaign to apprise health care employers of precautionary safeguards to minimize exposure to HBV and HIV; 2) begin the rulemaking process for promulgating a permanent standard under Section 6(b) of the OSH Act; and 3) commence enforcement of existing standards regarding these hazards, such as OSHA's regulation for personal protective equipment and the general duty clause. [n29]

On October 30, 1987, the United States Department of Health and Human Services (HHS) and Department of

Labor (DOL) issued a JAN establishing guidelines to protect health care employees from occupational exposure to HBV and HIV. [n30] In a cover letter mailed to approximately 500,000 health care employers, the Secretaries of DOL and HHS requested voluntary adherence to the JAN, as well as adherence to CDC guidelines for the prevention of the occupational transmission of HBV and HIV. [n31]

The JAN includes facilities that employ health care workers who may be exposed to HBV and HIV, but also recommends that other employers whose personnel may be exposed (e.g., firefighters or law enforcement personnel) should utilize appropriate precautions. Specifically, the JAN recommends the following steps:

- * identify and categorize job-related tasks according to three risk classifications:

- Category I. Tasks that may involve exposure to blood, body fluids, or tissues,

- Category II. Tasks that may require unplanned Category I tasks,

- Category III. Tasks that do not involve exposure to blood, body fluids, or tissues;

- * develop written standard operating procedures to reduce exposure and monitor their effectiveness;

- * follow CDC's universal precautions, providing personal protective clothing and equipment for Category I workers, and making such items accessible to Category II workers;

- * make available, at no cost to the worker, voluntary HBV immunization for all Category I workers who test negative for HBV antibodies;

- * establish a training and education program for Category I and II employees;

- * adopt, at no cost to employees, medical surveillance procedures that address preventive treatment, monitoring and counseling;

- * maintain records documenting all standard operating procedures, results of routine surveillance of conditions in the workplace, and participation in training sessions. [n32]

The JAN does not specifically recommend routine post-vaccination testing to determine whether the HBV vaccine has induced a protective level of antibodies in workers who have received the vaccine. Rather, employers are urged to complete post-vaccination testing for select individuals, such as dialysis patients and staff or persons in whom sub-optimal response may be anticipated. [n33]

OSHA's Compliance Instruction

The second source of guidance for employers is the OSHA Instruction originally issued August 15, 1988, and clarified on February 27, 1990. [n34] This Instruction outlines the procedures OSHA personnel must utilize when inspecting health care facilities for occupational exposure to HBV or HIV. Employers should comply with this Instruction until OSHA promulgates a final standard on bloodborne pathogens. Where employers desire more detail, they can supplement the procedures contained in the Instruction with the voluntary guidelines set forth in the JAN. To the extent the JAN conflicts with the Instruction, the Instruction should be followed since it forms the basis for citations which OSHA may issue. [n35]

The Instruction generally tracks the JAN, with a few notable differences. [n36] The Instruction requires the employer to develop an oral or written infection control program for the potential exposure of employees to body fluids. [n37] The JAN's comparable procedures require a written infection control program. [n38] Although the Instruction theoretically eases an employer's obligation, from a practical standpoint it may be difficult to maintain an adequate oral policy. Moreover, it is much easier to prove the existence of a written policy.

The Instruction does not establish categories of risk as the JAN did. [n39] Instead, employers must follow universal precautions recommended by the CDC "whenever an employee may reasonably be expected to have direct contact with bodily fluids." [n40] The concept underlying universal precautions is treatment of all bodily fluids as potentially infectious, because there is no ready way to distinguish those that are infectious from those that are not. [n41]

In the 1990 clarification, OSHA requires employers to document employee needlestick injuries on OSHA Form 200 if medical treatment is required as a result of the needlestick. [n42] The use of fluid-proof or fluid resistant clothing is required when splashes of body fluids are likely. [n43] Recapping needles by hand is specifically prohibited, although resheathing instruments, self-sheathing needles, and forceps can be used instead of recapping by hand. [n44]

Relying upon the general duty clause, the Instruction obligates employers to provide the HBV vaccine free of charge to employees who are "at substantial risk of directly contacting body fluids." [n45] The Instruction notes that failure to provide the vaccine is likely to result in continued existence of a serious hazard and, therefore, may be a violation of section 5(a)(1) of the OSH Act. [n46] In fact, since 1988, numerous health care facilities have been cited for failing to provide the vaccine to workers and for failing to abate unsafe work practices. [n47]

Although the original 1988 OSHA Instruction did not expressly require the employer to offer HBV vaccine at no cost to the employee, [n48] the February 1990 clarification returns to OSHA's policy expressed in the JAN specifying the vaccine must be offered "free of charge." [n49] Thus, the employer is now obligated to provide free vaccinations to employees in much the same way employers are required by other OSHA standards and guidelines to assume the cost of other abatement methods which address health and safety hazards under OSHA's general duty clause.

The Instruction obligates employers to develop training and education programs for workers employed in occupations with a high risk for bloodborne infections. [n50] Employers are required to educate such high-risk employees on epidemiology, modes of transmission, and prevention of HBV and HIV. Employees must be trained concerning the location and use of personal protective equipment, implementation of proper work practices, labeling and handling of contaminated articles or infectious waste, and post-exposure procedures following needlesticks and other types of exposures. [n51]

Follow-up procedures are delineated for incidents which result in possible exposure, such as a needlestick injury or cut. According to the Instruction if such an event occurs, the "source patient," *i.e.*, the one with whose blood the health care worker had contact, must be informed of the incident and, with the patient's consent, be tested for HBV infection. [n52] Follow-up procedures depend on whether the employee has received the HBV vaccination and whether antibody response is adequate. [n53] Recommendations regarding HBV post-exposure prophylaxis are contained in a CDC publication referred to in the Instruction. [n54] The Instruction also states that if an employee refuses to submit to any of the testing or post-exposure procedures medically indicated, no adverse action can be taken against the employer for that reason. [n55]

Future Obligations

On May 30, 1989, OSHA published a proposed standard (OSHA Proposal) to govern occupational exposure to all bloodborne diseases, not just HBV and HIV. [n56] During 1989, five informal hearings took place in Washington, D.C., Chicago, San Francisco, New York, and Miami, at which over 420 witnesses testified about the OSHA Proposal. [n57] OSHA has also received over 2,900 comments on the OSHA Proposal, which is the largest docket of comments and information submitted in any OSHA rulemaking to date. [n58] In spite of OSHA's initial reluctance to regulate the health care industry, both OSHA and the Department of Labor now have made promulgation of a bloodborne disease standard a top priority with full support of the Secretary of Labor.

The OSHA Proposal includes all occupational exposure to blood and other potentially infectious materials, which include body fluids, tissues, or HIV or HBV containing cells or tissues. The OSHA Proposal defines "occupational exposure" as "reasonably anticipated . . . contact" with blood or other potentially infectious materials that "may result

from the performance of an employee's duties." [n59] The definition excludes incidental occupational exposures that are "neither reasonably nor routinely" anticipated.

OSHA estimates that approximately 616,880 establishments and 5.3 million workers will be protected by the standard. [n60] Approximately 87 percent of these workers are employed in health care occupations. [n61] The remaining affected workers are mainly in law enforcement, fire protection and rescue services, correctional facilities, and funeral services industries. Research laboratories and research facilities which produce industrial scale or research laboratory scale amounts of HBV or HIV will be required to satisfy additional requirements. [n62]

The OSHA Proposal, like earlier OSHA guidelines, requires employers to follow universal precautions, whereby all human blood and certain body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens. [n63] The OSHA Proposal will require employers to implement other protective measures involving engineering controls and work practices, personal protective equipment, warning labels and signs, housekeeping and waste disposal, and training and education. These precautions are not mandatory if the precautions interfere with the proper delivery of health care or public safety services, or create a significant risk to the personal safety of the worker. [n64]

Within 150 days after the OSHA Proposal's effective date, employers will be required to make HBV vaccination available to susceptible workers willing to be vaccinated. [n65] Susceptible workers for purposes of this provision are all employees exposed to blood or other potentially infectious materials on an average of one or more times per month. [n66] If any employee is found to be immune through HBV antibody testing, the employer will not be required to provide such employee with a vaccination. [n67] Although the OSHA Proposal does not explicitly require the employer to pay for the vaccination, the current 1990 Instruction does state that vaccine must be offered without charge to the employee. [n68] It is expected that OSHA's final standard will require that the vaccination be free.

Although the employer must offer HBV vaccination under the OSHA Proposal, an employee is not required to accept vaccination. In the introduction to the Proposal, however, OSHA expressed some uncertainty about whether the voluntary approach was the correct approach. [n69] After explaining that OSHA has not previously mandated medical procedures, OSHA referred to the value of HBV vaccination in saving lives from HBV infection, and the value of complete vaccination of the health care work force. [n70] For this reason OSHA asked for public comment on whether the HBV vaccination should be mandated. OSHA also asked for comment on legal, ethical, medical, or other issues which a mandate would raise. [n71]

EMPLOYER LIABILITY FOR FAILURE TO OFFER VACCINE

OSHA Enforcement

The primary means of establishing employer liability for failure to offer HBV vaccine will be through OSHA's enforcement of its Compliance Instruction. [n72] This author has obtained data from Federal OSHA revealing that from January 1988 to June 1990, over 944 health care facilities have been cited for violations of the OSH Act, discovered during inspections initiated to determine compliance with obligations to prevent HBV and HIV infection in the workplace. [n73] One hundred sixty-three of these citations alleged violation of the general duty clause and total penalties paid amounted to approximately \$ 73,000. [n74] Although anecdotal evidence suggests a number of these citations relate to the failure to comply with the vaccine requirement, the exact number which include or are solely related to the vaccination requirement is unavailable. A sample of the citations demonstrates that final penalties paid for failure to offer vaccine ranged from \$ 60 to \$ 1,000 for each cited instance. The facilities cited in this sample mainly were traditional health care facilities such as hospitals, **nursing homes**, clinics, laboratories, and dental offices. An automotive manufacturing **company**, however, was cited because its nurses and other first aid personnel had not been offered HBV vaccine. Based on the evidence of citations, it is clear OSHA is currently enforcing its requirement that HBV vaccination be offered to employees who are exposed to HBV as an occupational risk.

Other citations have been issued by OSHA during HBV-HIV related inspections to employers who have allegedly failed to provide protective equipment, proper disposal of waste, and/or follow appropriate housekeeping procedures. Employers must keep in mind that once an OSHA inspector is on the premises, the employer can be cited for failure to comply with other OSHA regulations. Thus, even if the inspector's visit originated in a complaint about failure to offer free HBV vaccination, the inspector may cite the employer for failure to provide proper stair handrails, despite the fact that handrails have no relationship to HBV or HIV prevention.

Tort Liability

To the extent that offering HBV vaccination to employees has become standard practice in the health care industry, failure to offer the vaccine could render an employer liable in tort. [n75] Liability to an employee for negligence, however, is more theoretical than real because of employer immunity under state workers' compensation laws. [n76] An employee who contracts HBV as a result of an employer's failure to provide vaccination would find his or her exclusive remedy under the workers' compensation program, [n77] unless the employee is able to avoid this bar under the very limited dual persona [n78] or intentional harm [n79] exceptions.

Employer immunity from tort suits by an employee has been eroded slightly by dual persona and intentional harm cases. The dual persona doctrine, which permits an employee to sue an employer in its capacity as manufacturer or provider of a product, has been virtually eliminated in all jurisdictions. [n80] The intentional harm doctrine, which can be asserted if the employer is aware of a risk, but intentionally disregards it by failing to disclose information or take remedial action, is allowed in only a small minority of states. [n81] Thus, in most jurisdictions failure to provide HBV vaccination will be the subject of a workers' compensation claim rather than a tort suit.

EMPLOYER LIABILITY ASSOCIATED WITH OFFERING VACCINE

Vaccine Related Injuries

In the very unlikely event of an adverse reaction to the HBV vaccine, an employee would be eligible for compensation under state workers' compensation program. [n82] Courts have held that where the vaccination is at the direction of the employer, or for the mutual benefit of employee and employer, any adverse reaction to the vaccine will be held to arise in the course of employment; and the employee is entitled to workers' compensation. [n83] Fortunately, there is an extremely low incidence of adverse reaction from HBV vaccination. [n84]

Infringement of Privacy Rights

The use of HBV testing to determine whether or not an employee has immunity to HBV, or should be vaccinated, could theoretically lead to a claim of invasion of privacy. [n85] Claims of this type are based on the concept that public disclosure of private facts is injurious to an individual. However, such a claim is unlikely to be successful because infection with HBV does not carry a social stigma, as does HIV infection; and, therefore, the value of the health information should clearly outweigh any injury from disclosure of the employee's HBV immunity status. As an added protection, however, employers should restrict disclosure of health status to those who have a legitimate need to know such facts. [n86]

Although unreasonable search and seizure and religious concerns have been raised as issues with respect to AIDS testing [n87] and drug testing, [n88] these issues appear less significant in the case of HBV vaccination because employees are not required to accept vaccination or testing.

RECOMMENDATIONS FOR EMPLOYERS

The first recommendation is that an employer follow the February 27, 1990 OSHA Instruction. [n89] If further detail is needed, the JAN is helpful. [n90]

It is also important for an employer to obtain documentation of the employee's acceptance or refusal of HBV vaccination. If the employee agrees to be vaccinated, a form which includes an explanation of the risks of contracting HBV, the benefits of HBV vaccination, and potential adverse consequences of vaccination should be provided to the employee prior to vaccination. Employees should be given an opportunity to ask questions about the vaccination process. The form should include a place for the employee to state his or her acceptance, signature, and date. The signed form may be useful in proving an employee was informed of the risks of vaccination.

Similarly, if an employee refuses HBV vaccination, he or she should be asked to sign a written waiver or "informed refusal." The waiver can be a separate part on the same consent form; it should also include information concerning the benefits of vaccination and potential adverse consequences. This written approach is advisable for two reasons. First, the waiver may serve as evidence the employer satisfied its obligation to make the vaccine available. Second, the employer will be in a better position to demonstrate it satisfied its duty of due care should the employee later contract HBV and attempt to bring an action against the employer. Although the written waiver will not guarantee complete protection from all liability, it is more likely to afford protection because the employee is well informed about the risk of HBV and effective means of prevention.

In addition to providing the vaccine, employers should provide education and training to employees regarding all aspects of compliance, including vaccination. It is well established that an employer "has a duty under section 5(a)(1) to take whatever measures may be required" to protect workers. [n91] This duty clearly includes the requirement that an employer provide an adequate safety and training program for its employees. In fact, during the enactment of the OSH Act, "congressional floor debates, committee reports, and individual and minority views . . . [were] replete with discussions of . . . unsafe work practices and inadequate safety training, and the like." [n92]

The courts have regularly found training is necessary to abate a recognized hazard; and, correspondingly, the omission of training is itself a recognized hazard. [n93] To determine whether an employee training program is adequate, the program is measured against the standard of care which would be adopted by a conscientious expert seeking to prevent all hazards which are reasonably foreseeable. [n94] Therefore, development of a training and educational program which informs employees about epidemiology, modes of transmission of HBV, various precautionary measures, and safe work practices is essential.

Another employer precaution is to offer to pay for vaccination regardless of where and by whom the vaccination is administered. In this way the employer may avoid liability for negligent selection of the health care provider in the rare circumstance in which an employee may suffer an adverse reaction to the vaccine. [n95]

This discussion of an employer's obligations to provide HBV vaccine to health care employees illustrates some of the complications that accompany this health requirement. None of the complications are insurmountable and all are well justified by the result of greater safety for the employee. Perhaps the best suggestion is vaccination prior to employment. Universal vaccination during childhood or adolescence would not only be more convenient for employers, but would also protect the vast majority of the population who do not enter the health care professions but, nevertheless, may be at risk of HBV infection. [n96]

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REFERENCE: [n2.] Centers for Disease Control, Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus and Other Bloodborne Pathogens in Health-Care Settings, 37 *MORBIDITY & MORTALITY WEEKLY REP.* 377 (1988).

[n1.] See generally, *CONTROL OF COMMUNICABLE DISEASES IN MAN* (A. Benenson ed. 1985). Acute hepatitis

is caused by one of several viruses. Type A or infectious hepatitis results from fecal to oral transmission. *Id.* at 162. Type B or long incubation hepatitis is found in body secretions, particularly blood, saliva, and semen. Transmission within the health care industry is usually by percutaneous (intravenous, intramuscular, subcutaneous, or intradermal) inoculation of human blood or blood products from an infected person. *Id.* at 166. Type C or non-A, non-B hepatitis is usually seen post-transfusion. *Id.* at 169.

[n3.] 52 Fed. Reg. 41,818 (1987).

[n4.] See Work Practices by Healthcare Workers to Avoid Hepatitis Risk Suggested by OSHA, 13 O.S.H. Rep. (BNA) 765 (Dec. 8, 1983) (discussing OSHA Instruction CPL 2-2.36).

[n5.] OSHA Instruction CPL 2-2.44A, Office of Health Compliance Assistance, August 15, 1988; this Instruction was revised by OSHA Instruction CPL 2-2.44B, Office of Health Compliance Assistance, Feb. 27, 1990. See O.S.H. Rep. (BNA) Ref. file 21:9607.

[n6.] Occupational Exposure to Bloodborne Pathogens; Proposed Rule and Notice of Hearing, 54 Fed. Reg. 23,042 (May 30, 1989) (to be codified at 29 C.F.R. Pt. 1910) [hereinafter OSHA Proposal].

[n7.] 29 U.S.C.A. § 655(b) (West Supp. 1990).

[n8.] See, e.g., *O'Connor v. Armour Packing Co.*, 158 F.2d 241, 242 (5th Cir. 1908) (slaughter house employer liable for infectious diseases, such as anthrax); *Morris v. Dines Mining*, 174 Kan. 216, 223, 256 P.2d 129, 135 (1953) (employee recovered damages for employer's negligent operation of lead and zinc mines causing employee to contract silicosis); *Triff v. National Bronze & Aluminum Foundry*, 135 Ohio St. 191, 206, 20 N.E.2d 232, 239 (1939) (employee has right of action against employer for damages resulting from contracting silicosis caused by employer's negligence).

[n9.] See, e.g., *Zajkowski v. American Steel & Wire Co.*, 258 F.9, 11 (6th Cir. 1918) (cause of action for damages due to an occupational disease stood).

[n10.] See, e.g., *Peerless Woolen Mills v. Pharr*, 74 Ga. App. 459, 466, 40 S.E.2d 106, 111 (1946) (employer liable for knowledge that dye or soap used in industrial process was poisonous and injurious).

[n11.] See *Walsh v. Cullen*, 235 Ill. 91, 96, 85 N.E. 223, 225 (1908) (employer liable for unsafe elevator); *Graham v. Arall, Inc.*, 80 S.D. 13, 15, 117 N.W.2d 491, 492 (1962) (employer liable for negligent placement of skids supporting pipe being welded).

[n12.] See, e.g., *Smith v. Western Electric Co.*, 643 S.W.2d 10, 13 (Mo. Ct. App. 1982) (quoting *Thompson v. Kroeger*, 380 S.W.2d 339, 343-44 (Mo. 1964)). The Smith court found the defendant had the authority, ability, and reasonable means to control smoking in the work area, along with the knowledge tobacco smoke was harmful to plaintiff's health. *Id.* The court further noted the standard was "what ought to be done . . . fixed by a standard of reasonable prudence, whether it is usually complied with or not." *Id.*

[n13.] See, e.g., OHIO REV. CODE ANN. § 4123.74 (Baldwin 1990).

[n14.] See *infra* notes 75-84 and accompanying text.

[n15.] 29 U.S.C.A. §§ 651-78 (West 1990).

[n16.] 29 U.S.C. § 651(b) (1988).

[n17.] *Id.* § 654.

[n18.] *Id.* § 654(a)(1).

[n19.] B. MINTZ, OSHA HISTORY, LAW AND POLICY 437 (1984) (quoting S. Rep. No. 1282, 91st Cong., 2d Sess. (1970)). As permitted by the OSH Act, some jurisdictions have their own state occupational safety and health statutes with general duty clauses which are interpreted similarly to the federal statute's clause. See, e.g., ARIZ. REV. STAT. ANN. § 23-403 (1989); CAL. LAB. CODE § 6400 (Deering 1990); ILL. REV. STAT. ch. 48, P137.3 (1988).

[n20.] 29 C.F.R. 1910.132 (a), (c) (1989).

[n21.] Id. at 1910.22 (a)(1), (2).

[n22.] Id. at 1910.141 (a)(4)(i), (ii).

[n23.] Id. at 1910.145 (f).

[n24.] 52 Fed. Reg. 41,818 (1987).

[n25.] CPL 2-2.44B, Office of Health Compliance Assistance, Feb. 27, 1990. See O.S.H. Rep. (BNA) Ref. file 21:9607.

[n26.] See Work Practices by Health Care Workers to Avoid Hepatitis Risk Suggested by OSHA, 13 O.S.H. Rep. (BNA) 765 (Dec. 8, 1983).

[n27.] See State, County Workers Union Petitions OSHA for Emergency Rule on Hepatitis, 16 O.S.H. Rep. (BNA) 421 (Sept. 24, 1986).

[n28.] Id.

[n29.] See Letter from John A. Pendergrass, Assistant Secretary, U.S. Dep't of Labor to Gerald McEntree, Int'l President, Am. Fed. of State, County, and Municipal Employees (Oct. 21, 1987).

[n30.] 52 Fed. Reg. 41,818 (1987).

[n31.] Id.

[n32.] Id. at 41,821-22.

[n33.] Id. at 41,822.

[n34.] OSHA Instruction CPL 2-2.44A, Office of Health Compliance Assistance, August 15, 1988; OSHA Instruction CPL 2-2.44B, Office of Health Compliance Assistance, Feb. 27, 1990. See O.S.H. Rep. (BNA) Ref. file 21:9607.

[n35.] Under the original statute, the penalties for violation of the OSH Act began at \$ 1,000 for minimal violations, but repeated or willful violations were subject to a \$ 10,000 penalty. 29 U.S.C. § 666 (1988). Penalties have been increased to \$ 7000 for minimal violations and \$ 70,000 for each willful or repeated violation. OSHA Still Forming Policy to Implement New Fine Structure, 20 O.S.H. Rep. (BNA) 1139 (Dec. 12, 1990). See *infra* notes 72-74 and accompanying text for a discussion of citations issued by OSHA pursuant to the Instruction.

[n36.] OSHA Instruction CPL 2-2.44B (Feb. 27, 1990). See O.S.H. Rep. (BNA) Ref. file 21:9607; Joint Advisory Notice, 52 Fed. Reg. 41,818 (1987).

[n37.] OSHA Instruction CPL 2-2.44B (Feb. 27, 1990). See O.S.H. Rep. (BNA) Ref. file 21:9608.

[n38.] Joint Advisory Notice, 52 Fed. Reg. 41,821 (1987).

[n39.] Id.

[n40.] OSHA Instruction CPL 2-2.44B (Feb. 27, 1990). See O.S.H. Rep. (BNA) Ref. file 21: 9610.

[n41.] See Centers for Disease Control, *supra* note 2, at 377-78.

[n42.] OSHA Instruction CPL 2-2.44B (Feb. 27, 1990). See O.S.H. Rep. (BNA) Ref. file 21: 9610.

[n43.] Id. at 9611.

[n44.] Id. at 9612.

[n45.] Id. at 9613.

[n46.] Id.

[n47.] See *infra* notes 72-74 and accompanying text.

[n48.] OSHA Instruction CPL 2-2.44A (Aug. 15, 1988). See generally New OSHA Compliance Instruction Requires Free Hepatitis B Vaccine, 10 O.S.H. Rep. (BNA) 1804 (March 7, 1988).

[n49.] OSHA Instruction CPL 2-2.44B (Feb. 27, 1990). See O.S.H. Rep. (BNA) Ref. file 21: 9613.

[n50.] Id. at 9614.

[n51.] Id.

[n52.] Id.

[n53.] Id.

[n54.] Id. (citing Immunization Practice Advisory Committee, Recommendations for Protection Against Viral Hepatitis, 34 MORBIDITY & MORTALITY WEEKLY REP. 313, 324 (1985)).

[n55.] Id. at 9614.

[n56.] See OSHA Proposal, *supra* note 6. OSHA has recently estimated that it will issue a final standard by May 1991. See Oversight Hearings on OSHA Proposed Standard to Protect Health-Care Workers Against Blood-borne Pathogens Including the AIDS and Hepatitis B Viruses Before the Subcommittee on Health and Safety Committee on Education and Labor, House of Representatives (May 24, 1990) (statement of Gerard F. Scannell, Assistant Secretary of Labor, OSHA, DOL) [*hereinafter*, OSHA Hearing].

[n57.] See generally OSHA Hearing, *supra* note 56.

[n58.] Id. at 8.

[n59.] See OSHA Proposal, *supra* note 6, at 23,134.

[n60.] Id. at 23,073.

[n61.] Id.

[n62.] Id. at 23,138.

[n63.] Id. at 23,135.

[n64.] Id.

[n65.] Id. at 23,139.

[n66.] Id.

[n67.] Id. at 23,137.

[n68.] OSHA Instruction CPL 2-2.44B (Feb. 27, 1990). See O.S.H. Rep. (BNA) Ref. file 21:9613.

[n69.] OSHA Proposal, *supra* note 6, at 23, 045.

[n70.] Id.

[n71.] Id.

[n72.] OSHA Instruction CPL 2-2.44B (Feb. 27, 1990). See O.S.H. Rep. (BNA) Ref. file 21: 9607.

[n73.] Correspondence between author and OSHA pursuant to a Freedom of Information Act request.

[n74.] Id.

[n75.] By not providing the HBV vaccine, the employer breached the duty to provide a safe workplace by refusing to furnish protection from a disease about which the employer has greater knowledge than the employee. See *supra* note 9 and accompanying text. See also *Smith v. Western Elec.*, 643 S.W.2d 10, 11 (Mo. Ct. App. 1982) (employer breached duty to provide a reasonably safe workplace by not assuming responsibility to eliminate hazardous condition caused by tobacco smoke); *Shimp v. New Jersey Bell Telephone*, 145 N.J. Super. 516, 530-31, 368 A.2d 408, 415-16 (1976) (employer has affirmative duty to provide work area free from unsafe conditions, including cigarette smoke).

[n76.] A. LARSON, *WORKMEN'S COMPENSATION FOR OCCUPATIONAL INJURIES AND DEATH*, § 1.10 (1989).

[n77.] Tort liability for an employer might arise, however, if an employee's family member could prove that he or she contracted HBV from an employee who contracted it on the job as a result of the employer's failure to provide the vaccine. In asbestos cases, where family members were exposed to asbestos through the employee's work clothes, at least one court has found the employer negligent for failing to warn domestic bystanders of the dangers of exposure. The employer was thus responsible, together with the asbestos product manufacturer, for causing the death of a domestic bystander. *Dube v. Pittsburgh-Corning*, Civ. No. 83-0224 (D. Maine, June 19, 1988), *rev'd*, 870 F.2d 790 (1st Cir. 1989). The issue in *Dube* was whether the government employer was negligent in causing the death of plaintiff's decedent, who was the daughter of a shipyard worker who carried asbestos fibers home on his work clothes. *Id.* at 791. The lower court found the government immune from liability pursuant to the Federal Tort Claims Act (FTCA), but the U.S. Court of Appeals reversed on issue of immunity under FTCA. *Id.* at 800.

[n78.] See generally A. LARSON, *supra* note 76, § 72.81. Larson defines dual persona doctrine: "An employer may become a third person, vulnerable to tort suit by an employee, if - and only if - he [or she] possesses a second persona so completely independent from and unrelated to his [or her] status as employer that by established standards the law recognizes it as a separate legal person." *Id.*

[n79.] *Id.* § 68.00. Larson defines intentional injury by employer or his or her agent as injury "inflicted by the employer in person on his [or her] employee. . . . The common-law liability of the employer cannot be stretched to include accidental injuries caused by the gross, wanton, reckless, culpable or malicious negligence, or other misconduct of the employer short of genuine intent to injure." *Id.* (emphasis added).

[n80.] Only two jurisdictions, California and Ohio, have recognized a true version of the dual capacity doctrine, which allows an employee to bring an action against his or her immediate employer. See, e.g., *Douglas v. E. & J. Gallo Winery*, 69 Cal. App. 3d 103, 137 Cal. Rptr. 797 (1977); *Mercer v. Uniroyal*, 49 Ohio App. 2d 279, 361 N.E.2d 492 (1976). Neither state now follows these cases. See A. LARSON, *supra* note 76, § 72.81(c).

[n81.] In Vermont and Pennsylvania, employees have been permitted to sue their employers for intentional harm. See *Neal v. Carey Canadian Mines*, 548 F. Supp. 357 (E.D. Pa. 1982), *aff'd*, 760 F.2d 481 (3rd Cir. 1985) (liability for failure to warn); *Wade v. Johnson Controls*, 693 F.2d 19 (2nd Cir. 1982) (liability for ignoring unsafe conditions). A few other states allow actions against employers for causing a second injury or for aggravating an injury by concealing medical information. See, e.g., *Johns-Manville Products v. Contra Costa Superior Court*, 27 Cal. 3d 465, 612 P.2d 948, 165 Cal. Rptr. 858 (1980) (liability for fraudulent concealment of asbestos).

[n82.] See, e.g., *Maher v. Workers' Comp. Appeals Bd.*, 33 Cal. 3d 729, 738, 661 P.2d 1058, 1063, 190 Cal. Rptr. 904, 909 (1983) (nurse who suffered adverse reaction to tuberculosis treatment entitled to workers' compensation benefits); *Lampkin v. Harzfeld's*, 407 S.W.2d 894, 898 (Mo. 1966) (influenza inoculation causing reaction and injury arose out of and in the course of employment which precluded employee from maintaining action against employer for personal injuries); *Lee v. Wentworth Mfg.*, 240 S.C. 165, 169, 125 S.E.2d 7, 10 (1962) (infection resulting from tuberculosis test was an accident that arose out of and in the course of claimant's employment); *Roberts v. U.S.O. Camp Shows*, 91 Cal. App. 2d 884, 886, 205 P.2d 1116, 1117 (1949) (encephalitis resulting from immunizations compensable under workers' compensation act only).

[n83.] *City of Austin v. Smith*, 579 S.W.2d 84, 87 (Tex. Civ. App. 1979) (swine flu vaccination); *Lampkin*, 407 S.W.2d at 898 (fact that employee paid for inoculation did not mean she was not an employee); *Lee*, 240 S.C. at 166, 125 S.E.2d at 8 (tuberculin test); *Roberts*, 91 Cal. App. 2d at 886, 205 P.2d at 1117 (vaccination); *Spicer Mfg. v. Tucker*, 127 Ohio St. 421, 430, 188 N.E. 870, 873 (1934) (vaccination); *Suniland Toys & Juvenile Furniture v. Karns*, 148 So. 2d 523, 525 (Fla. Dist. Ct. App. 1963) (typhoid inoculation); *contra City of Littleton v. Schum*, 38 Colo. App. 122, 124-25, 553 P.2d 399, 401-02 (1976) (firefighter was not entitled to cost of gamma globulin he received after work place exposure to HBV because HBV was not listed as an occupational disease under the then existing workers' compensation act). See also *Krout v. J.L. Hudson Co.*, 200 Mich. 287, 290, 166 N.W. 848, 849 (1918) (employee injured by small pox vaccination received at request of employer not entitled to compensation from employer because employee did not show connection between her employment and the infection following vaccination).

[n84.] See *Concerning the Proposed Standard to Reduce Occupational Exposure to Blood Borne Pathogens: Hearings on OSHA Proposal Before the Dep't of Labor Occupational Safety and Health Administration* (Sept. 18, 1989) (statement of Merck & Co. Inc.). The testimony reported there had been no serious side effects attributable to vaccination: "About 20% of the adult vaccine recipients reported injection site discomfort, The most frequent systemic complaints, which have been reported at somewhat lower frequencies, include headache or fatigue and weakness." *Id.* at 12.

[n85.] See generally Comment, *Privacy and the Employment Relationship*, 25 HOUST. L. REV. 389, 417 (1988).

[n86.] See, e.g., *Bratt v. International Business Machines*, 392 Mass 508, 524, 467 N.E.2d 126, 137 (1984) (where the court applied a balancing test: degree of intrusion against the employer's need for the medical information).

[n87.] See, e.g., *People v. Thomas*, 529 N.Y.S.2d 429, 431, 139 Misc.2d 1072, 1075 (1988) (where the court held AIDS antibody test against defendant's consent was a minimal intrusion compared to the victim's mental anguish resulting from the forced rape by defendant).

[n88.] See e.g., *Rushton v. Nebraska Pub. Power Dist.*, 844 F.2d 562, 564-67 (8th Cir. 1988) (court held that employer's drug testing program did not violate employee's right to free exercise of religion nor employee's right to be free from unreasonable searches and seizures).

[n89.] OSHA Instruction CPL 2-2.44B (Feb. 27, 1990). See O.S.H. Rep. (BNA) Ref. file 21: 9607.

[n90.] 52 Fed. Reg. 41,818 (1987).

[n91.] *International Union, UAW v. General Dynamics and Systems Div.*, 13 O.S.H. Cas. 1201, 1206-7 (BNA) (D.C. Cir. 1987).

[n92.] *American Cyanamid Company*, 9 O.S.H. Cas. 1596, 1599 (BNA) (1981) (citing Subcommittee on Labor of the Committee on Labor and Public Welfare of the United States Senate, 92d Cong., 1st Sess., LEGISLATIVE HISTORY OF THE OCCUPATIONAL SAFETY AND HEALTH ACT OF 1970, at 324 (Comm. Print 1971)).

[n93.] See, e.g., *General Dynamics v. Occupational Safety & Health Review Comm'n*, 599 F.2d 453 (1st Cir. 1979). The *General Dynamics* court found the "duty imposed by section 5(a)(1) to furnish employees with a workplace free from recognized hazards likely to cause death or serious physical injury requires an employer to take steps to prevent and suppress hazardous conduct by employees, including proper training and supervision of employees." *Id.* at 458.

[n94.] *Id.* at 464.

[n95.] Because an employer has a duty under common law to exercise reasonable care in selecting a health care provider for employees, he or she could be liable for the malpractice of the selected provider in administering the HBV vaccine. See *Virginia Iron, Coal & Coke Co. v. Odle's Adm'r*, 128 Va. 280, 291-92, 105 S.E. 107, 112 (1920); *Guy v. Lanark Fuel*, 72 W. Va. 728, 732, 79 S.E. 941, 942 (1913). More recent cases have also referred to this duty. See, e.g., *Rich v. Atlantic Coast Line R.R.*, 192 So. 2d 2, 3 (Fla. 1966). If payment for the vaccine came out of an employee benefit health plan, an employer's responsibility in the selection of a physician may be determined by the federal Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1001 (1988) rather than by common law, but this issue has not yet been resolved by the courts. See generally Fitzgerald and Soffin, *Employer Liability for Malpractice by PPO Providers -- Minimizing Risk During the Selection Process*, BENEFITS L.J., Summer 1988, at 103. In view of the fact that vaccination would be a job-related event, an employee's injury would probably be covered under workers' compensation rather than allowed in tort.

[n96.] See Alter, Hadler, Margolis, Alexander, Hu, Judson, Mares, Miller & Moyer, *The Changing Epidemiology of Hepatitis B in the United States: Need for Alternative Vaccination Strategies*, 263 J.A.M.A. 1218 (1990).

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SUMMARY: ABSTRACT: Off-label drug or medical device "use" is the practice of prescribing drugs or medical devices to patients for a purpose not included on the federally approved label. Off-label "marketing" is the practice of attempting to influence physicians to prescribe drugs or devices for off-label purposes. The federal Food and Drug Administration (FDA) maintains regulatory authority over the proper labeling of drugs and medical devices. Although not illegal, off-label use of certain drugs has led to controversy in recent years, especially in light of alleged behind-the-scenes marketing practices intended to increase off-label prescribing. Off-label marketing practices are prohibited and could result in criminal charges against a manufacturer, depending upon the circumstances. Yet a vast gray area exists for subtle marketing practices, such as circulating published medical studies about off-label uses to physicians. This article summarizes the legal and medical standards associated with off-label use and marketing of drugs, provides summaries of recent enforcement activities regarding off-label marketing, and explains the current federal regulatory issues surrounding off-label marketing practices. The authors provide practical pointers on regulatory compliance and the risks associated with fraud and abuse laws for drug **companies** and practitioners.

TITLE: Enforcement Related to Off-Label Marketing and Use of Drugs and Devices: Where Have We Been and Where Are We Going?

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TEXT:

OFF-LABEL MARKETING

Introduction

Lured by the opportunity to apply his scientific research skills, David Franklin got a job as a medical liaison for a pharmaceutical **company**. He held a doctorate in biology, and was employed to relay medical information about the **company's** drug products to physicians. Soon after he started, however, David grew dissatisfied. The medical liaison position was not the science-based position he believed it would be, but basically a sales position--one where David allegedly was expected to engage in aggressive sales practices. Only a few months after David was hired, he filed a nine-count *qui tam* action alleging the pharmaceutical **company** had violated the federal False Claims Act. n397

n397 Complaint, U.S. *ex rel.* David Franklin v. Parke-Davis, No. 96-11651PBS (D. Mass. Aug. 13, 1996) (on file with authors).

Filing a whistleblower case is an extreme response to a bad employment situation, so what happened? The short answer is that David disagreed with the **company's** marketing campaign, allegedly designed to convince physicians to prescribe the drug Neurontin(R) for conditions for which the drug was not approved by the Food and Drug Administration (FDA). In other words, David's former employer allegedly was marketing Neurontin for "off-label" uses. The drug was prescribed for off-label uses in such volume that David believed the **company** violated the law. The government agreed (and pursued a separate criminal proceeding parallel to the civil case). The **company** ultimately settled the federal allegations. n398

n398 Verdict/Settlement, U.S. *ex rel.* David Franklin v. Parke-Davis, No. 96-11651PBS (D. Mass. May 13, 2004); *see also* Press Release, Dep't of Justice, Warner-Lambert to Pay \$ 430 Million to Resolve Criminal and Civil Health Care Liability Relating to Off-Label Promotion (May 13, 2004), *available at* www.usdoj.gov/opa/pr/2004/May/04_civ_322.htm.

The long answer to what happened is more complicated. David's case was controversial. The laws related to off-label promotion are broad and have raised significant First Amendment concerns. With FDA trying to keep pace with court decisions by issuing revised rules and guidance, there are few practical guideposts for drug or device manufacturers interested in addressing the off-label use of their products. The *Franklin* case also raised novel issues regarding the use of false claims allegations as a regulatory tool to police the marketing of prescription drugs.

This article discusses the legal and medical standards associated with off-label use and marketing of drugs and devices, and summarizes recent enforcement activities of off-label marketing practices. n399 This discussion is followed by a brief description of the FDA's current position on the subject, including proposals not yet finalized. Finally, the authors describe practical considerations.

n399 The issues discussed in this article apply to both prescription drugs and medical devices. Because the pharmaceutical industry has seen a greater number of cases addressing off-label use, the majority of this article uses examples from the pharmaceutical industry.

Legal and Medical Standards

FDA regulates, among other things, the introduction of prescription drugs and medical devices into commerce. Upon application from a manufacturer, with supporting scientific research into safety and efficacy for a specific proposed use, FDA decides whether to approve or clear the particular drug or device for the applied-for use or indication. n400 With respect to a new drug, FDA's paramount concerns for approval are patient safety and benefit from

the intended use. n401 The package insert that physically accompanies a drug sets forth the approved uses for that product; in FDA's parlance, the package insert is the "approved professional labeling." n402 Manufacturer promotion to prescribers and customers is strictly limited to the particular FDA-approved, or "on-label," use or uses. Promotion of a drug for a use that is not on-label--off-label promotion--is strictly prohibited. The government has levied significant civil and criminal sanctions on manufacturers that allegedly have engaged in off-label promotion, as outlined below.

n400 For medical devices, the approval process varies depending on the risk classification of the device. This article uses the term "approved" to include devices "cleared" by FDA.

n401 21 U.S.C. §§ 355(a), 355(d).

n402 Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64074, 64075 (Dec. 3, 1997).

Although the rules prohibiting off-label promotion of prescription drugs and devices seem relatively straightforward, the concept is murky. Asymmetrically, while manufacturers cannot promote potential off-label uses to prescribers, prescribers (e.g., providers, hospitals, physicians) routinely prescribe for off-label uses that they believe, based on their medical judgment, will be beneficial. FDA has long acknowledged the value of off-label uses in medical treatment. n403 Through government-sponsored healthcare programs like Medicare and Medicaid, the federal government reimburses providers for many off-label uses of FDA-approved drugs. n404 Indeed, FDA recognizes the "important role" that "drug and device manufacturers have... in legitimate scientific and educational discussions, including discussions of unapproved products and unapproved uses." n405 Manufacturers typically have the most comprehensive access to data for their products, and in theory would be best suited to disseminate information to practitioners. The difficulty comes in predicting when disseminating information about off-label use becomes prohibited off-label promotion.

n403 See 59 Fed. Reg. 8798, 8803 (Mar. 19, 1997).

n404 Many off-label uses are included in medical compendia or recognized in peer-reviewed studies and are reimbursable under these federal programs. See 42 U.S.C. §§ 1395x(t)(2)(B), 1396r-8(k)(6).

n405 62 Fed. Reg. 64074, 64081 (Dec. 3, 1997).

FDA's role and regulatory power over off-label promotion

FDA regulates the manufacture, labeling, and promotion of drugs and medical devices. Congress delegated broad powers to FDA under the Food, Drug, and Cosmetic Act (FDCA). n406 The agency's mission includes promoting and **protecting** the public health by balancing two fundamental interests. On the one hand, FDA must ensure that drugs and devices are safe and effective, which protects against the introduction of dangerous or ineffective products into the marketplace. On the other hand, FDA must not unduly delay the availability of safe and effective products to patients in need. n407 (For a related discussion concerning patients' efforts to gain access to unapproved therapies, see *Patient Access to Unapproved Therapies: The Leading Edge of Medicine and Law*, page 45.)

n406 21 U.S.C. § 301 *et seq.*

n407 See FDA, FDA's Mission Statement, available at www.fda.gov/opacom/morechoices/mission.html (last visited Oct. 21, 2008).

FDA's safety requirements vary greatly depending on the disease condition the drug or device is aimed at treating and the availability of alternatives for patients. Thus, if the targeted condition is serious, a drug can be quite dangerous but still be approved by FDA for that indication if tests show that the drug effectively treats the targeted condition. For example, FDA is willing to accept significantly more toxicity in a drug aimed at treating aggressive cancer than in a drug aimed at treating a childhood ear infection. n408 Hence, FDA's determination that a drug is "safe" for marketing for a specific use is not equivalent to a determination that the drug is safe generally. Context is important in the drug approval process.

n408 Michelle Meadows, *Why Drugs Get Pulled Off the Market*, FDA CONSUMER MAG., Jan-Feb 2002, available at www.fda.gov/FDAC/features/2002/102_drug.html.

Arguably, then, FDA's mission would be undermined if manufacturers were permitted to seek approval for one indication, then to market the product broadly for all other potential indications. A manufacturer could identify the indication for which it could obtain FDA approval most quickly and cheaply--regardless of how limited the use for that indication. Therefore, off-label marketing restrictions are an essential component of FDA's ability to regulate drugs and devices effectively; these restrictions ensure that FDA reviews safety and effectiveness data for each indication prior to a manufacturer's promotion. Proponents of off-label marketing restrictions argue that eliminating such restrictions would

- . diminish or eliminate a manufacturer's financial incentive to study a drug's use and obtain definitive data,
- . result in harm to patients from unstudied uses that are ineffective or would lead to bad results,
- . diminish the use of evidence-based medicine, and
- . could ultimately erode FDA's efficacy standard by allowing manufacturers to end-run the efficacy requirements by marketing for a multitude of uses after approval without proving efficacy for the additional marketed uses. n409

n409 Janet Woodcock, *A Shift in the Regulatory Approach* (June 23, 1997), available at www.fda.gov/CDER/present/diamontreal/regappr/index.htm. Dr. Woodcock was the director of the FDA's Center for Drug Evaluation and Research (CDER), and is currently the Deputy Commissioner and Chief Medical Officer of the FDA.

Accordingly, FDA has several methods of regulating off-label marketing. For example, an approved or cleared drug or device marketed for an off-label use may be "misbranded" under the FDCA. Under 21 U.S.C. Section 352, FDA may deem a drug or device misbranded if the label does not bear adequate directions for use. n410

n410 FDA can grant technical exemptions to the labeling requirement while seeking administrative action against manufacturers it deems to be engaging in unlawful off-label promotion. See 21 U.S.C. § 352(f).

In an enforcement action under Section 352, the premise of the misbranding theory is that a drug that is promoted and intended for off-label use cannot bear adequate directions for use, because an FDA-approved label has directions for approved uses only. For example, in *United States v. Articles of Drug*, the United States brought action seeking to seize large quantities of drugs on the ground that the labeling did not contain adequate directions for use and did not meet a regulatory exemption. n411 Every drug has an approved indication for use set forth under the heading "Indication and Usage" on the FDA-approved label. Unapproved use is any use of the drug not identified in the

"Indication and Usage" section. The federal district court held that the label met the adequate directions for use requirement because of the inclusion of: (1) a cautionary legend on the drugs' labels stating federal law prohibits dispensing without prescription; and (2) sufficient directions to a physician, so the drugs could be prescribed safely and for their intended purposes. On appeal, however, the Fifth Circuit held that a drug's labeling must contain adequate directions for a consumer to engage in self-medication. Because prescription drugs by definition can be used only under a physician's supervision, such drugs must qualify under a regulatory exemption (i.e., have an approved label for the use). Misbranded drugs could be subject to administrative action against the manufacturer, seizure of the drug, and probable civil lawsuits against the manufacturer by patients who consumed the drug.

n411 *United States v. Articles of Drug*, 625 F.2d 665, 666 (5th Cir. 1980).

Off-label prescribing by physicians

Although FDA regulates promotion of drugs and devices by manufacturers, as a matter of policy, the agency generally does not interfere with the practice of medicine. n412 Physicians may prescribe approved or cleared drugs or devices for off-label uses in the exercise of their professional judgment. Although FDA may take action if safety issues with the use of any drug or device become a public health concern (as discussed above), once a drug or device has been approved or cleared for sale for one purpose, physicians may prescribe it for any other purpose that, in their professional judgment, is safe and effective. n413

n412 *See* 21 U.S.C. § 396; *see also* *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350-51 & n.5 (2001) ("FDA is charged with the difficult task of regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals"). *Id.* at 350.

n413 *See, e.g.*, 59 Fed. Reg. 59820, 59821 (Nov. 18, 1994) (noting that the agency has restated this policy on numerous occasions).

Off-label prescribing is most common with older medications that have developed into new uses for which manufacturers have not yet submitted applications and studies required by FDA. n414 For example, FDA approved Risperidone (Risperdal(R)) in 1993 for the treatment of schizophrenia, but the drug also is used for treating agitation in Alzheimer's patients. n415 There are several reasons for this trend toward unapproved additional uses. First, the cost of clinical testing and submitting a supplemental application for a new indication often outweighs the potential revenue from marketing the drug for an additional indication. Second, if the off-label use is widespread, the manufacturer stands to gain little additional benefit from marketing the new indication. Third, if generic versions of the drug are available, it may not be economically feasible to obtain an additional indication, because the **company** would incur additional marketing costs (generics are not typically marketed) and the benefit of the new indication would be spread across the various generic versions.

n414 Randall S. Stafford, *Regulating Off-Label Drug Use--Rethinking the Role of the FDA*, 358 NEW ENG. J. MED. 1427-1429 (2008).

n415 Charles D. Motsinger et al., *Use of Atypical Antipsychotic Drugs in Patients with Dementia*, 67 AM. FAM. PHYSICIAN 2335 (2003).

Off-label use of pharmaceuticals is relatively widespread. A 2006 study estimated that more than 20% of all prescriptions written by doctors were for unapproved uses. n416 The Government Accountability Office (GAO) found that about 25% of anticancer drugs were prescribed for off-label uses. n417 Off-label prescribing was higher for certain subgroups of patients. For example, 56% of cancer patients were given at least one drug off-label. n418 Another study

found that 81% of HIV patients received at least one drug off-label as part of their regimen. n419 The off-label use of medications is especially prevalent in pediatrics because most drugs are not tested in children. n420

n416 David C. Radley et al., *Off-Label Prescribing Among Office-Based Physicians*, 166 ARCHIVES INTERNAL MED. 1021 (2006).

n417 U.S. GEN. ACCOUNTING OFFICE, OFF-LABEL DRUGS: REIMBURSEMENT POLICIES CONSTRAIN PHYSICIANS IN THEIR CHOICE OF CANCER THERAPIES 4 (1991), available at <http://archive.gao.gov/d18t9/144933.pdf>.

n418 *Id.*

n419 Carol L. Brosgart et al., *Off-Label Drug Use in Human Immunodeficiency Virus Disease*, 12 J. ACQUIRED IMMUNE DEFICIENCY SYNDROMES & HUM. RETROVIROLOGY 56 (1996).

n420 See e.g., Nancy Monestime-Williams et al., *Off-Label Prescribing of Medications for Children*, 103 J. S.C. MED. ASS'N 130 (2007).

In some cases, there can be extensive medical experience supporting the off-label use of a drug or device. For example, FDA approved Trazodone (Desyrel(R)) in 1981 for the treatment of depression. The label noted that "the mechanism of DESYREL's antidepressant action in man is not fully understood." n421 FDA has never evaluated, much less approved, Trazodone for the treatment of insomnia. Yet, according to a 2005 NIH conference statement, Trazodone is the most commonly prescribed insomnia medication in the United States. n422

n421 Desyrel label, available at www.fda.gov/medwatch/SAFETY/2004/Desyrel_PI.pdf.

n422 NIH, NIH State-of-the-Science Conference Statement on Manifestations and Management of Chronic Insomnia in Adults, June 13-15, 2005, <http://consensus.nih.gov/2005/2005InsomniaSOS026html.htm>.

In short, off-label prescribing is permitted as part of the legitimate and effective practice of medicine. Unfortunately, aside from FDA's published policy that it will not intrude upon a physician's medical judgment, there is little regulatory or other legal guidance for healthcare practitioners who prescribe for off-label uses. Practitioners often are left to rely on ethical guidance to determine when it is acceptable to subject a patient to a potentially unknown/unsubstantiated risk for a potentially unknown/ unsubstantiated benefit. For example, the American Medical Association (AMA) adopted a policy for its members that provides, in part:

[A] physician may lawfully use an FDA-approved drug product or medical device for an unlabeled indication when such use is based upon sound scientific evidence and sound medical opinion...

[W]hen the prescription of a drug or use of a device represents safe and effective therapy, third party payors, including Medicare, should consider the intervention as reasonable and necessary medical care, irrespective of labeling, [and] should fulfill their obligation to their beneficiaries by covering such therapy. n423

n423 Am. Med. Ass'n, Policy H-120.988: Patient Access to Treatments Prescribed by Their Physicians, available at www.ama-assn.org/ by using "Policy Finder".

FDA's stated policy and the AMA's ethical guidelines do not have the effect of law, however, and by themselves do

not prevent third-party payors from attempting to deny payment for off-label use by designating it as "experimental." For example, some managed care organizations and private health insurers denied reimbursement for off-label use of drugs in oncology settings, designating the treatments experimental or investigational. n424 Congress began to address this issue for cancer drugs in the 1993 Omnibus Budget Reconciliation Act (OBRA), which expanded Medicare coverage for off-label use of anticancer drugs as long as the drugs were included in certain standard medical compendia. n425

n424 Am. Soc'y of Clinical Oncology, *Reimbursement for Cancer Treatment: Coverage of Off-Label Drug Indications*, 24 J. CLIN. ONCOL. 3206 (2008).

n425 *Id.*

Practitioners take some malpractice risk if something goes wrong with a prescribed off-label use. For example, if a patient suffers a serious adverse reaction to a drug taken for an unapproved use, the practitioner may have difficulty establishing that the treatment was within the standard of care. However, practitioners generally can point to good-faith reliance on FDA and AMA policies regarding off-label use as the basis for their actions.

In summary, although the practitioner prescribing off-label uses may be mostly free from FDA intervention, reimbursement and malpractice risks can be just as critical to the physician's practice.

FDA's position on what constitutes improper off-label promotion

As noted earlier, the most difficult task for a manufacturer is knowing what distinguishes direct or indirect promotion for off-label uses (which are not permitted by FDA) as opposed to communicating about off-label uses in a strictly non-promotional and scientific context (which is permitted commercial speech).

As noted above, FDA categorizes prohibited off-label marketing as violating statutory prohibitions against either misbranding (introducing into commerce devices or drugs lacking adequate directions for use) n426 or distributing unapproved new drugs under the FDCA. n427 Under either theory, the main factual issue is whether the manufacturer is promoting an "intended use" for the device or drug that has not been approved by FDA. n428

n426 21 U.S.C. §§ 331(a), 331(b), 352(f)(1), 355(a); 21 C.F.R. §§ 201.5, 801.5.

n427 21 U.S.C. § 331(d).

n428 *See* 21 U.S.C. § 321(k)-(n).

According to FDA's interpretation, intended use refers to the manufacturer's objective intent, as determined by its expressions and the circumstances surrounding the distribution of the product. Thus, in FDA's view, not only product labeling, but also information disseminated by or on behalf of manufacturers in other contexts (e.g., scientific and educational meetings, symposia, reprints of journal articles, continuing medical education, etc.) can establish an intended use. n429 According to FDA, it is of no legal consequence if any information alleged to constitute off-label promotion by a manufacturer is truthful, fair, and balanced. n430 In FDA's view, it is legal for independent parties to disseminate the same type of information, and for providers to use such information in medical decision-making. Conversely, FDA takes the position that it is improper, and in certain instances even criminal, for drug manufacturers to disseminate that same truthful information. As discussed later in this article, however, court rulings based on manufacturers' First Amendment rights have tempered this FDA stance.

n429 21 C.F.R. §§ 201.128, 801.4; 62 Fed. Reg. 64074, 64075 (Dec. 3, 1997).

n430 Of course, as a practical matter, if these were the only facts, the equities in favor of prosecution would be low. *But see* United States v. Caputo, 288 F. Supp. 2d 912, 920-23 (N.D. Ill. 2003), *cert. denied*, 77 U.S.L.W. 3197 (2008) (government could restrict dissemination of non-scientific, off-label information and other forms of off-label promotion because "permitting Defendants to engage in *all* forms of truthful, non-misleading promotion of off-label use would severely frustrate FDA's ability to evaluate the effectiveness of off-label uses." *Id.* at 922).

Enforcement Activities

At one time, enforcement of drug marketing was conducted primarily through the FDA in an administrative setting, with much of the focus on traditional labeling issues. This is no longer the case. Federal investigations are conducted jointly by agents of the FDA and the Department of Justice (DOJ). DOJ agents and prosecutors are fueled by their perception that enormous financial recoveries, including treble damages, can be--and have been--achieved through the vehicle of the False Claims Act. n431 The government's legal argument is that off-label marketing, rather than independent medical judgment, "causes" the prescription of unapproved prescription drugs and therefore provider claims for federal reimbursement for off-label uses are "false" under the False Claims Act. In the government's view, treble damages and an \$ 11,000 penalty *per claim* are due. With the "nuclear option" of potential federal program exclusion n432 or even criminal prosecution on the table, significant settlements, corporate Deferred Prosecution Agreements, and Corporate Integrity Agreements may appeal to manufacturers.

n431 31 U.S.C. § 3729(a); 64 Fed. Reg. 47099, 47104 at § 85.3(a)(9) (Aug. 30, 1999).

n432 42 U.S.C. § 1320a-7.

The consequences of criminal exposure can be severe--and difficult to prevent, even with a disciplined compliance program. Under the FDCA, for instance, a misdemeanor conviction does not require *any* proof of intent to defraud or mislead, essentially imposing strict liability for violations of the act. A misdemeanor conviction carries a maximum sentence of one year in jail plus a fine. n433 Felony liability under the FDCA, which does require proof of intent to defraud or mislead, carries a maximum sentence of five years in jail plus a fine. n434 If promotional practices can be shown to be *de facto* kickbacks to providers, e.g., payments to physician-speakers in amounts well above fair market value, then criminal liability under the federal Anti-Kickback Statute is possible as well. n435

n433 21 U.S.C. § 333(a)(1).

n434 21 U.S.C. § 333(a)(2).

n435 The corporate penalties for a federal Anti-Kickback Statute (AKS) violation include a \$ 500,000 fine plus restitution and a probable corporate integrity/compliance plan as a condition of probation. 42 U.S.C. § 1320a-7b(b)(2)(A); 18 U.S.C. § 3571. Violations also may result in the imposition of civil monetary penalties, 42 U.S.C. § 1320a-7a(a)(7), and, most significantly, program exclusion for the provider. 42 U.S.C. § 1320a-7. For individual offenders, maximum criminal penalties are set by statute; actual prison sentences are set by federal Sentencing Guidelines. The maximum individual criminal penalty for just one healthcare-related kickback is five years in jail and a \$ 250,000 fine. 42 U.S.C. § 1320a-7b(b); 18 U.S.C. § 3571.

Global criminal and civil resolutions

Since about 1999, the law enforcement community, which once limited its off-label investigations to sales of dubious "snake oils," has focused on pharmaceutical manufacturers--both large and small. The following is a discussion of the major settlements that provide the backdrop for today's investigations.

Cephalon: Actiq(R), Provigil(R), Gabitril(R) (E.D. Pa.)

In November 2007, Cephalon pleaded guilty to a misdemeanor violation of the FDCA and entered into a \$ 425 million settlement with the government to resolve an investigation into off-label marketing of Actiq, a berry-flavored lollipop narcotic approved for pain relief in connection with cancer treatments. n436 The investigation was initially triggered by the death of a 20-year-old woman who overdosed, and it was spurred by Cephalon's use of aggressive marketing tactics of Actiq. n437 According to the Connecticut Attorney General, Cephalon engaged in "questionable" practices to increase sales of Actiq. Alleged marketing activities that caused concern included:

- . Setting high sales quotas and encouraging prescriptions with larger doses. Specifically, although the Actiq label says patients initially should be prescribed no more than six lollipops containing a 200-microgram dose of fentanyl (the smallest of six possible dosages) to minimize the risk of overdosing, Cephalon allegedly encouraged doctors to start patients on 24 lollipops containing 400 micrograms of fentanyl each.

- . Targeting non-cancer doctors, especially neurologists, with small medical studies done without control group data, suggesting that Actiq could be used to treat migraine headaches and back pain. Internal Cephalon marketing documents encouraged sales reps to refer to Actiq as an "ER" on a stick.

- . The authors of the studies were paid lecturers for Cephalon, and were flown into seminars to present their "findings."

- . The use of free Actiq coupons for doctors who were not cancer doctors and who stated that they were unlikely to treat a cancer patient.

n436 See Stephen McGuire, *Cephalon Pays \$ 425 Million to Settle Claims of Off-Label Marketing*, MED. MARKETING & MEDIA, Nov. 12, 2007, available at www.mmm-online.com/Cephalon-pays-425-million-to-settle-claims-of-offlabel-marketing/article/96321/. The investigation and resolution also covered aggressive off-label marketing tactics in connection with two other Cephalon drugs, the narcolepsy pill Provigil and the epilepsy treatment Gabitril.

n437 FDA approved Actiq in 1998 for use by cancer patients who suffer intense pain for which other narcotics proved ineffective. Surveys suggested that more than 80% of patients who use the drug do not have cancer.

Because of Cephalon's aggressive marketing tactics, doctors prescribed the fentanyl-based narcotic to relieve non-cancer related pain, such as migraine headaches and back pain. The ever-increasing use of Actiq concerned doctors and government regulators because of the highly addictive nature of fentanyl. n438 Besides the guilty plea to a single misdemeanor charge and \$ 425 million settlement, the Office of the Inspector General for the Department of Health and Human Services (HHS-OIG) imposed a Corporate Integrity Agreement on Cephalon. Although the settlement resolved the federal investigation into Cephalon's marketing practices, a statement issued at the time of the settlement by the Connecticut Attorney General's Office, which also had been investigating Cephalon for off-label marketing, indicated that the Connecticut investigation would continue.

n438 See Actiq label, available at www.fda.gov/cder/foi/label/2007/020747s0271bl.pdf.

Specialty Distribution Services (SDS): Human Growth Hormone (HGH) (D. Mass.)

In September 2007, SDS, a subsidiary of Express Scripts, admitted that it had distributed HGH for purposes other than those approved by FDA. n439 The distribution of anabolic steroids and/or human growth hormone for muscle enhancement purposes may involve conduct designed both to defraud the United States and to violate federal law. n440

Since 1938, federal law has prohibited the distribution of anabolic steroids and/or human growth hormone outside a legitimate doctor-patient relationship. n441 In addition, prescription drugs such as anabolic steroids and/or human growth hormone can be legally distributed only in those instances in which a physician, based upon an individualized determination of a proper course of treatment, authorizes the drug's distribution to a patient under his or her supervision. n442 Distribution of these drugs outside these restrictions has resulted in the prosecution and conviction of laypersons, pharmacists, and physicians. n443

n439 Associated Press, *Firm Must Pay Fine, Cooperate with Ongoing Investigations*, ESPN, Sept. 19, 2007, available at <http://sports.espn.go.com/espn/news/story?id=3025958> [hereinafter *Associated Press*]; Michael S. Schmidt, *Company Agrees to a Fine Over Shipments of H.G.H.*, N.Y. TIMES, Sept. 19, 2007, available at www.nytimes.com/2007/09/19/sports/othersports/19doping.html [hereinafter *Schmidt*].

n440 UNITED STATES ATTORNEYS' MANUAL, CIVIL RESOURCE MANUAL, § 19, HUMAN GROWTH HORMONE/STEROID STATUTORY OVERVIEW, available at www.usdoj.gov/usao/eousa/foia_reading_room/usam/title4/civ00019.htm [hereinafter UNITED STATES ATTORNEYS' MANUAL].

n441 *Id.*

n442 See *DeFreese v. United States*, 270 F.2d 730, 733 & n.5 (5th Cir. 1959), *cert. denied*, 80 S. Ct. 810 (1960); *Brown v. United States*, 250 F.2d 745, 746-47 (5th Cir. 1958), *cert. denied*, 78 S. Ct. 779 (1958); see also *United States v. Zwick*, 413 F. Supp. 113, 115 (N.D. Ohio 1976) (holding that it is not proper for the physician dispensing and prescribing anorectic controlled drugs to adopt a unitary approach to the treatment of obesity in that no standard approach to treatment exists).

n443 See, e.g., *United States v. Shields*, 939 F.2d 780 (9th Cir. 1991), *superseded after remand by United States v. Von Mitchell*, 984 F.2d 338 (9th Cir. 1993); *United States v. Siler Drug Store*, 376 F.2d 89 (6th Cir. 1967); *De-Freese v. United States*, 270 F.2d 730, 733 & n.5 (5th Cir. 1959), *cert. denied*, 80 S. Ct. 810 (1960); *Brown v. United States*, 250 F.2d 745, 746-47 (5th Cir. 1958), *cert. denied*, 78 S. Ct. 779 (1958).

In 1990, Congress amended the FDCA in an effort to crack down on illegal use of anabolic steroids, particularly HGH. n444 Specifically, Congress enacted higher criminal penalties for offenses involving the illegal distribution of anabolic steroids and HGH. This new legislation, enacted as part of the Anabolic Steroids Control Act, n445 resulted in a reconfiguration of the statutory scheme regulating the distribution of both anabolic steroids and HGH. The act reclassified anabolic steroids as Schedule III controlled substances. n446 It also amended the FDCA to criminalize, as a five-year felony, the distribution and possession with intent to distribute of human growth hormone

for any use... other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Human Services... and pursuant to the order of a physician... n447

n444 See 21 U.S.C. § 333(e).

n445 Pub. L. No. 101-647, tit. XIX, §§ 1901-05.

n446 See 21 U.S.C. § 812(c).

n447 *Id.* § 333(e)(1).

The amended FDCA makes the prosecution of HGH off-label cases different from that of other drugs, because doctors may not prescribe HGH for any reason other than to treat a disease or other recognized medical condition. According to the *United States Attorneys' Manual*, prosecuting for the distribution of human growth hormones is different from prosecuting virtually any other drug distribution under the FDCA. For example, proof of interstate distribution is unnecessary. Additionally, the *mens rea* requirement for a felony is "knowing distribution" or "knowing possession with intent to distribute," not "intent to defraud or mislead." n448 Thus, prosecuting non-physicians, including manufacturers, for distributing HGH is akin to prosecuting a narcotics case under the Controlled Substances Act. As a result, establishing liability in such cases is simpler than for other FDCA offenses. n449

n448 UNITED STATES ATTORNEYS' MANUAL, at § B.

n449 *Id.*

It is in this context that SDS entered into a Deferred Prosecution Agreement with the U.S. Attorney's Office for the District of Massachusetts. As part of the deal, SDS paid the government \$ 10.5 million and agreed to cooperate with the government investigation for the next three years. Although not as large as other off-label marketing settlements, this case is notable for two reasons: (1) it exemplifies the extreme regulatory position in the off-label context; and (2) several professional athletes and entertainers have been accused of abusing HGH for cosmetic or performance enhancement purposes--the Massachusetts investigation arose out of SDS's deliveries of HGH to a prominent Boston athlete in 2002 and 2003. n450

n450 *Associated Press; Schmidt*. In an unrelated investigation out of Albany, New York, the Albany County District Attorney's Office investigated and charged Specialty Pharmacy, an Orlando, Florida business, and its corporate officials with illegally dispensing performance-enhancing drugs to professional athletes. *Schmidt*.

Orphan Medical: Xyrem(R) (E.D.N.Y)

In July 2007, Orphan Medical, collectively with its parent corporation, Jazz Pharmaceuticals, resolved an Eastern District of New York off-label investigation by pleading guilty to a felony charge of misbranding in violation of 21 U.S.C. Sections 331(a) and 333(a)(2) and agreeing to pay nearly \$ 20 million in fines and penalties. n451 The settlement resulted from the government's investigation arising out of a qui tam action brought by a former Orphan Medical sales representative. This case is notable because it involved the illegal marketing of Xyrem, also known as gamma-hydroxybutyrate or GHB, the highly controversial drug commonly known as the "date rape drug." Orphan Medical reportedly marketed the drug for numerous unapproved uses, including fatigue, pain, and psychiatric disorders.

n451 Press Release, U.S. Attorney's Office for the E. Dist. of N.Y., Jazz Pharmaceuticals, Inc. Agrees to Pay \$ 20 Million to Resolve Criminal and Civil Allegations in "Off-Label" Marketing Investigation (July 13, 2007), *available at* www.drugs.com/news/jazz-pharmaceuticals-inc-agrees-pay-20-million-resolve-criminal-civil-allegations-off-label-6486.html.

Xyrem was approved in 2002 for cataplexy, a condition characterized by weak or paralyzed muscles in connection with narcolepsy. In 2005, Xyrem was approved for a condition known as Excessive Daytime Sleepiness, or EDS. In pleading guilty to the felony misbranding charge, Orphan admitted that it paid a psychiatrist tens of thousands of dollars to give seminars around the country to promote Xyrem for off-label uses. FDA required black-box warnings on the label, stating that Xyrem's safety had not been established for children and that there was only limited data for elderly patients. Despite that, an Orphan-paid psychiatrist allegedly told his audiences that Xyrem was safe to prescribe to children and the elderly. n452 The psychiatrist, with the full knowledge and approval of Xyrem's sales force, made other misleading statements, including minimizing the potential side effects and dangers of overdose. This paid

surrogate even suggested that GHB was not really the date rape drug. The government alleged that in conjunction with his off-label promotion, the psychiatrist, with the knowledge of Orphan representatives, advised doctors how to bill to conceal the off-label uses and thus ensure reimbursement from insurers.

n452 *Id.*; see also Press Release, U.S. Attorney's Office for the E. Dist. of N.Y., Psychiatrist Charged with Conspiracy to Illegally Market the Prescription Medication Xyrem, Also Known as "GHB," for Unapproved Medical Uses on Behalf of Its Manufacturer (Apr. 5, 2006), available at www.usdoj.gov/usao/nye/pr/2006/2006apr05.html [herein-after *Press Release, U.S. Attorney's Office for the E. Dist. of N.Y.*].

Xyrem sales representatives allegedly used the psychiatrist in connection with efforts to promote Xyrem for a number of off-label uses, including fatigue, insomnia, chronic pain, EDS (prior to its approval), weight loss, depression, bi-polar disorders, and movement disorders such as Parkinson's Disease. Orphan allegedly sent drug representatives across the country to visit doctors who did not specialize in treating narcolepsy. Orphan rewarded physicians who were prescribing Xyrem, and made unrestricted educational grants to induce physicians to prescribe Xyrem for off-label uses. Xyrem representatives also disseminated written materials relating to off-label uses of Xyrem that did not meet FDA standards.

Orphan/Jazz pleaded guilty to a felony violation of the FDCA and agreed to pay \$ 5.5 million in criminal penalties, \$ 12.2 million in reimbursement to private and public health insurers to cover payments for off-label scripts, and \$ 3.75 million to resolve the government's civil False Claims Act case. Jazz also entered into a five-year Corporate Integrity Agreement with the OIG. n453 In addition, a former Orphan sales manager pleaded guilty to a single felony count of introducing a misbranded drug into interstate commerce, and the paid psychiatrist was indicted on conspiracy charges. The psychiatrist, Dr. Peter Gleason, referred to as a "carnival snake oil salesman" by the prosecutors, has responded to the indictment by fighting the charges and insisting that Xyrem is both safe and effective for off-label uses. n454 Dr. Gleason also claims that the federal charges are unconstitutional because they violate his free speech rights.

n453 A copy of the Jazz Corporate Integrity Agreement can be found at www.oig.hhs.gov/fraud/cia/agreements/Jazz%20CIA.pdf.

n454 *Press Release, U.S. Attorney's Office for the E. Dist. of N.Y.*

*Purdue Frederick **Company**: OxyContin(R) (W.D. Va.)*

In May 2007, the Purdue Frederick **Company**, as well as its president, chief legal officer, and former chief medical officer, pleaded guilty to charges of misbranding with intent to mislead under the provisions of the FDCA. n455 Although the **company** pleaded guilty to a felony charge, the individual corporate officials pleaded guilty to misdemeanor charges. The investigation stemmed from the **company's** fraudulent marketing of OxyContin. The **company's** liability stemmed from false claims that OxyContin was less addictive, less subject to abuse, and less likely to cause withdrawal symptoms than other pain relievers; FDA had vetted none of these statements. According to the investigation, the use of OxyContin may have contributed to a number of deaths. Purdue misbranded OxyContin as follows:

. Using various visual aids and training materials, Purdue sales representatives fraudulently told healthcare providers that OxyContin was less likely to be abused and was less addictive because OxyContin had a less euphoric effect than short-acting opioids. These presentations also were used in role-play training at Purdue's headquarters.

. Despite information suggesting that OxyContin was addictive even at low doses, Purdue supervisors and employees drafted an article about a study on the use of OxyContin in osteoarthritis patients that suggested OxyContin was not addictive and could be stopped abruptly without any negative

effects. Purdue sales representatives were encouraged to use the published article as part of their marketing efforts.

. Purdue sales representatives falsely led providers to believe that the delayed release of OxyContin made it less euphoric and therefore less addictive and less likely to be abused. The false statements were based on language in the package insert stating, "Delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug." n456 Supervisors told sales representatives they could tell healthcare providers that OxyContin potentially creates less chance for addiction than immediate-release opioids, ignoring reports of OxyContin abuse and diversion.

n455 Press Release, U.S. Attorney's Office for the W. Dist. of Va., The Purdue Frederick **Company**, Inc. and Top Executives Plead Guilty to Misbranding OxyContin; Will Pay Over \$ 600 Million (May 10, 2007), *available at* www.usdoj.gov/usao/vaw/press_releases/purdue_frederick_10may2007.html. Purdue, through its own press release, emphasized that the misbranding charges did not mean that FDA-approved prescribing information was incorrect, but only that statements of some employees went beyond the approved FDA information in promoting OxyContin to some healthcare professionals. *See* Press Release, Purdue Pharma L.P., Purdue Pharma L.P.'s Agreement with the Government, *available at* www.purduepharma.com/pressroom/news/wdvaresolution/Terms_of_WDVA_Agreement.pdf.

n456 FDA, LCDR Kristina C. Arnwire, Acting Team Leader, Div. of Medication Error Prevention, Office of Surveillance & Epidemiology, Reported Manipulation of OxyContin Tablets (May 5, 2008), *available at* www.fda.gov/ohrms/dockets/ac/08/slides/2008-4356s1-04-FDA-corepresentations.ppt.

The price to settle the OxyContin charges was substantial; the **company** and the individuals paid more than \$ 634 million in fines, penalties, and civil settlements. Specifically, pursuant to the plea agreements, \$ 276.1 million was forfeited to the federal treasury, \$ 160 million was paid to Medicaid-participating states, \$ 130 million was set aside for liability to private payors, \$ 5.3 million was paid to the Virginia Attorney General's Medical Fraud Control Unit to fund future fraud investigations, and \$ 20 million was paid to the Virginia Prescription Monitoring Program. The **company** also entered into a Corporate Integrity Agreement n457 requiring it to implement an effective compliance program and engage an independent review organization to monitor the **company's** compliance for five years.

n457 A copy of the Purdue Corporate Integrity Agreement can be found at www.oig.hhs.gov/fraud/cia/docs/CIAPurdue.pdf.

*Pharmacia & Upjohn **Company**: Genotropin(R) (D. Mass.)*

In April 2007, Pharmacia entered into a three-year Deferred Prosecution Agreement regarding an off-label matter and paid the government \$ 15 million. n458 Like the SDS case described above, Pharmacia had promoted its drug Genotropin, a Human Growth Hormone, for off-label uses such as anti-aging, cosmetic, or other athletic performance enhancement purposes. Pharmacia's conduct was brought to the federal government's attention through a disclosure by Pfizer, Pharmacia's parent **company**. n459 Pfizer disclosed the conduct, which predated Pfizer's acquisition of Pharmacia. This case illustrates that acquisitions can lead to off-label disclosures and investigations--the fact that the new owner did not engage in unlawful conduct did not insulate the new owner from liability.

n458 *See* Press Release, U.S. Attorney's Office for the Dist. of Mass., Pfizer Subsidiary Agrees to Plead Guilty for Offering Kickback and Pay \$ 19.68 Million Criminal Fine; Second Subsidiary Agrees to Pay Additional \$ 15 Million Penalty to Resolve Allegations of Illegal Promotion of Human Growth Hormone (Apr. 2, 2007), *available at* <http://boston.fbi.gov/dojpressrel/pressrel07/kickbackplea040207.htm>. A related **company**, Pharmacia & Upjohn **Company**, Inc., was involved in a concurrent anti-kickback investigation. The anti-kickback side of the case, which dealt with Pharmacia's contract with a patient assistance program manager, resulted in a felony guilty plea, an additional criminal fine of \$ 19.7 million, and the permanent exclusion of that Pharmacia **company** from all federal healthcare programs. *Id.*

n459 Press Release, Pfizer NV/SA, Pharmacia Subsidiaries Reach \$ 34.7 Million Settlement with DOJ and Resolve Allegations of Improper Activities Prior to Acquisition by Pfizer (Apr. 2, 2007), *available at* www.pfizer.be/Media/Press+bulletins/In+General/Pharmacia+subsidiaries+reach+settlement+with+DOJ.htm.

InterMune: Actimmune(R) (N.D. Cal.)

In October 2006, InterMune entered into a Deferred Prosecution Agreement, as well as a five-year Corporate Integrity Agreement with the OIG related to its marketing of Actimmune for the treatment of idiopathic pulmonary fibrosis (IPF), a fatal disease. n460 Actimmune had been approved by FDA only for the treatment of chronic granulomatous disease n461 and malignant osteopetrosis, n462 not IPF. InterMune's marketing materials included press releases touting clinical trial results tending to indicate that Actimmune benefited patients with IPF. According to the government, however, these clinical trials did not demonstrate any statistically significant benefit. InterMune paid nearly \$ 37 million (roughly \$ 30 million to the federal government and almost \$ 7 million to state governments) to settle the matter.

n460 Press Release, U.S. Dep't of Justice, Biopharmaceutical Firm Intermune to Pay U.S. Over \$ 36 Million for Illegal Promotion and Marketing of Drug Actimmune (Oct. 26, 2006), *available at* www.usdoj.gov/opa/pr/2006/October/06_civ_728.html. A copy of the InterMune Corporate Integrity Agreement can be found at www.oig.hhs.gov/fraud/cia/docs/InterMuneCIA.pdf.

n461 Chronic granulomatous disease is a hereditary disease that impairs the function of white blood cells in the immune system.

n462 Malignant osteopetrosis is a hereditary disease that adversely affects bone development and function.

More recently, in March 2008, the government indicted former InterMune CEO Scott Harkonen on charges of wire fraud and felony violations of the FDCA for his role in the off-label marketing of Actimmune. n463 Specifically, the government alleged that Harkonen, as a doctor and chief executive officer of InterMune, directed that Actimmune be marketed to treat IPF. In marketing Actimmune for this unapproved treatment, Harkonen claimed that Actimmune was safe and effective for use in treating IPF. More problematic was Harkonen's claim that Actimmune helped IPF patients live longer by reducing mortality by up to 70%, a claim without FDA-approved support. According to the indictment, Harkonen and other InterMune executives were told explicitly that it was unlikely FDA would approve Actimmune for the treatment of IPF given the failure of InterMune's studies to show that it was effective for IPF. It cost \$ 50,000 to treat an IPF patient for one year with Actimmune, and prescriptions to treat patients with IPF generated the vast majority of Actimmune sales. Thus, considerable sales were falsely billed, increasing the risk of enforcement.

n463 Press Release, U.S. Dep't of Justice, Former Intermune CEO W. Scott Harkonen Indicted for Wire Fraud and FDA Violations (Mar. 18, 2008), *available at* www.usdoj.gov/opa/pr/2008/March/08_civ_217.html.

Schering Sales Corporation and Schering-Plough Corporation: Temodar(R), Intron(R) A (D. Mass.)

One off-label settlement that has provoked some criticism due to its potential impact on the dissemination of scientific data about potentially beneficial off-label uses of drugs is the March 2008 settlement between Schering Sales Corporation and the government. Schering pleaded guilty to a felony conspiracy to make false statements to FDA and the Health Care Financing Administration involving among other things, off-label promotion of Temodar and Intron A. n464 The underlying investigations were initiated as a result of three qui tam actions. The Schering **companies** paid a combined total of \$ 435 million to settle the civil qui tam and criminal investigations against them, and Schering Sales Corporation was permanently excluded from participating in federal healthcare programs.

n464 Press Release, U.S. Attorney's Office for the Dist. of Mass., Schering to Pay \$ 435 Million for the Improper Marketing of Drugs

and Medicaid Fraud (Aug. 29, 2006), *available at* <http://www.usdoj.gov/usao/ma/Press%20Office%20-%20Press%20Release%20Files/Schering-Plough/press%20release.pdf> [hereinafter *U.S. Attorney's Office for the Dist. of Mass.*]. The settlement also required Schering to enter into an agreement to augment its existing Corporate Integrity Agreement. *See* Addendum to the Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Schering-Plough Corporation (Aug. 25, 2006), *available at* www.oig.hhs.gov/fraud/cia/agreements/Schering_Plough_Corporation_08252006_addendum.pdf. Subsequent to the settlements with the government, Schering became involved in several class action lawsuits arising in part out of the **company's** alleged off-label marketing practices. *See* Charles Toutant, *Schering-Plough Defends Suits Over Marketing of "Off Label" Drug Uses*, N.J. L. J., Aug. 31, 2007, *available at* www.law.com/jsp/article.jsp?id=1188464549972.

The off-label portion of these federal investigations stemmed from the marketing of Temodar and Intron A for unapproved uses. n465 Specifically, Temodar was developed and approved for a particular type of brain cancer resistant to other drugs. Schering, however, allegedly marketed Temodar for other uses, including other brain cancers and cancers that had spread to other parts of the body. Similarly, Schering allegedly promoted the use of Intron A for the treatment of certain superficial bladder cancers when it was approved only for use in treating Hepatitis C, AIDS-related Kaposi's sarcoma, melanoma, and lymphoma.

n465 The other object of the federal investigations involved a non-off-label issue related to allegations of Medicaid fraud associated with the pricing of Schering's Claritin RedTabs.

The government's allegations centered on direct statements made by Schering officials to FDA designed to reassure the agency that certain off-label promotional activities of Schering sales representatives were an isolated occurrence. However, the off-label promotion of Temodar and Intron A allegedly were directed from headquarters as part of a national corporate marketing plan. n466 The government further alleged that Schering later made statements to FDA causing the agency to believe that Schering was addressing this illegal conduct when it was expecting to pursue a national marketing strategy based on promoting off-label usage of these drugs. n467

n466 *U.S. Attorney's Office for the Dist. of Mass.*

n467 *Id.*

The Schering national marketing plan for Temodar and Intron A sought to induce doctors to prescribe these drugs for unapproved off-label uses through various strategies, including

- . sham advisory boards,
- . improper preceptorships,
- . lavish entertainment, and
- . improper distribution of peer reviewed clinical trials.

It is the last point that has been a source of frustration for critics of off-label prosecution. Whether there is reliable scientific data supporting the off-label use of Temodar and Intron A is of no import to the government. However, to the extent that the settlement results in a decrease in treatment with drugs that have some supported benefit for off-label uses, the government could be construed as chilling this beneficial use. n468 Critics of the government's approach argue that, to the extent that sales remain the same or grow, Schering's conduct does not appear to have been material to the overall sales of Temodar and Intron A. n469 The crux of this argument is based on free speech rights.

n468 *Critics Blast Off-Label Component of Schering-Plough's Global Settlement*, 5 RX COMPLIANCE REP., Oct. 4, 2006, at 6, available at www.wlf.org/upload/100406rxcomp.pdf.

n469 *Id.*

Eli Lilly: Evista(R) (S.D. Ind.)

The December 2005 Eli Lilly settlement further highlights that **companies** cannot market drugs for off-label uses even if scientific data support those uses. Eli Lilly pleaded guilty to a misdemeanor violation of the FDCA and paid \$ 36 million to the government: \$ 24 million in equitable disgorgement tied to a consent decree of permanent injunction, \$ 6 million in a criminal fine, and \$ 6 million in asset forfeiture. n470 The settlement ended the government's investigation into Eli Lilly's marketing of the osteoporosis drug Evista for off-label uses. Specifically, Eli Lilly allegedly promoted Evista for preventing and reducing the risk of breast cancer and reducing the risk of heart disease, both off-label uses. (Ironically, in late 2007, FDA approved Evista for use as a breast cancer preventative. n471)

n470 Press Release, U.S. Dep't of Justice, Eli Lilly and **Company** to Pay \$ 36 Million Relating to Off-Label Promotion (Dec. 21, 2005), available at www.usdoj.gov/opa/pr/2005/December/05_civ_685.html.

n471 *FDA Approves Eli Lilly's Osteoporosis Drug Evista to Prevent Breast Cancer*, **Company** Says, MED. NEWS TODAY, Sept. 19, 2007, available at www.medicalnewstoday.com/articles/82754.php.

Evista's brand team allegedly engaged in off-label promotion after FDA initially rejected proposed labeling concerning use of the drug to prevent breast cancer. According to the government's investigation, the Evista brand team resorted to the off-label strategy after disappointing revenues for Evista's first year. Some of the alleged sales tactics employed by the Evista sales representatives included:

- . Personal one-on-one sales pitches regarding potential off-label uses of Evista, where sales personnel asked "bait" questions to trigger an inquiry from the doctor regarding unapproved off-label uses.
- . Sales representatives sending unsolicited letters to physicians on their sales routes touting Evista's potential efficacy for unapproved uses.
- . Organizing a "market research summit" where Evista was discussed with doctors for unapproved off-label uses, including the prevention of breast cancer.
- . Producing and distributing a promotional video demonstrating "Evista Best Practices," in which Evista sales representatives explicitly state that Evista is the best drug for preventing osteoporosis (its approved use), as well as for preventing breast cancer and heart disease (off-label uses).
- . Training Evista sales representatives to use reprinted medical articles to unfairly highlight the results of using Evista to treat unapproved indications by hiding the disclosure page that revealed that the article's authors were employed by Eli Lilly and that Evista's effectiveness in reducing the risk of breast cancer had not yet been established.

In addition to pleading guilty to misdemeanor charges of misbranding, Eli Lilly agreed to a civil consent decree that required equitable disgorgement of \$ 24 million. The terms of the consent decree and permanent injunction are similar to a Corporate Integrity Agreement in that they require Eli Lilly to refrain from promoting Evista for off-label uses, to implement compliance procedures, and to hire an independent review organization to monitor Eli Lilly's compliance with the terms of the decree. Thus, even if the drug's off-label claims are accurate, a **company** runs a significant risk when marketing its drug for an off-label indication before FDA approves the drug for that use.

Serono Labs: Serostim(R) (D. Mass.)

Serono Labs pleaded guilty to felony criminal charges in connection with its AIDS wasting drug Serostim in October 2005. n472 The case was not a strict off-label marketing case; rather, Serono pleaded guilty to conspiring with medical device manufacturer, RJL Sciences, n473 to market RJL's bioelectrical impedance analysis (BIA) computer software for use in calculating body cell mass and diagnosing AIDS wasting--uses for which the FDA had not approved the software. Serono had experienced a decline in Serostim sales because of the market introduction of protease inhibitors (protease inhibitors are a mainstay of HIV anti-viral therapy and can help reduce the effects of AIDS wasting). n474 Serono partnered with RJL to market RJL's product as a means of diagnosing AIDS wasting by calculating body cell mass. The purpose of the agreement, from Serono's perspective, was to increase the overall patient base diagnosed with AIDS wasting and thereby boost Serostim sales. AIDS wasting however, is not diagnosed by body cell mass but by changes in weight and lean body mass. Serono paid a total of \$ 704 million to the government: a \$ 137 million criminal fine and \$ 567 million to settle civil liabilities. Further, Serono agreed to be excluded from all federal healthcare programs for five years and to enter into a Corporate Integrity Agreement n475 with HHS. Serono Labs and its related **companies** settled a civil class action suit related to Serostim for \$ 24 million in late 2007. This case illustrates that the government will not limit enforcement discretion to traditional "marketing" activities.

n472 Press Release, U.S. Dep't of Justice, Serono to Pay \$ 704 Million for the Illegal Marketing of AIDS Drug (Oct. 17, 2005), available at www.usdoj.gov/opa/pr/2005/October/05_civ_545.html.

n473 RJL and its president had pleaded guilty for their role in the conspiracy in April 2005. See William M. Bulkeley, *RJL Sciences and Its President Plead Guilty in Medical-Device Case*, WALL ST. J., Apr. 20, 2005, available at www.aegis.com/news/wsj/2005/wj050408.html.

n474 William A. McGrath, *Serono Settlement Should Highlight Need for Compliance, Not Chill Legitimate Off-Label Communication*, 13 FDA ADVERTISING & PROMOTION, Dec. 2005, at 14, available at www.wileyrein.com/docs/publications/12471.pdf.

n475 A copy of the Serono Corporate Integrity Agreement can be found at www.oig.hhs.gov/fraud/cia/agreements/SeronoHoldings_101405.pdf.

*Warner-Lambert **Company**: Neurontin(R) (D. Mass.)*

In May 2004, Warner-Lambert pleaded guilty to a felony violation of the FDCA and paid the government \$ 430 million to settle the investigation related to Warner-Lambert's marketing of the anti-seizure drug Neurontin. n476 (This settlement was in addition to the settlement of the civil False Claims Act case instituted by qui tam relator David Franklin highlighted in the Introduction to this article.) The **company** allegedly marketed Neurontin for a number of unapproved uses, including bipolar disorder, pain disorders, amyotrophic lateral sclerosis, attention deficit disorder, migraines, withdrawal-related seizures, restless leg syndrome, and as a first-line, isolated treatment for epilepsy. Among the numerous off-label marketing practices in which Warner-Lambert allegedly engaged, the **company**:

- . Promoted Neurontin for use as a sole drug in the treatment of epileptic seizures, even though FDA had rejected the monotherapy indication;
- . Promoted Neurontin for the treatment of bipolar disease, even though a scientific study had not demonstrated efficacy against a placebo;
- . Encouraged sales representatives to proactively pitch Neurontin for off-label uses to physicians;
- . Through its sales representatives, made false or misleading statements about FDA approval of Neurontin in response to physician questions; and

. Used sham consultants' meetings and sham independent medical education to promote Neurontin for off-label uses.

n476 Press Release, U.S. Dep't of Justice, Warner-Lambert to Pay \$ 430 Million to Resolve Criminal & Civil Health Care Liability Relating to Off-Label Promotion (May 13, 2004), available at www.usdoj.gov/opa/pr/2004/May/04_civ_322.htm. A copy of the Warner-Lambert settlement agreement can be found at www.usdoj.gov/civil/foia/elecread/2004/Warner-Lambert%202004.pdf.

The \$ 430 million settlement was comprised of \$ 240 million in a criminal fine, \$ 83.6 million (plus interest) in False Claims Act liability, and \$ 106.4 million in state Medicaid and consumer fraud liabilities. Pfizer, which had acquired Warner-Lambert after the charged off-label marketing occurred, entered into a Corporate Integrity Agreement n477 to ensure that the compliance program it had implemented upon acquiring the **company** would continue to be effective.

n477 A copy of the Pfizer Corporate Integrity Agreement can be found at www.oig.hhs.gov/fraud/cia/agreements/pfizer_5_11_2004.pdf.

Genentech: Protropin(R) (N.D. Cal.)

In April 1999, Genentech reached a settlement agreement with the government regarding marketing of the HGH Protropin, which FDA had approved for treating children with growth hormone deficiency. n478 In the settlement, Genentech pleaded guilty to a misdemeanor violation of the FDCA, paid a \$ 30 million criminal fine, and paid an additional \$ 20 million in civil restitution to Medicaid and CHAMPUS (a federal military insurance program) for improper reimbursements. Further, the **company** admitted that it had marketed the drug for off-label uses, including for use in children who were short but not growth hormone deficient, children with a certain form of juvenile obesity, and some burn victims. As an additional component of the settlement, the government acknowledged that the off-label marketing of Protropin had occurred from 1985 to 1994, and ceased in 1994 after the **company** implemented stricter compliance and training programs.

n478 See *Genentech Confirms Settlement Agreement with U.S. Government*, BUSINESS WIRE, Apr. 14, 1999, available at http://findarticles.com/p/articles/mi_m0EIN/is_1999_April_14/ai_54376955; Tamar Nordenberg, *Maker of Growth Hormone Feels Long Arm of Law*, FDA CONSUMER, Sept. 1999, available at http://findarticles.com/p/articles/mi_m1370/is_5_33/ai_55928683.

Civil Settlements

In certain instances where intent rises only to the level of "reckless disregard" or "deliberate ignorance," the government enters civil resolutions that do not globally resolve all potential claims. These cases address the same promotional conduct and usually involve a Corporate Integrity Agreement.

*Bristol-Myers Squibb **Company** (BMS) and Otsuka America Pharmaceutical: Abilify(R) (D. Mass. & S.D. Fla.)*

In September 2007, BMS entered into a civil settlement agreement to pay \$ 515 million to settle a wide range of government investigations dating back as far as 1994 n479 that included alleged off-label promotion of Abilify. FDA approved Abilify, an atypical anti-psychotic drug, for the treatment of adult schizophrenia and bi-polar disorder. Abilify carried a black box warning regarding use in treating dementia-related psychosis. The government alleged that notwithstanding lack of FDA approval for pediatric and geriatric patients, BMS instructed its sales force to call on child psychologists and pediatricians to promote Abilify for the treatment of dementia and psychosis. Allegedly, BMS also created a specialized sales force designed to service **nursing homes** and long-term care facilities, where dementia is much more widespread than the approved conditions of schizophrenia and bi-polar disorder. Of the \$ 515 million BMS

paid, \$ 328 million went to the federal treasury, of which \$ 25 million represented disgorgement of profits allegedly derived from off-label marketing of Abilify. More than \$ 187 million went to Medicaid-participating states. n480 In addition, BMS agreed to enter a five-year Corporate Integrity Agreement n481 with HHS-OIG.

n479 Press Release, U.S. Dep't of Justice, Bristol-Myers Squibb to Pay More Than \$ 515 Million to Resolve Allegations of Illegal Drug Marketing and Pricing (Sept. 28, 2007), *available at* www.usdoj.gov/opa/pr/2007/September/07_civ_782.html. This settlement resolved seven qui tam actions filed in Massachusetts and Florida. Other components of the settlement involved investigations into the pricing of BMS drugs and remuneration offered to physicians to induce them to write prescriptions for BMS drugs.

n480 In March 2008, shortly after the BMS settlement, Otsuka, which had partnered with BMS to co-promote Abilify, settled its case with the government related to the off-label marketing for \$ 4 million. Press Release, U.S. Dep't of Justice, Otsuka to Pay More than \$ 4 Million to Resolve Off-Label Marketing Allegations Involving Abilify (Mar. 27, 2008), *available at* www.usdoj.gov/opa/pr/2008/March/08_civ_244.html.

n481 A copy of the BMS Corporate Integrity Agreement can be found at www.oig.hhs.gov/fraud/cia/agreements/BMS_CIA.pdf. Otsuka also entered into a Corporate Integrity Agreement, which can be found at www.oig.hhs.gov/fraud/cia/agreements/otsuka_america_pharmaceutical_inc_03252008.pdf.

Cell Therapeutics (CTI): Trisenox(R) (W.D. Wash.)

In April 2007, CTI settled an off-label marketing investigation related to their anti-cancer drug Trisenox. n482 The investigation was triggered by a qui tam action alleging Trisenox was promoted and prescribed to treat patients with cancers for which Trisenox was not an approved treatment. FDA approved Trisenox A in 2000 for the limited use of treating patients with acute promyelocytic leukemia, which affects approximately 400 people annually. According to the qui tam allegations and the federal investigation, CTI allegedly used sham consulting agreements to pay doctors \$ 500 to \$ 1000 to attend dinners and conferences to learn about various off-label uses of Trisenox. Doctors who prescribed Trisenox frequently were eligible for and received additional payments of up to \$ 1500 in alleged illegal kickbacks for speaking at conferences promoting Trisenox. The government alleged that CTI misled doctors into believing that Trisenox was medically accepted for a number of different cancers in addition to its approved use.

n482 See John Cook, *Cell Therapeutics to Pay \$ 10.5 Million*, SEATTLE POST-INTELLIGENCER, Apr. 17, 2007, *available at* http://seattlepi.nwsourc.com/business/311948_cell18.html; Kirsten Orsini-Meinhard, *Cell Therapeutics to Pay \$ 10.5 Million to Settle Feds' Suit*, SEATTLE TIMES, May 2, 2007, *available at* http://seattletimes.nwsourc.com/html/business/technology/2003670653_cell18.html. As a part of the settlement, Cell subsequently entered into a Corporate Integrity Agreement, which can be found at www.oig.hhs.gov/fraud/cia/agreements/cell_therapeutics_inc_12222007.pdf.

The government alleged that these meetings caused thousands of false claims for prescriptions for unapproved uses to be submitted and paid through Medicare. In the settlement, CTI paid \$ 10.5 million to the government to resolve the civil qui tam allegations of off-label marketing, as well as allegations that it used illegal kickbacks to encourage physicians to prescribe Trisenox. CTI denied any wrongdoing and has since filed a lawsuit against its consultant, the Lash Group, alleging that the **company** provided negligent advice.

Gilead Sciences: Viread (R) (N.D. Cal. & 9th Cir.)

In a recent case, private civil exposure to a manufacturer came in the form of a securities action instead of a civil false claims action. In *Gilead*, n483 a group of individual investors brought a securities fraud action "alleg[ing] violations of sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. 78j(b), 78t(a), and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5." n484 The plaintiffs' complaint stated that Gilead, a biopharmaceutical **company** whose biggest commercial product is the HIV drug Viread, "misled the investing public by representing that demand for [Viread] was strong without disclosing that unlawful [off-label] marketing was the cause of that strength." n485 The

plaintiffs alleged that FDA approved Viread for use in approximately 40% of HIV patients, but that Gilead repeatedly violated FDA's off-label marketing regulations in an effort to have Viread prescribed to the remaining HIV patients. n486 These efforts allegedly lead to between 75 and 95% of Viread's sales deriving from off-label uses. n487 On March 14, 2002, FDA sent an "Untitled Letter" to Gilead accusing the **company** of understating the risks of Viread, a form of off-label marketing, and ordered Gilead to "immediately cease" the practice. n488 The plaintiffs claimed that Gilead's off-label marketing only increased after FDA's demand. By the summer of 2003, Gilead raised the price of Viread and announced "that it anticipated [that] its second quarter financial results would exceed analysts' expectations...." n489

n483 *In re Gilead Scis. Secs. Litig.*, 536 F.3d 1049 (9th Cir. 2008), *rev'g*, Nos. C03-4999 MJJ, C03-5391 MJJ, C04-0100 MJJ, C03-5088 MJJ, C03-5592 MJJ, C03-5113 MJJ, C03-5805 MJJ (N.D. Cal. May 12, 2006).

n484 *Id.*

n485 *Id.* at 1052.

n486 *Id.* at 1051. According to the complaint, the off-label marketing took three forms: (1) marketing to HIV patients co-infected with Hepatitis B, which was not an approved use; (2) marketing Viread as a first-line or initial therapy for HIV infection, even though Viread was approved only as adjunct therapy; and (3) marketing against Viread's safety profile (i.e., that Viread was safer than the label indicated).

n487 *Id.*

n488 *Id.*

n489 *Id.* at 1052.

FDA issued a Warning Letter that chastised Gilead for statements made by one of its sales representatives at the 15th National HIV/AIDS Update Conference in March and April of 2003. The letter stated that the employee "made oral statements that minimized the risk information and broadened the indication for Viread." FDA ordered Gilead to make corrective disclosures, which Gilead did on November 7, 2003. Prior to Gilead's disclosure, FDA made its Warning Letter public on August 7, 2003. According to the plaintiffs, Viread suffered a drop in sales starting in August. Gilead's officers sold a large number of shares, while the public did not fully understand the significance of the FDA Warning Letter until Gilead's press release on October 28, 2003, "detailing [its] third quarter financial results." n490

n490 *Id.* at 1054.

The district court dismissed the case, holding that the investors failed to allege loss causation. The plaintiffs appealed. On appeal, the court found that "the complaint sufficiently allege[d] a causal relationship between (1) the increase in sales resulting from the off-label marketing, (2) the Warning Letter's effect on Viread orders, and (3) the Warning Letter's effect on Gilead's stock price." n491

n491 *Id.* at 1057.

Although *Gilead* has not yet been adjudicated on its merits, the appellate court's ruling highlights how the business risk to pharmaceutical and medical device **companies** from off-label promotion of drugs can vary. Off-label use could lead to civil lawsuits from investors, third-party payors or individual patients, depending on the circumstances.

The criminal and civil cases highlighted above clearly indicate that off-label marketing practices can result in significant monetary penalties. A fair amount of controversy exists regarding the use of statutes such as the criminal or civil False Claims Act to police the pharmaceutical industry. Another source of controversy stems from the lack of clear regulatory guidance for off-label use and marketing, which is discussed in more detail below.

Administrative Guidance

Regulation of off-label marketing can seem complex and ambiguous. At one extreme, intentional off-label promotion of a drug or device without scientific support for its promoted use has--and continues to be--prohibited. This scenario implicates one of FDA's fundamental missions--to protect the public's safety in the use of prescription drugs. Although this situation can occur, it is rare for a drug or device manufacturer to engage in such unsubstantiated off-label promotion. Simply put, it would be difficult to convince physicians to prescribe a drug for a specific indication if no scientific evidence exists to support that use.

At the other extreme, a manufacturer's best defense against the accusation of off-label promotion is not to market its product. Such a course of conduct is not viable from a marketing perspective, and a regulatory scheme that would foster such a conservative approach raises significant commercial free speech concerns.

In practice, if a drug or device has exceptional therapeutic value, or a substantial market potential for a use not included in the initial label, the manufacturer is almost certain to seek a label revision to include the additional indication and subsequently will market the drug or device accordingly. Minoxidil serves as one such example. FDA approved Minoxidil as an oral antihypertensive n492 under the trade name Loniten(R) in 1979. n493 After Minoxidil entered the market, the drug was associated with hair growth. Obviously, treatment for baldness was not a labeled indication for Loniten. Nevertheless, in 1988, UpJohn received FDA approval for Rogaine(R), a topical form of Minoxidil for hair growth. n494

n492 Medication used to treat high blood pressure.

n493 MedlinePlus, Drugs, Supplements, and Herbal Information, www.nlm.nih.gov/medlineplus/druginfo/medmaster/a682608.html (last visited Oct. 25, 2008); Loniten, www.fda.gov/cder/foi/label/2002/18154s23lbl.pdf (last visited Oct. 25, 2008). See also www.fda.gov/cder/foi/label/2002/18154s23lbl.pdf (Loniten label) (last visited Nov. 3, 2008) and www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm (search Loniten approval history).

n494 FDA, Drugs@FDA, www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm (last visited Oct. 25, 2008); Rogaine, www.fda.gov/cder/foi/label/2005/019501s020,0251bl.pdf (last visited Oct. 25, 2008).

In between these extremes lies almost every real-world situation. The most common scenario involves the dissemination by a manufacturer of scientific data and publications in support of emerging or potential off-label uses. It is precisely in this situation that FDA's recent position is not clear, because over the last decade, the regulatory structure for off-label marketing has been, and remains, in a state of flux. The best a manufacturer can do is to review the history of FDA's position, understand how and why it changes over time, and try to anticipate what may be waiting on the horizon.

Before 1997, there was a long-standing prohibition on the dissemination of information about unapproved uses of drugs and devices by manufacturers, subject to very limited exceptions. Two events changed this approach to regulating off-label marketing. First, in 1997, Congress enacted the Food and Drug Administration Modernization Act (FDAMA), n495 amending the FDCA. n496 Section 401 of FDAMA described certain conditions under which a drug or medical device manufacturer could choose to disseminate medical and scientific information discussing unapproved uses of approved drugs (as well as cleared or approved medical devices) to healthcare professionals and certain entities (including pharmacy benefits managers, health insurance issuers, group health plans, and federal or state governmental

agencies). n497

n495 Food and Drug Administration Modernization Act of 1997 (FDAMA), Pub. L. No. 105-115 (Nov. 27, 1997), at § 401, *codified at* 21 U.S.C. § 360aaa *et seq.*

n496 Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*

n497 Sec. 401, Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115 (1997), *codified at* 21 U.S.C. § 360aaa *et seq.*

Second, in a July 30, 1998, District of Columbia district court opinion, the Washington Legal Foundation (WLF) successfully convinced the court that FDA's regulation of off-label marketing violated manufacturers' First Amendment rights. n498 The WLF argument focused on the fact that a manufacturer's lawful claims about a drug do not match the scope of a physician's lawful prescriptions. However, WLF did not argue that a manufacturer could disseminate inaccurate or misleading information, an allegation in many of the enforcement actions described above. In ruling that the FDA's Guidance Documents are more extensive than necessary to serve the asserted government interest and unduly burden important speech, n499 the court struck down FDA's (1) Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data; n500 (2) Guidance for Industry Funded Dissemination of Reference Texts; n501 and (3) Final Guidance on Industry Supported Scientific and Educational Activities. n502

n498 Wash. Legal Found. v. Friedman, 13 F. Supp. 2d 51 (D.D.C. 1998).

n499 *Id.* at 71-72.

n500 61 Fed. Reg. 52800 (Oct. 8, 1996).

n501 *Id.*

n502 62 Fed. Reg. 64074 (Dec. 3, 1997).

Shortly before publication of the court's opinion, in June 1998, FDA issued a proposed rule for dissemination of information on unapproved and new uses for drugs and devices. n503 The proposed rule would create a new Code of Federal Regulations Part, entitled "Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices," to implement section 401 of the FDMA. n504 These changes were only the beginning of the flux in regulatory structure. Congress had built a sunset provision into FDAMA Section 401, that effectively nullified the changes to the FCDA by September 26, 2006, or seven years from the date FDA promulgated accompanying regulations. Before FDA managed to finalize its rule, however, it was dealt another setback by the courts.

n503 63 Fed. Reg. 31143 (June 8, 1998).

n504 *Id.*

In 2000, the WLF renewed its action against the FDA in *WLF v. Hennerly*. n505 The court granted a permanent injunction declaring the FDAMA and its implementing regulations unenforceable, and denied the FDA's motion to confine application of an injunction to express provisions of guidance documents. n506 The FDA appealed. The Court

of Appeals dismissed the appeal and vacated the injunction for lack of constitutional controversy after FDA conceded the position that the FDAMA did not provide it with independent authority to proscribe speech, and WLF responded that it no longer had constitutional objection to FDAMA or guidance.

n505 Wash. Legal Found. v. Hennery, 202 F.3d 331 (D.C. Cir. 2000), *motion denied*, 128 F. Supp. 2d 11 (D.D.C. 2000). Note that *Hennery* is a continuation of *Friedman*, and substituted Dr. Hennery because she was the new FDA Commissioner.

n506 *Id.*

Subsequent to the *Hennery* decision, FDA published a clarification on the applicability of FDAMA section 401, establishing a "safe harbor" for a manufacturer that complies with the FDAMA before and while disseminating journal articles and reference publications about new uses of approved or cleared products. n507 FDA retained the right, in the context of case-by-case enforcement, to determine from a manufacturer's written materials and activities how the manufacturer intended its products to be used. FDA also recognized that if the agency brought an enforcement action, a manufacturer could raise a First Amendment defense.

n507 65 Fed. Reg. 14286 (Mar. 16, 2000).

Thus, by the time the implementing regulations were codified at 21 C.F.R. Part 99 in 2001, more than three years after the passage of the FDMA, the force behind the rules had dramatically changed. Nevertheless, the final rule provided in relevant part: n508

A manufacturer may disseminate to a health care practitioner, a pharmacy benefit manager, a health insurance issuer, a group health plan, or a Federal or State Government agency written information concerning the safety, effectiveness, or benefit of a use not described in the approved labeling for an approved drug or device or in the statement of intended use for a cleared device, provided that the information:

(1) is about a drug or device that has been approved, licensed, or cleared for marketing by FDA;

(2) is an unabridged reprint or copy of a peer-reviewed article (excludes: letters to the editor; abstracts of a publication; anything regarding Phase 1 trials in healthy people; flagged reference publications that contain little or no substantive discussion; and observations in four or fewer people that do not reflect any systematic attempt to collect data, unless the manufacturer demonstrates to FDA that such reports could help guide a physician);

(3) is an article about a clinical investigation with respect to the drug or device;

(4) does not pose a significant risk to the public health;

(5) is not false or misleading (considered misleading if, among other things, the information includes only favorable publications when unfavorable publications exist, excludes articles, or the information presents conclusions that clearly cannot be supported by the results of the study);

(6) is not derived from clinical research conducted by another manufacturer unless that manufacturer gives permission; and

(7) with some exception, that sixty days before disseminating any such written information, a manufacturer submit to the FDA an identical copy of the information to be disseminated, and an

explanation of the manufacturer's method of selecting the articles. n509

n508 These regulations did not apply to unsolicited requests for information by a healthcare provider.

n509 21 C.F.R. Part 99. The requirement that a manufacturer essentially seek approval of the off-label use to lawfully disseminate articles about the use was the most burdensome aspect of C.F.R. pt. 99.

As noted earlier, section 401 of FDAMA ceased to be effective on September 30, 2006. Thus, these implementing regulations are no longer applicable. The controversy continues. On January 30, 2008, the WLF issued a report claiming that FDA regulation of prescription drug promotion "is being conducted in a manner that routinely violates both the First Amendment and FDA's statutory mandate." n510 The WLF's conclusion could indicate another round of litigation ahead:

FDA routinely orders suppression of truthful speech, demands that manufacturers engage in "corrective advertising" in the absence of any evidence that consumers have been misled by supposedly misleading advertising, and violates federal administrative law by using compliance letters (rather than established notice-and-comment procedures) to adopt new agency policies regarding product promotion. n511

n510 Press Release, Wash. Legal Found., Report Concludes that Regulation of Drug Promotion Violates First Amendment and Federal Law (Aug. 7, 2006), *available at* www.wlf.org/upload/080706RS.pdf.

n511 Wash. Legal Found., CaseDetail: Report on FDA First Amendment Abuses (Aug. 7, 2006), *available at* www.wlf.org/Litigating/casedetail.asp?detail=440.

In February 2008, FDA released draft guidance that would renew the procedures for dissemination of scientific literature on off-label uses. n512 Under the draft guidance, FDA would permit drug and device **companies** to disseminate articles to doctors if the articles were peer-reviewed and came from a journal with an expert editorial board. However, the draft guidance does contain a significant change. FDA would drop the requirement that drug and device makers provide the studies to FDA beforehand or promise to seek approval of the discussed use, but the article must be accompanied by a prominent warning that the use described is not approved or cleared by FDA. Other highlights of the draft guidance include:

- . FDA regulations generally prohibit manufacturers from distributing products not approved as safe and effective or cleared through a substantial equivalence determination.

- . FDA claims its legal authority to determine whether distribution of medical or scientific information constitutes promotion of an unapproved new use, or whether such activities cause a product to be misbranded or adulterated, has not changed.

- . FDA recognizes the important public policy reasons for allowing manufacturers to disseminate truthful and non-misleading medical journal articles, and medical or scientific reference publications, on unapproved uses to healthcare professionals and entities.

- . Off-label uses may be important and even may constitute a medically recognized standard of care. Accordingly, the public health may be advanced by healthcare professionals' receipt of medical journal articles, and medical or scientific reference publications, on unapproved or new uses, if the materials are

truthful and not misleading.

. FDA will allow distribution of scientific or medical journal articles that meet a more rigorous set of quality standards than before. For example, the article must be published by an organization with an editorial board independent of the organization, with a publicly stated disclosure policy for conflict of interest. The publication should not be:

- (1) primarily distributed by a drug or device manufacturer (but should be generally available);
- (2) written, edited, excerpted, or published specifically for, or at the request of, a drug or device manufacturer; or
- (3) edited or significantly influenced by a drug or device manufacturer or any individuals having a financial relationship with the manufacturer.

n512 See FDA, [Draft] Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices (Feb. 2008), available at www.fda.gov/oc/op/goodreprint.html.

The draft guidance is not without controversy. Representative Henry Waxman (D-California) claims that the proposed guidelines will leave consumers at risk and sent a letter to FDA stating that the new proposal "would open the door to abusive marketing practices that will jeopardize safety, undermine public health, and lead to an increase in unapproved uses of powerful drugs." n513 Representative Waxman also argued that the new FDA off-label use proposal would discourage drug **companies** and medical device makers from conducting definitive scientific studies and seeking formal FDA approval for alternative uses of drugs and devices if they could profit from off-label uses without such studies. Other critics say the proposed guidance, as currently written, will allow **companies** to selectively use peer-reviewed journal articles that support off-label use of their products as marketing tools. n514

n513 Letter from Henry A. Waxman, Chairman, House of Representatives Committee on Oversight and Government Reform (Nov. 30, 2007), available at <http://oversight.house.gov/documents/20071130102744.pdf>.

n514 See e.g., Angie Drakulich, FDA to Allow Off-Label Information, Draft Guidance May Be Too Soon, Too Simple, *ePT--The Electronic Newsletter of Pharmaceutical Technology* (Feb 21, 2008), available at <http://pharmtech.findpharma.com/pharmtech/article/articleDetail.jsp?id=492953> (last visited Nov. 3, 2008).

Conclusion

The future of FDA's draft guidance, and its role in regulating the dissemination of information relating to the off-label use of approved and cleared drugs and devices, remains uncertain. The agency must balance the risk of drug or device misuse or suboptimal use against the reality that off-label drug or device use may represent the standard of care and the best medical option for patients; the needs of healthcare practitioners to have access to the latest medical information; and the First Amendment rights of manufacturers. As FDA attempts to reach this balance, drug and device manufacturers face a world of uncertainty. Although the trend over the past decade has been to allow greater dissemination of reliable scientific information on off-label use, the *Gilead* case and others discussed above highlight the dangers a drug or device manufacturer faces if FDA accuses it of off-label promotion.

What does the current status of the law and recent enforcement activity mean in everyday, operational terms? Of course, a manufacturer's *express* marketing and promotional activities may not tout a particular off-label use. Sales

representatives "detailing," advertisements, and promotional conferences with physicians should not affirmatively initiate communications about off-label uses. Prescribing attendees to a sales pitch or conference cannot receive payment in cash or kind, lest a kickback be inferred.

Even activities not expressly categorized or budgeted as promotional may--in FDA's or DOJ's view--cross the line into off-label promotion if those activities address off-label uses and are in some way pretexts for promotion. Thus, the government has raised concerns where:

- . the size of the sales force appears disproportionate to the size of the on-label market;
- . providers targeted for detailing do not, or do not primarily, treat the on-label disease state(s);
- . medical literature disseminated about an off-label use is not based on good science or is otherwise misleading, unfair, or unbalanced;
- . marketing is not consistent with the drug's or device's safety profile (i.e., marketing the product as being safer than the label indicates);
- . customers are solicited or encouraged by the manufacturer to ask medical questions about off-label uses (even if the resulting answers are scientifically accurate);
- . CMEs concern off-label uses and the content, faculty, and/or number of CMEs is dictated by the manufacturer; n515
- . the manufacturer's marketing budget is used to support ostensibly non-promotional events, like CMEs;
- . the manufacturer conducts return-on-investment analyses (ROI) with respect to either ostensibly independent CMEs on off-label topics or ostensibly non-promotional advisory boards/consultants;
- . "investigator-initiated" studies of off-label uses are suggested or encouraged by the manufacturer or its sales representatives;
- . manufacturer-initiated studies of off-label uses are completed and disseminated without an intent to seek approval for the off-label use (sometimes called a "publication strategy");
- . studies with "bad" results are not published or otherwise made available; n516
- . educational grants, invitations to conferences, and other perks are distributed to high-level, off-label device users selectively; and/or
- . feedback from paid consultants and advisory boards is not really needed, collected, or reviewed, but such arrangements are used merely as opportunities to educate (and perhaps reward with honoraria) opinion leaders about an off-label use. (This practice could create kickback concerns, too.)

n515 For guidance in this area, *see* Accreditation Council for Continuing Medical Education (ACCME), Standards for Commercial Support, Standards to Ensure the Independence of CME Activities (Sept. 2004), *available at* http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf.

n516 For suggested publication and disclosure policies, *see, e.g.*, the PhRMA "Principles of Conduct of Clinical Trials and Communication of Trial Results," *available at* www.phrma.org/files/Clinical%20Trials.pdf; the International Committee of Medical Journal

Editors (ICGME) "Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication," *available at* www.icmje.org/; the "Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases" issued by the four major international pharmaceutical associations, *available at* <http://www.phrma.org/files/2005-01-06.1113.PDF>; and the revised CONSORT (Consolidated Standards of Reporting Trials) statement developed by investigators and editors to help authors, *available at* www.consort-statement.org/?o=1011.

Accordingly, to reduce the risk of exposure, compliance audits of vendor sales and marketing practices, or of provider purchasing practices, should take into account these red flags.

Similar common sense precautions are recommended for healthcare professionals who prescribe medications. In particular, prescribing professionals ought to carefully examine their financial relationships with drug and device manufacturers, because financial relationships often form the basis for impugning the integrity of the medical professional in off-label cases.

Finally, from a fraud and abuse perspective, both manufacturers and providers need to be mindful of evolving enforcement activity. In particular, if federal prosecutors treat certain off-label promotional activities as false claims, there will be a significant financial incentive for disgruntled employees to file qui tam actions. Although it remains to be seen how viable a false claims theory will be as an enforcement tool, in addition to the criminal and civil penalties that exist under the FDCA itself, off-label "education," "promotion," and "marketing" of FDA-approved drugs and devices will require continued due diligence in an evolving regulatory landscape.

REFERENCE: CITATION: John N. Joseph, David Deaton, Houman Ehsan, and Mark A. Bonanno, Enforcement Related to Off-Label Marketing and Use of Drugs and Devices: Where Have We Been and Where Are We Going?, J. HEALTH & LIFE SCI. L., January 2009, at 73. (C) 2009 American Health Lawyers Association, www.healthlawyers.org/bookstore. All rights reserved.

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LENGTH: 15800 words**TITLE:** Article: The Spotlight on PBMs: Federal Enforcement of the Anti-Kickback Statute on the Pharmaceutical Benefit Management Industry**AUTHOR:** Greg Radinsky *

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TEXT:

ABSTRACT: Pharmaceutical benefit management **companies** (PBMs) act as intermediaries between pharmaceutical manufacturers and third-party payors to administer prescription drug benefits. While PBMs have increased in importance in recent years, they have simultaneously become the target of critics, including United States Attorneys and the Federal Trade Commission. This Article gives a brief overview of the federal enforcement environment in which PBMs are conducting business and discusses how PBMs' rebates are negotiated. It then discusses the applicability of the federal Anti-Kickback Statute, which is the likeliest enforcement tool for prosecutors to use against PBMs. The Article concludes by discussing the steps PBMs can take to minimize their liability and provides insight into how effective the federal government will be in building fraud cases against PBMs' current business practices.

Pharmaceutical benefit management **companies** (PBMs) act as intermediaries between pharmaceutical manufacturers and third-party payors n1 to administer prescription drug benefits. n2 PBMs have gained significantly in importance over the past few years. n3 Managing drug costs has become the number one priority of health plans, states, and employers in their ongoing quest to lessen the increases in overall healthcare costs. n4 PBMs, which operate drug plans for approximately 200 million Americans, negotiate discounts with drug manufacturers in exchange for including a **company's** drug on a formulary of preferred medicines. n5 They manage nearly 70% of the more than 3.2 billion prescriptions dispensed in the United States each year. n6 The PBM industry is a growing economic force--the top four PBMs have combined revenues of \$ 57 billion. n7 In addition, many of the Medicare drug benefit proposals before Congress have proposed using PBMs to administer drug benefits. n8

n1 Third-party payors include, among others, "employers, managed care organizations, labor unions, and state-funded pharmaceutical assistance programs for the elderly." NAT'L HEALTH POL'Y FORUM, *The ABCs of PBMs*, ISSUE BRIEF NO. 749 (Oct. 27, 1999), available at www.nhpf.org/pdfs_ib/IB749_ABCsofPBMs_10-27-99.pdf.

n2 *Id.* PBMs also have created pharmacy networks and initiated mail service benefits that enable patients to receive prescription drugs through the mail at discounted prices. In addition, PBMs have made the entire claims process paperless by establishing links with

pharmacies to enable two-way communication of both claims and clinical data. *Id.* at 3.

n3 *See id.* *See also* PHARM. CARE MGMT. ASS'N, ISSUE BRIEF: PBMs DELIVER VALUE TO PATIENTS AND PAYERS 1 (2002).

n4 *Pharmacy Benefit Managers Deliver Prescription Drug Cost Savings Through Physician and Patient Education, Other Strategies*, MANAGED CARE WEEK (Atlantic Info. Servs., Inc., Washington, D.C.), Nov. 22, 1999, available at www.mcareol.com/mcolfree/mcolfre1/artcl397.htm. *See* Katherine Levit et al., *Inflation Spurs Health Spending in 2000*, 21 HEALTH AFFAIRS 1, 3 (Jan./Feb. 2002) (stating that drug costs continue to comprise the fastest-growing component of health care expenditures); Robert Pear & Robin Toner, *Amid Fiscal Crisis, Medicaid is Facing Cuts from States*, N.Y. TIMES, Jan. 14, 2002, at A1 (discussing the difficult budget dilemmas states are facing as healthcare costs continue to soar).

n5 *Employers and Government Officials Say Pharmacy Benefit Managers Have Failed to Control Drug Costs*, DAILY HEALTH POL'Y REP.: PRESCRIPTION DRUGS (Henry J. Kaiser Fam. Found., Menlo Park, CA), Jan. 7, 2002, available at www.kaisernet.org/daily_reports/rep_index.cfm?hint=3&DR_ID=8818 [hereinafter DAILY HEALTH POL'Y REP.].

n6 PHARM. CARE MGMT. ASS'N, *supra* note 3, at 1. *See also* *Medicare Endorsed Prescription Drug Discount Cards and Their Impact on Small Business, Hearing Before the House Comm. on Small Bus.*, 105th Cong. (2001) (statement of LaVarne Burton, President, Pharm. Care Mgmt. Ass'n), available at www.house.gov/smbiz/hearings/107th/2001/011025/burton.html (last visited Mar. 29, 2003).

n7 *See* Julian E. Barnes, *When is a Rebate a Kickback? Discounts by Pharmaceutical Companies to Middlemen are Under Fire*, U.S. NEWS & WORLD REP., Aug. 12, 2002, at 31.

n8 *See* HENRY J. KAISER FAMILY FOUND., THE ROLE OF PBMS IN MANAGING DRUG COSTS: IMPLICATIONS FOR A MEDICARE DRUG BENEFIT ix (2000), available at www.kff.org/content/2000/1543/PBMPaper.pdf.

Many commentators believe that PBMs change the quality of healthcare for both patients and payors by increasing quality and safety, while also reducing costs. n9 PBMs' pharmaceutical care programs can promote best clinical practices and increase patient safety by monitoring prescription records and the medical literature. These practices reduce each patient's potential for adverse effects from medication. n10 For example, PBMs conduct drug interaction screenings as part of each claim processed to determine if a prescribed drug is contraindicated by another prescription on file for that patient. In addition, they monitor patient adherence by looking at refill patterns. n11

n9 Sara Fritz, *Mail-Order Medicine*, ST. PETERSBURG TIMES, Sept. 15, 2002, at 1H.

n10 *Id.*

n11 NAT'L HEALTH POL'Y FORUM, *supra* note 1, at 6.

PBMs also try to reduce costs by using formularies, utilization review, patient cost-sharing, generic drugs, and negotiated rebates on brand-name products. n12 For example, therapeutic substitution programs encourage physicians and patients to switch to lower-cost, comparable drugs. n13 Further, drug switching can prompt physicians to prescribe a more efficacious and less expensive drug that they may have overlooked. n14 PBMs also reduce the cost of prescription drugs and promote safety by encouraging physicians to adopt electronic prescribing. n15 PBM rebate arrangements have helped stimulate competition among drug manufacturers to lower pharmaceutical costs. A Health Care Financing Administration (HCFA) study found a drug benefit managed by a PBM offers an average cost savings of thirty-four percent over a traditional, unmanaged prescription drug benefit. n16 A recent General Accounting Office (GAO) report further supports the conclusion that PBMs offer significant cost savings to the American public. n17 For example, the GAO report found that the average price PBMs obtained from retail pharmacies for fourteen brand name drugs was approximately eighteen percent below the average price paid by cash customers. n18

n12 *Id.* at 7-8.

n13 See PRICEWATERHOUSE COOPERS, LLC., HCFA STUDY OF PHARMACEUTICAL BENEFIT MANAGEMENT INDUSTRY 9 (June 2001), available at cms.hhs.gov/researchers/reports/2001/cms.pdf (last visited Mar. 29, 2003) [hereinafter HCFA STUDY].

n14 Deborah Gesenway, *Drug Switching: Lowering Costs vs. Adverse Interactions, Potential Errors*, ACP-ASIM OBSERVER, July/Aug. 2000, available at www.acponline.org/journals/news/jul-aug00/drugswitching.htm (last visited Mar. 9, 2003).

n15 See MEDCO HEALTH SOLUTIONS, INC., SEC FORM S-1/A, at 74, July 9, 2002.

n16 HCFA STUDY, *supra* note 13, at 59, 60.

n17 GAO, REPORT TO THE HONORABLE BYRON L. DORGAN, U.S. SENATE, FEDERAL EMPLOYEES' HEALTH BENEFITS, EFFECTS OF USING PHARMACY BENEFIT MANAGERS ON HEALTH PLANS, ENROLLEES, AND PHARMACIES (2003), available at www.gao.gov/new.items/d03196.pdf (last visited Mar. 29, 2003).

n18 *Id.* at 4.

A few advocacy groups, however, believe that PBMs cost the public more because they do not effectively promote generic drugs to help reduce healthcare costs. n19 For example, one study last year found that the average prescription cost through a PBM was \$ 46.84, compared to \$ 40.22 for cash customers at a pharmacy. n20 Another study, reported in the *Wall Street Journal*, found that some copayments for prescription drugs are higher than the price PBMs pay for the medication. n21 In addition, the ability of PBMs to foster drug savings has been questioned by federal and state governments. n22

n19 See Mary Guiden, *States Take Closer Look At Drug Discount Brokers*, STATELINE.ORG (July 31, 2001), available at stateline.org/story.do?storyId=139145 (last visited Mar. 31, 2003). See also NAT'L HEALTH POL'Y FORUM, *supra* note 1, at 8.

n20 *Seniors Need Real Medicare Drug Benefit, Beware of PBMs*, ACTION ALERT (Gray Panthers, Washington, D.C.) (June 2002), available at http://66.200.57.70/graypanthers/Action_Alerts.htm. According to this study, only 28% of the drugs dispensed by PBM mail order pharmacies were generics, compared to 54% by local pharmacies. *Id.* A different study by the Kaiser Family Foundation found that patients of the Merck-Medco PBM saw their prescription drug costs rise from \$ 18 billion in 1999 to \$ 23 billion in 2000. Jeanne Lenzer, *The Benefit of the Bargain*, PRAXIS POST (June 27, 2001), available at www.healthyskepticism.org/reports/2001/pharmacy%20010627.htm. (Merck-Medco argued that this still resulted in savings of 2% based on the average rate of drug price increases that year.)

n21 See DAILY HEALTH POL'Y REP., *supra* note 5.

n22 See Guiden, *supra* note 19.

The most vocal threat to PBMs has come from the United States Attorney's Office in the Eastern District of Pennsylvania. n23 Assistant United States Attorney Jim Sheehan has been investigating PBMs for potential kickbacks they may have received from drug manufacturers. n24 A few government prosecutors also suspect that some PBMs switch patients to more expensive, brand-name drugs, which can increase patients' overall costs and may be in violation of federal laws **protecting** health plan beneficiaries. n25 In particular, the federal government is concerned that PBMs may be misrepresenting information about patients' conditions. n26 In addition, the federal government believes

switches to more expensive drugs often occur because drug manufacturers offer PBMs rebates to designate their drugs as "preferred" in the PBMs' formularies. n27 In fact, recently unsealed documents by a federal judge revealed that Medco, a subsidiary of Merck, promoted Merck's products even when they were priced higher than those of its competitors. n28

n23 See Lenzer, *supra* note 20; Allan Rubin, *Medicare and Medicaid to Revise Reimbursement for Prescription Drugs*, available at www.therubins.com/legal/PBMinvest.htm (last modified Sept. 20, 2000).

n24 See Rubin, *supra* note 23.

n25 Gesenway, *supra* note 14. See Barbara Martinez, *AdvancePCS Battles with Lawyer Probing Pharmaceutical Deals*, WALL ST. J., Aug. 1, 2002, at C1; GAO, *supra* note 17, at 14 n.13.

n26 Gesenway, *supra* note 14.

n27 *Id.*

n28 See Karen Pallarito, *GAO Report Ducks Issue of Drug Company Fees*, REUTERS HEALTH (Reuters Health Info., New York, N.Y.), Jan. 10, 2003, available at www.drboobmartin.com/2003k_01_10news03.html (last visited Mar. 30, 2003).

Critics also believe that some price concessions obtained by PBMs are not disclosed to health plan sponsors and serve only to enrich the PBM. n29 Opponents assert that the cost savings delivered to the public by PBMs could be overstated because there are no benchmark data to accurately determine the price discount health plans would obtain without a PBM. n30 Critics also claim that PBM rebates may amount to ten percent of the \$ 122 billion American drug market. n31 Moreover, skeptics believe that when a new drug is introduced to the market, the manufacturer of the old drug will pay more money to the PBM to keep its drug on the formulary. n32 Consequently, they believe the drug manufacturer passes those costs onto the consumer in the form of higher prices. n33 Furthermore, some critics have argued that PBMs' use of restrictive pharmacy networks and mail-orders has disrupted relationships between pharmacists and patients, which are necessary for the "appropriate and safe use of drugs." n34 In fact, some private employers and consumers have filed lawsuits against PBMs for promoting their interests over the interests of their clients. n35

n29 *Id.* See Liz Hicks, *Prescription-Drug Bills Provide Too Little Service*, WICHITA EAGLE, Aug. 29, 2002, available at www.timesleader.com/mld/eagle/2002/08/29/news/editorial/3957459.htm (last visited Mar. 30, 2003).

n30 See GAO, *supra* note 17, at 11.

n31 See Barnes, *supra* note 7.

n32 *Id.*

n33 *Id.*

n34 In addition, critics are worried that the number of adverse interactions and prescription-writing errors will increase from drug switching. See CONNECTICUT PHARMACY ASSOCIATION, *Pharmacy Benefit Managers: Bad Medicine for Medicare*, available at www.ctpharmacists.org/PDF/PBMTalking802.pdf (last visited Mar. 31, 2003).

n35 Milt Freudenheim, *Drug Middlemen Are Facing Pressure Over Rising Prices*, N.Y. TIMES, Jan. 5, 2002, at C1.

The Federal Trade Commission (FTC) has also voiced concerns about a drugmaker-owned PBMs' ability to remain impartial in reducing costs and medication errors. n36 As a result, the FTC enforced consent decrees against some manufacturers, which required them to establish independent pharmacy and therapeutic committees and to create firewalls between the manufacturer and the PBM. n37 In addition, the Office of Inspector General (OIG) for the United States Department of Health and Human Services (HHS) specifically mentioned in its 2002 work plan that it will be evaluating PBMs' financial and contractual arrangements with state Medicaid programs. n38

n36 Lenzer, *supra* note 20.

n37 *Id.* Many PBMs merged or formed alliances during the 1990s in order to remain competitive. As a result, the FTC has scrutinized PBMs for possible antitrust violations during this time. See NAT'L HEALTH POL'Y FORUM, *supra* note 1, at 2.

n38 *Pharmaceutical Issues Get Attention in HHS Inspector General 2002 Work Plan*, 5 Health Care Fraud Rep. (BNA) No. 5, Oct. 3, 2001, at 19. See also McKenna & Cuneo, LLP, *Impact of Sales and Marketing Practices on Medicaid Best Price Under Scrutiny*, PHARMACEUTICAL INDUSTRY NEWS UPDATE, Apr. 1, 2002, at 1, available at www.dclinkonline.com/files/PHARMNEWSUPDATE402.pdf.

The disagreement among policymakers as to the desirability of having PBMs manage drug costs has not helped the PBMs' case in the enforcement environment. This increased attention has caused federal and state enforcement agencies to evaluate further whether PBMs are responsible for fraud and abuse within the federal healthcare system. PBMs also have become an attractive target because the PBM industry is projected to grow by at least twenty-five percent annually, and rapidly growing industries are likely targets for investigation. In addition, the government may have focused on PBMs relationships to help identify fraudulent business practices with their clients such as pharmacies, drug manufacturers and physicians. Finally, PBMs are being considered as a means of managing Medicare drug benefits, n39 which provides yet another reason for increased scrutiny.

n39 Craig L. Fuller, *Pondering a Problematic Paradigm Shift*, MONDAY MORNING (National Association of Chain Drug Stores, Alexandria, Va.), Apr. 9, 2001, available at www.nacds.org/wmspage.cfm?parm1=1985 (last visited Mar. 30, 2003).

This Article provides an overview of the various legal challenges faced by PBMs, with particular emphasis on the way in which PBMs negotiate rebates and its impact on possible actions under the federal Anti-Kickback Statute--the most likely enforcement tool in the prosecutor's arsenal. After analyzing these issues, the Article concludes by presenting steps that PBMs can take to minimize their risk of liability in any actions brought by federal prosecutors.

I. A Brief History of the Past and Current Enforcement Environment

The United States government began cracking down on healthcare fraud and abuse in 1996. n40 At that time, Janet Reno put healthcare fraud second only to violent crime as the top enforcement priority of the Clinton administration. n41 In addition, the passage of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the enactment of the 1997 Balanced Budget Act added an arsenal of new enforcement weapons and funding to complement the administration's goals. n42 Over the past few years, the government has restored over a billion dollars to the Medicare Trust Fund through its enforcement efforts. n43 In addition, the OIG has advocated a two-prong approach that focuses not only on enforcement, but also on encouraging healthcare providers and suppliers to develop voluntary compliance programs. n44

n40 *Hearing before Senate Spec. Comm. On Aging*, 106th Cong. 3 (2001) (statement of Lewis Morris, Assistant Inspector General for

Legal Affairs, U.S. Dep't. of Health and Human Services). See CENTERS FOR MEDICARE & MEDICAID SERVS., FACT SHEET: THE CLINTON ADMINISTRATION'S COMPREHENSIVE STRATEGY TO FIGHT HEALTH CARE FRAUD, WASTE, AND ABUSE (1998), available at www.cms.hhs.gov/media/press/release.asp?Counter=336.

n41 Pam Belluck, *In Crackdown on Health Care Fraud, U.S. Focuses on Training Hospitals and Clinics*, N.Y. TIMES, Dec. 22, 1995, at A32.

n42 Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) [hereinafter HIPAA]; Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251 (1997).

n43 See DEPT OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GENERAL SEMI-ANNUAL REPORT FOR APRIL 1, 1998 - SEPT. 30, 1998, at 3.

n44 Open Letter from Janet Rehnquist, Office of Inspector Gen., to Health Care Providers (Nov. 20, 2001), available at www.oig.hhs.gov/fraud/docs/openletters/openletter111901.htm; Open Letter from June Gibbs Brown, Office of Inspector Gen., to Health Care Providers (Mar. 9, 2000), available at www.oig.hhs.gov/fraud/docs/openletters/openletter.htm; Open Letter from June Gibbs Brown, Office of Inspector Gen., to Health Care Providers (Feb. 1997), available at www.oig.hhs.gov/fraud/docs/openletters/ltrhcp.htm (last visited Mar. 30, 2003). See Greg Radinsky, *The Compliance Officer Conundrum: Assessing Privilege Issues In a Health Care Setting*, 5 DEPAUL J. OF HEALTH CARE L. 1 (2002).

As a result of the government's approach, virtually every hospital initiated a comprehensive compliance program by 2000. n45 Moreover, the government believes its two-prong approach is primarily responsible for reducing improper federal healthcare program payments by several billion dollars. n46 The government first focused its efforts on evaluating hospitals, home health agencies, laboratories, and durable medical equipment **companies**, because these entities were responsible for the greatest Medicare expenditures. n47 As a result, the government has initiated very few fraud cases against large drug manufacturers or PBMs. n48

n45 HEALTH CARE COMPLIANCE ASS'N, PROFILE OF HEALTH CARE COMPLIANCE OFFICERS 2 (1999), available at www.hcca-info.org/documents/survey99.pdf (last visited Mar. 30, 2003).

n46 *IG Reports Savings of \$ 6.8 Billion in Most Recent Semiannual Report*, 8 Health Law Rep. (BNA) No. 8, June 17, 1999, at 985.

n47 See OFFICE OF THE INSPECTOR GEN., DEP'T. OF HEALTH AND HUMAN SERVS., COMPLIANCE GUIDELINES AND PRESS RELEASES, at oig.hhs.gov/fraud/complianceguidance.html. The first compliance guidance the OIG drafted did not focus on drug manufacturers.

n48 See generally OFFICE OF INSPECTOR GENERAL, DEP'T. OF HEALTH AND HUMAN SERVS., CORPORATE INTEGRITY AGREEMENTS, available at oig.hhs.gov/fraud/cia/index.html (last visited Mar. 30, 2003). The majority of fraud settlements and corporate integrity agreements were with hospitals.

In 1995, however, Caremark, Inc., one of the nation's largest home infusion therapy suppliers, entered into a \$ 161 million settlement after it provided kickbacks to physicians to induce them to prescribe the drug it distributed. n49 Unfortunately, this was not a large enough wake-up call to focus the drug manufacturing industry on compliance with federal fraud and abuse laws.

n49 Press Release, Dep't. of Justice, Caremark to Pay \$ 161 Million In Fraud And Kickback Case: Latest Step in Health Care Fraud Initiative Involved Numerous Federal Agencies (June 16, 1995), available at www.usdoj.gov/opa/pr/Pre_96/June95/342.txt.html.

It was not until the \$ 875 million TAP Pharmaceutical criminal and civil fraud case that the industry began to take a proactive interest in fraud and abuse compliance. At that time, the industry began demanding that the government

provide specific guidance concerning compliance with federal fraud and abuse laws. n50 The OIG answered the industry's request on October 3, 2002, by publishing the *Draft OIG Compliance Guidance for Pharmaceutical Manufacturers*. n51 While this guidance focuses specifically on pharmaceutical manufacturers and does not address PBMs and retail pharmacies, these segments of the pharmaceutical market can draw important insights from it.

n50 *Lupron: TAP Pays for Fraud*, CURRENT DRUG DISCOVERY, Nov. 2001, at 13, available at www.current-drugs.com/cdd/cdd/cddpdf/issue%208/lupron.pdf; Press Release, Office of the Attorney General State of Utah, Attorney General Announces Cancer Drug Settlement (Oct. 3, 2001), available at www.attorneygeneral.utah.gov/PrRel/proct32001.htm (last visited Mar. 30, 2003); *It's Time to Look Closely at Your Relationship with Pharmaceutical Companies*, US ONCOLOGY, available at www.usoncology.com/CompanyInfo/article.asp?aid=386 (last visited Mar. 31, 2003).

n51 62 Fed. Reg. 62,057 (Sept. 26, 2002).

PBMs first drew the attention of federal prosecutors shortly after *Caremark*. n52 The first false claims settlement with a PBM was reached on June 30, 2000, when the United States Attorney for the Western District of Tennessee settled fraud allegations against ProMark Holdings, the predecessor **company** of MIM Corp, for \$ 2 million. n53 The government alleged ProMark employees diverted prescription drug benefit funds from beneficiaries of Medicaid to themselves through bonuses, loans, excessive compensation, pharmaceutical rebates, and other means. n54

n52 Charles Choi, *First Settlement for Pharmacy Benefits Manager Costs \$ 2M* (July 14, 2000), available at www.geocities.com/choi9998/stories/UCG/ucg-jul142000a.html (last visited Mar. 30, 2003).

n53 *Id.*

n54 *Id.*

Federal prosecutors have continued to watch PBMs closely n55 and the government recently issued a number of subpoenas to leading PBM **companies** at the request of several United States Attorneys. n56 The government believes that there is a significant potential for fraud and abuse, given that the pharmaceutical industry, including PBMs, currently spends \$ 12 billion a year on marketing to providers. n57 Moreover, some federal prosecutors are concerned that PBMs will misuse the formulary management process for financial gain. n58 Assistant United States Attorney Jim Sheehan has even suggested that PBM contractual arrangements may violate the federal Anti-Kickback Statute if they reward the PBM for the volume of drugs purchased by its client managed care organizations (MCOs). n59

n55 See *Legal Issues Facing the PBM Industry*, PBM News (Pharm. Benefit Mgmt. Inst., Inc.), Spring 2000 (presentation by James G. Sheehan, Chief, Civil Division, Dep't. of Justice), available at www.pbmi.com/v5n2.pres.html (last visited Mar. 31, 2003).

n56 *Id.*

n57 Susan W. Berson & Carolyn J. McElroy, *Establishing Responsible Relationships with Drug and Device: How Physician Practices and Hospitals Can Safeguard Against Fraud and Abuse*, ONCOLOGY ISSUES, July/Aug. 2002, at 32.

n58 Gesenway, *supra* note 14. See Debbie McAllister & Nicole DeVuono, *Pharmaceutical Industry Next Target For Developing, Implementing Comprehensive Compliance Programs*, 5 FOOD AND DRUG L. INST. UPDATE 20 (2001).

n59 *PBM/Manufacturer Deals May Draw Scrutiny of Federal Prosecutors Under Arrangements that May Be Interpreted as Attempts to Skirt Medicaid Rebate Law*, Assistant U.S. Attorney Says, HEALTH NEWS DAILY, Dec. 21, 1998, available at

www.healthnewsdaily.com/NR/FDC/FDCSearchsearch.asp?sheet=hnd&q2=PBM&pubs=hnd&sortresults=date&sortorder=d&search1=TOC&RecordNum=51# this article.

A major fraud investigation, however, has not been announced since the issuance of the subpoenas. As such, PBMs are pondering whether their current practices would be considered fraudulent by the federal government. The following analysis describes how most PBM contracts are structured. While PBM contracts differ somewhat, this section provides the general framework to understand whether the PBM industry is complying with the applicable federal statutes and regulations.

II. How PBM Rebates Are Negotiated and Shared

PBMs receive a majority of their revenue from drug manufacturers and health plans. n60 They typically receive both an administrative fee n61 and a rebate from drug manufacturers. n62 This rebate is in return for the PBM giving the drug manufacturer preferential treatment and increasing the market share of its drugs. n63 At a minimum, drug manufacturers typically require PBMs to include the contracted drugs on the formulary with no restrictions. PBMs may receive a larger rebate from a drug manufacturer when formularies provide stronger incentives to use specific drugs. n64 As noted in a HCFA report, "rebates and administrative fees are commonly paid as a percent of the drug's wholesale acquisition cost (WAC)--which represents the manufacturer's sale price." n65 These rebates typically range from five percent to fifteen percent of the wholesale acquisition costs, while administrative fees range from one percent to three percent. n66 The PBM usually shares these rebates with the health plan n67 which typically receives seventy to ninety percent of the rebate. n68 PBMs rely on their share of these rebates to maintain profitability in a highly competitive marketplace; n69 therefore, they consider the details of the negotiated rebates to be proprietary and do not disclose them unless required by a subpoena. n70

n60 See generally *PCS Rebates from Pfizer on Seven Products Totaled over \$ 10 million in First 21 Months of 1994-1998 Contract*, The Pink Sheet (F-D-C Reports), June 10, 1996 [hereinafter The Pink Sheet]. See also Pallarito, *supra* note 28.

n61 U.S. CONG. BUDGET OFFICE, THE EFFECT OF MANAGED CARE ON THE PHARMACEUTICAL MARKET (1998), available at www.cbo.gov/showdoc.cfm?index=655&sequence=3 (last visited Mar. 30, 2003).

n62 *Id.* See GAO, *supra* note 17, at 27 ("we estimate the rebates retained by the PBMs we reviewed represented less than half of one percent of total plan drug spending").

n63 The Pink Sheet, *supra* note 60.

n64 See GAO, *supra* note 17, at 12.

n65 HCFA STUDY, *supra* note 13, at 78. Wholesale acquisition cost (WAC) is "the price paid by a wholesaler for drugs purchased from the wholesaler's supplier, typically the manufacturer of the drug. On financial statements, the total of these amounts equals the wholesaler's cost of goods sold. Publicly disclosed or listed WAC amounts may not reflect all available discounts." POWERS PILES SUTTER & VERVILLE, PC, DRUG PRICING GLOSSARY AND OTHER KEY TERMS (2002), available at www.phpcrx.org/Glossary.html (last visited Mar. 31, 2003).

n66 HCFA STUDY, *supra* note 13, at 18. Another federal government study estimates that drug manufacturer rebates range from 2% to 21% of the acquisition price and may be as high as 35% for selected drugs. See FOOD & DRUG ADMIN., PROFILE OF THE PRESCRIPTION DRUG WHOLESALING INDUSTRY: EXAMINATION OF ENTITIES DEFINING SUPPLY AND DEMAND IN DRUG DISTRIBUTION § 2.2 (2001), available at www.fda.gov/oc/pdma/report2001/attachmentg/5.html (last visited Mar. 30, 2003).

n67 Drug companies often pay rebates at the end of each calendar quarter; however, it can take three to six months for the PBM to receive payment from the drug manufacturer. See Chris Nee, *Uncovering the Mysteries Behind Rebates*, MANAGED CARE ADVISER

(Atlantic Info. Servs., Inc., Washington, D.C.), *available at* www.aishealth.com/ManagedCare/MgdCareAdvisor/MCWRebateMysteries.html (last visited Mar. 30, 2003). This delay occurs because PBMs can elect to take "45 days to submit the rebate information to the manufacturers, and the manufacturers in turn need time to verify the rebate information." *Id.* After the PBM receives the rebate check, it recalculates the rebates for all rebate-eligible clients and process checks to them. *Id.* Another level of complexity is that either the PBM or the drug manufacturer may "detect an error and call for an audit." *Id.*

n68 *See* FOOD & DRUG ADMIN., *supra* note 66, § 2.2.

n69 *See* The Wall Street Transcript, Interview with Eric Veiel, Analyst, Deutsche Banc Alex. Brown Inc. (Feb. 25, 2002), *available at* www.twst.com/perl/txt_search.pl?search=Eric+Veiel (subscription required) (hereinafter Veiel Interview). For a further description of the rebate process, see HENRY J. KAISER FAMILY FOUND., *supra* note 8, at 20, 50-51, 54.

n70 *See* Milt Freudenheim, *Pharmacy-Benefit Companies Won't Disclose Fees*, N.Y. TIMES, Jan. 10, 2003, at C3.

Rebates have a negative connotation with the public, because they have been associated with the Anti-Kickback Statute as a potential "kickback." The federal and state governments, however, historically have encouraged PBMs to use rebates and themselves rely on rebates and discounts to offset pharmacy costs for the Medicaid program. n71 For example, HHS "has approved Medicaid program waivers to expand coverage to a state's Medicare beneficiaries primarily through the creation of formularies and pharmaceutical manufacturer rebate arrangements." n72 In addition, the federal government has recently published draft guidelines for its proposed Medicare Discount Card Program, which promotes rebates as a way to make prescription drugs more affordable to the American public. n73 Finally, the MCOs that retain PBMs capture most of the savings of rebates through their contracts with the PBM. Pharmaceutical rebates received by PBMs generally are divided with the client organization in one of three ways: 1) fee-for-service contracts; 2) risk sharing or shared savings contracts; or 3) capitated contracts.

n71 *See* Letter from LaVarne Burton, President, Pharmaceutical Care Mgmt. Ass'n, to The Honorable Janet Rehnquist, Inspector Gen., Office of Inspector Gen. 4 (Nov. 27, 2002), *available at* [www.pcmanet.org/regul_state_pdfs/Clean%20Final%20PCMA\(v1\).pdf](http://www.pcmanet.org/regul_state_pdfs/Clean%20Final%20PCMA(v1).pdf).

n72 *Id.* at 4.

n73 *See id.*

A. Fee-for-Service Contracts

"Flat rebates are typically based on a fixed percentage of the number of units of a particular medication that are dispensed, sold, or processed through the PBM." n74 These types of rebates are the most common for the leading PBM **companies** and are dealt with in a fee-for-service contract between the client n75 and the PBM. n76

n74 Nee, *supra* note 67. *See* HCFA STUDY, *supra* note 13, at 88.

n75 "Client" is broadly defined. PBMs negotiate a variety of contracts with both drug manufacturers and health plans. For purposes of this Article, most of the federal government's inquiries have referred to rebate contracts with drug manufacturers and health plans. The description of all of these contracts, however, is also applicable to large employers and other healthcare entities. *Id.* at 5.

n76 *See* John Carroll, *When Success Sours: PBMs Under Scrutiny*, MANAGED CARE 11-9, Sept. 2002, *available at* www.managedcaremag.com/archives/0209/0209.pbms.html. In addition, access rebates are sometimes used. *Id.* This type of rebate is similar to the flat rebates because the percentage of the rebate remains constant. *See* Nee, *supra* note 67. The drug manufacturers may enter into a contract to gain access to the PBM's formulary or to prevent being blocked by the PBM's distribution channels. *Id.* The PBM typically negotiates an access rebate when the drug manufacturer's product fills a niche for a disease and is not highly utilized. *Id.*

In this type of a contract, the client is at risk for all claims and associated administrative expenses incurred while the contract is in effect. n77 The PBM acts as claims and utilization manager for this portion of a client's health plan. n78 The client's share of the rebate usually varies based on the size of the client, with large clients typically receiving the entire rebate. Some PBMs provide a variety of additional services, including disease management programs, n79 in which case it is important to ensure that the PBM is only being paid fair market value for these additional services.

n77 See Carroll, *supra* note 76. These types of contracts are also referred to as administrative services contracts.

n78 See HCFA STUDY, *supra* note 13, at 17; Carroll, *supra* note 76.

n79 See HCFA STUDY, *supra* note 13, at 18, 83-84.

B. Risk Sharing or Shared Savings Contracts

Market-share or tiered rebates are often based "on a sliding scale system according to the number of units of a particular medication that are dispensed, sold, or processed through the PBM as compared with its competitors in a class of medication." n80 The pharmaceutical **company's** goal is to give an incentive to the PBM to put its drug in a favorable position on the formulary and sell as much of it as possible.

n80 Nee, *supra* note 67.

These rebates are generally dealt with under one of two types of agreements. In a risk sharing agreement, the "client and the PBM both assume some risk for the total cost of the prescription drug program." n81 Depending on the contract, the risk may be for the total cost of the program or for a particular service within the program. Some common elements involved in this type of agreement are drug utilization review, prior authorization programs, and drug substitution programs. n82 PBMs will try to limit their financial liability to their total administrative costs. Some large customers, however, may be able to negotiate a contract with no limit on a PBM's liability. n83 PBMs are required to estimate their costs for each contract year, which include claims and administration fees. n84 The client pays the PBM either on a fee-for-service or a per-employee, per-month basis during the contract year. n85 An audit is done at the end of the contract year to compare actual program costs with budgeted costs. n86 The PBM and the client's risk are dependent upon the risk sharing formula negotiated. n87 "Rebate payments are based on the actual utilization pattern of the drug for the client . . . but most PBMs combine utilization by all clients into one total for the purpose of submitting rebates in order to maximize reimbursement." n88

n81 HCFA STUDY, *supra* note 13, at 91.

n82 Formulary rebates are usually negotiated outside the parameters of this agreement and are treated separately. *Id.*

n83 *Id.*

n84 *Id.* at 101.

n85 *Id.* at 60-63.

n86 HCFA STUDY, *supra* note 13, at 72.

n87 *Id.* at 90-92. There are numerous types of negotiated risk sharing percentages, but it is outside the scope of this Article to discuss in detail the factors that are used to determine these percentages.

n88 Nee, *supra* note 67. For example, "for market share rebates, the PBM's total volume may earn it a 20% rebate on a sliding scale, but when the rebate is paid to the PBM and rolled back for each client, a specific client may receive a lower payment if its market share did not reach the 20% threshold." *Id.*

The second type of agreement generally employed with market-share or tiered rebates is a shared savings contract. Instead of paying the PBM on a fee-for-service basis, the client pays a set percentage of all demonstrated savings from the PBM's various services. n89 The PBM typically will guarantee a minimum level of savings, with additional savings shared on a predetermined basis. n90 These types of arrangements provide incentives for both sides to work together and run the pharmaceutical benefit program effectively. Nonetheless, both risk sharing and shared services contracts are becoming less popular among many of the leading PBMs.

n89 HCFA STUDY, *supra* note 13, at 91. This typically includes such services as drug utilization review and drug substitution programs.

n90 *Id.* For example, the PBM may guarantee a minimum 5% savings from drug utilization review. Any savings above that level will be shared 75% by the client and 25% by the PBM. *Id.*

C. Capitated Contracts and Other Rebates

The PBM is at risk for all claims and basic administrative fees incurred under a capitation contract. n91 PBMs rarely use this type of contract because they have historically lost money on them; n92 consequently, this Article will not discuss capitation contracts in detail. PBMs receive other payments from manufacturers, which are not rebates and are paid separately. n93 These include administrative fees for services rendered in connection with rebate agreements, such as aggregating members, performing market share analysis used to calculate rebates, and consolidating billing for clients. n94 Administrative fees are based on the number of claims processed. n95

n91 *Id.* at 92.

n92 *Id.*

n93 *See id.* at 59.

n94 *See* HCFA STUDY, *supra* note 13, at 86.

n95 *Id.* at 86.

D. Summary of Rebate Contracts

All of these agreements have been under government scrutiny. The federal and state governments are concerned with many of these arrangements because some **companies** have not provided adequate information for regulators to verify compliance with the law. n96 Other PBMs, however, are already complying with the law and feel the government is overstepping its investigative authority. n97 The next section outlines the basic enforcement tools that the federal government might use against the PBM industry, and comments on whether the federal government's investigation could have legal merit. n98

n96 See Barbara Martinez, *States Work Together to Probe Merck's Drug-Benefits Affiliate*, WALL ST. J., Jan. 20, 2003, at B3 ("The attorneys general are looking for 'greater transparency' from the **companies** about how they conduct their business.").

n97 See Letter from Susan S. de Mars, Senior Vice President and General Counsel, AdvancePCS, to Janet Rehnquist, Inspector General, Office of Inspector General 9-10 (Dec. 2, 2002) (on file with author).

n98 See generally *id.* (regarding further discussion of the possible government concerns regarding the PBM industry).

III. Enforcement Tools and Regulatory Guidance for PBMs

A. Federal Anti-Kickback Statute

The Anti-Kickback Statute is a prominent enforcement tool that prosecutors will use to bring actions against PBMs if they find a violation regarding rebate arrangements. n99 This statute was enacted by Congress to prevent physicians from putting their own economic interests ahead of the welfare of their patients or the economic interests of the entity paying for the physician's services. n100 Congress also was concerned that financial incentives would lead to overutilization and increase the government's cost of providing healthcare. n101

n99 See Michael D.D. Geldart, *Federal Government Targets Fraud Enforcement Against Prescription Drug Manufacturers, Pharmacy Benefit Managers and Drug Marketers*, HEALTH LAW REP. (Holland & Knight LLP), May 2001, at 2, 5.

n100 See 42 U.S.C. § 1320a-7b (2003).

n101 See RICHARD P. WARD, A PRIMER ON FRAUD AND ABUSE IN THE HEALTHCARE INDUSTRY 10 (2001).

The statute makes it a criminal offense to "knowingly and willfully" offer, pay, solicit, or receive any "remuneration" to induce referrals of items or services reimbursable under the federal healthcare programs. n102 Courts have generally held that this statute is violated if *one* purpose, not just the sole or primary purpose, of a payment is to "induce" the purchase of healthcare. n103 This interpretation has created potential criminal liability for many transactions between a healthcare entity and a party with the power to refer or accept referrals. Courts may impose criminal sanctions of up to five years in prison and up to a \$ 25,000 fine on anyone convicted under the statute. n104

n102 42 U.S.C. § 1320a-7b(b) (2003).

n103 See *United States v. Greber*, 760 F.2d 68, 69 (3d Cir. 1985); see also *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 30 (1st Cir. 1989).

n104 See 42 U.S.C. §§ 1320a-7b(b)(1)(B), (2)(B) (2003).

In addition to these judicial penalties, the government can assess civil and administrative penalties for violating the Anti-Kickback Statute. n105 Not only can the OIG demand \$ 50,000 for each kickback violation under its administrative authority, but it also can exclude a PBM from participating in federal healthcare programs. n106 The administrative penalties and threat of exclusion from the federal healthcare programs may pose more of a threat to PBMs than the criminal sanctions, in that they combine lower standards of proof with onerous penalties. Moreover, in 1998, the OIG clarified that the government can exclude even a provider who never submitted a bill directly to the program; n107 thus, the administrative penalties have a very wide scope.

n105 *See id.* §§ 1320a-7a, 1320a-7b(a); 31 U.S.C. § 3729(a) (2003). PBMs also have potential liability for privacy violations for some of their day-to-day activities, such as disease management and counseling and support services. This topic will not be covered because it is outside the scope of this Article. In addition, it may be possible to hold PBMs responsible for the off-label promotion of a drug. *See* Paul E. Kalb & I. Scott Bass, *Government Investigations in the Pharmaceutical Industry: Off Label Promotion, Fraud and Abuse, and False Claims*, 53 FOOD & DRUG L.J. 63, 67 (1999).

n106 *See* 42 U.S.C. § 1320a-7a(7) (2003).

n107 Any individual entity that furnishes items or services that are reimbursable under the federal healthcare programs is subject to exclusion regardless of whether that individual or entity directly presents a bill to the program. *See* Health Care Programs: Fraud and Abuse; Revised OIG Exclusion Authorities Resulting from Public Law 104-191, 63 Fed. Reg. 46,676, 46,676 (Sept. 2, 1998) (codified in scattered sections of 42 C.F.R.).

To assess administrative penalties or invoke exclusion, the government need only prove that a PBM acted in "reckless disregard," instead of "willfully and knowingly." n108 There are also more relaxed evidence rules in an administrative setting. Previously, some healthcare entities and their attorneys may not have viewed the Anti-Kickback Statute as seriously as other enforcement statutes, because proving a criminal case can be very difficult. n109 Now that the OIG is beginning to utilize many of its new administrative authorities, however, healthcare entities need to be exceedingly cautious of even arguably gray-area violations. Finally, the Department of Justice has creatively brought anti-kickback cases under other civil statutes, such as the False Claims Act, that require a lesser standard of evidence. n110

n108 *See* 31 U.S.C. § 3729(b) (2003); 42 U.S.C. §§ 1320a-7a, 1320a-7b(b)(2) (2003).

n109 *See* WARD, *supra* note 101. The standard of criminal intent is a significant issue in prosecuting these cases. Courts disagree on what constitutes a "knowing and willful" violation of this statute. A widely cited decision, however, held that the government must prove the person 1) knew federal law proscribed payment or receipt of any remuneration to induce Medicare or Medicaid referrals; and 2) engaged in such conduct with specific intent to disobey that particular federal law. *Hanlester Network v. Shalala*, 51 F.3d 1390, 1400 (9th Cir. 1995).

n110 *See* United States *ex rel.* Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 903 (5th Cir. 1997); United States *ex rel.* Pogue v. American Healthcorp Inc., 914 F.Supp. 1507, 1508 (M.D. Tenn. 1996). A recent decision in the Southern District of New York rejected the notion that an anti-kickback violation automatically violates the False Claims Act--at least in situations in which the wrongdoer has not explicitly certified its compliance with those statutes or regulations as a condition of payment. *United States ex rel. Barmak v. Sutter Corp.*, 95 CV 7637(KTD)(RLE), 2002 U.S. Dist. LEXIS 8509 (S.D.N.Y. May 13, 2002); *see Judge's Decision Reflects Skepticism that Violations of the Anti-Kickback Act Constitute Infractions of the False Claims Act*, ALERT (Arent Fox, Attorneys at Law, Washington, D.C.), May 24, 2002, at 1, available at www.arentfox.com/alert2002-05-24ClarkR.pdf.

B. Applicable Exceptions and Safe Harbor Provisions

Assuming that the Anti-Kickback Statute is applicable, one must assess whether PBMs' contractual arrangements may be exempt from prosecution. The statute contains five specific exceptions. n111 The exceptions are for (1) certain properly disclosed discounts; (2) compensation paid to bona fide employees; (3) amounts paid to certain group purchasing agents; (4) waivers of coinsurance under Part B by federally qualified healthcare centers; and (5) remuneration paid as part of a risk-sharing arrangement involving managed care plans. n112 In addition, the statute lists as an exception to its provisions, "any payment practice specified by the Secretary." n113

n111 *See* 42 U.S.C. § 1320a-7b(b)(3).

n112 *See id.* § 1320a-7b(b)(3).

n113 *Id.* § 1320a-7b(b)(3)(E).

Due to the breadth and scope of the statute, Congress authorized the OIG to create "safe harbors," which provide direction for healthcare providers and suppliers in complying with the law. n114 Safe harbors are regulations that specify types of payments and business practices that are potentially capable of inducing referrals, but will not be prosecuted criminally or administratively. n115 If an arrangement or practice falls squarely within a safe harbor, it will not be subject to prosecution. It is important to note, however, that transactions which do not fit within a safe harbor are not necessarily illegal; they are simply more difficult to defend. n116 Unfortunately, no specific safe harbors exist for the PBM industry, and PBMs do not directly fit within any of the existing safe harbors. Nonetheless, those counseling PBMs as to compliance with this statute can draw important insights from analogous safe harbors.

n114 *See* Medicare & Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, § 14,101 Stat. 680, 697-98 (codified at 42 C.F.R. § 1001.952 (2003)). There are 21 safe harbors. This Article only examines those most relevant to the PBM industry, although other safe harbors arguably could apply to some of the specific business transactions of PBMs.

n115 *See* Federal Health Care Programs: Fraud and Abuse; Statutory Exception to the Anti-Kickback Statute for Shared Risk Arrangements, 64 Fed. Reg. 63,504, 63,504-06 (Nov. 19, 1999) (to be codified at 42 C.F.R. pt. 1001). The Anti-Kickback Statute lists as an exception to its provisions any payment practice specified by HHS. *See* 42 U.S.C. § 1320a-7b(b)(3)(E) (2003). In November 1999, the OIG published regulations that significantly clarified existing safe harbors and established new ones. *See* Federal Health Care Programs: Fraud and Abuse; Statutory Exception to the Anti-Kickback Statute for Shared Risk Arrangements, 64 Fed. Reg. at 63,504. The preamble also provides important information relating to the intent and reasoning behind the clarifications and the newly promulgated safe harbors. *See id.* at 63,505-06.

n116 *See* Federal Health Care Programs: Fraud and Abuse; Statutory Exception to the Anti-kickback Statute for Shared Risk Arrangements, 64 Fed. Reg. at 63,504.

1. Group Purchasing Organization Safe Harbor

One analogous safe harbor is that for Group Purchasing Organizations (GPOs). n117 It is arguable whether a PBM would qualify under this safe harbor, because the regulations require that the entity negotiate prices on behalf of "health care providers," and not just on behalf of employers. n118 While a PBM does not negotiate on behalf of a healthcare provider, it adds efficiency to the drug purchasing process by negotiating favorable prescription drug prices in exchange for drug manufacturer access to the plans and their members. Unfortunately, even though PBMs meet the same needs as GPOs, the government is likely to strictly apply the definition of a "GPO" in the context of this safe harbor.

n117 *See* 42 U.S.C. § 1320a-7b(b)(3)(C) (2003); *id.* § 1001.952(j) (2003).

n118 *See id.* § 1001.952(j)(2).

Even if it were deemed to qualify as a GPO, however, a PBM would have to adhere to the following requirements to qualify under this safe harbor: (1) a written agreement with each member that states either that the GPO will take a fee of three percent or less of the purchase price of sales from that vendor, or that specifies the amount (or, if not known, the maximum amount) the GPO will be paid by each vendor; and (2) if the GPO member is a hospital, skilled nursing facility, home health agency, or other "provider" of services, the GPO must disclose in writing to the member at least annually (and to HHS upon request) the amount received from each vendor with respect to purchases made by or on behalf of members. n119

n119 *See id.* § 1001.952(j).

The government may consider adopting a similar safe harbor for PBMs. Accordingly, to the extent possible, PBMs should adhere to requirements of the GPO safe harbor to mitigate their risk. In fact, federal representatives have indicated that their skepticism of PBMs' contractual arrangements would be diminished by full disclosure of the drug selection and decisionmaking process, as well as all financial incentives given to PBMs. n120

n120 See *Legal Issues Facing the PBM Industry*, *supra* note 55.

2. Discount Safe Harbor

The most applicable safe harbor is the discount safe harbor. The rationale of this safe harbor also is applicable to PBMs, even though their transactions may not fit squarely within the regulation's parameters. The discount safe harbor exempts any "discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program." n121

n121 42 U.S.C. § 1320a-7b(b)(3)(A). See also 42 C.F.R. § 1001.952(h). It is unclear whether the discount safe harbor, which was created by regulation, and the discount exception, which was created as part of the Anti-Kickback Statute itself, relate to each other. Charles B. Oppenheim, *OIG Misses Opportunity To Clarify Discount Safe Harbor*, 02-27 LAW WATCH (Foley & Lardner Attorneys at Law) Aug. 19, 2002, at 1, available at www.foleylardner.com/FILES/tbl_s31Publications/FileUpload137/1020/law_watch_2002v27.pdf.

A discount is defined under this safe harbor as a "reduction in the amount a buyer (who buys either directly or through a wholesaler or a group purchasing organization) is charged for an item or service based on an arms length transaction." n122 A discount also includes, "a rebate check, credit or coupon directly redeemable from the seller only to the extent such reductions in size are attributable to the original good or service that was purchased or furnished." n123 The regulations, however, provide that "discount" does not include "cash payments," "bundled product sales," or "a reduction in price applicable to one payer, but not to Medicare or a State health care program." n124 The discount safe harbor also requires certain reporting and documentation requirements depending upon the type of entities involved in the transaction. n125 These requirements generally require that invoices, claims, and cost reports disclose the existence of a discount program and the amount of any discounts. This allows the government to monitor the purported discount and ensure the benefit is passed on to the federal healthcare programs' beneficiaries. n126

n122 42 C.F.R. § 1001.952(h) (2003).

n123 Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,986 (July 29, 1991) (to be codified at 42 C.F.R. pt. 1001).

n124 42 C.F.R. § 1001.952(h)(5)(i)-(iii).

n125 See *id.* § 1001.952(h).

n126 Thomas N. Bulleit, Jr. & Joan H. Krause, *Kickbacks, Courtesies or Cost Effectiveness?: Application of the Medicare Antikickback Law to the Marketing and Promotional Practices of Drug and Medical Device Manufacturers*, 54 FOOD & DRUG L.J. 279, 290-91 (1999). See 42 C.F.R. § 1001.952(h) (2003).

Most PBMs would not qualify under the discount safe harbor because they are not themselves the purchasers of a drug manufacturer's product. There are, however, a few PBMs that also own their own mail order pharmacy and purchase drugs for resale. Depending on how the arrangement is structured, some PBM arrangements could qualify

under this safe harbor. In addition, some PBMs pay retrospective rebates to physicians and pharmacists. These arrangements will not likely qualify for this safe harbor because entities only receive protection when discounts are made either to providers that keep Medicare or Medicaid cost reports or to certain kinds of participating Medicare MCOs. n127 Finally, some PBMs engage in the practice of paying pharmacists a set fee for each consumer drug switch. This would not meet the discount safe harbor requirements because "discount" does not include "cash payments." n128

n127 See 42 C.F.R. § 1001.952(h).

n128 See *id.* § 1001.952(h)(5)(i).

Although PBMs may not fit squarely within the parameters of the discount safe harbor, the safe harbor provides valuable guidance as to how federal regulators could accept the discount practices of PBMs. If PBMs follow the safe harbor accurately and fully disclose discounts and rebates to their clients, the federal government may have less concern with their practices. n129 Much of the concern among federal enforcement authorities and policymakers may result from the federal government believing it has insufficient information to dismiss PBMs from scrutiny for their rebate arrangements. n130 To further address this issue, some PBMs have submitted comments to the OIG that propose language for the discount safe harbor to ensure that PBMs' current practices squarely fit within the requirements. n131

n129 See Regina Sharlow Johnson, *PBMs: Ripe for Regulation*, 57 FOOD & DRUG L.J. 323, 361 (2002). Some lawyers believe that the PBM industry could structure transactions to meet the requirements of the discount safe harbor to the extent the PBM industry passes through discounts to the health plans. *Id.*

n130 See Pallarito, *supra* note 28; News Release, Byron Dorgan, U.S. Senator (N.D.), Dorgan Says GAO Study on PBM's Fails to Gather Key Data (Jan. 10, 2003), available at dorgan.senate.gov/newsroom/record.cfm?id=189700.

n131 See Letter from Susan S. de Mars, *supra* note 97.

3. Personal Services and Management Contracts Safe Harbor

The personal services and management contracts safe harbor could also be relevant to PBMs that engage in arrangements which provide for varying rebates based on the amount of sales. This safe harbor requires that: (1) the services to be provided are set out in writing; (2) all services to be performed under the contract be specified in the contract; (3) the term of the contract cannot be less than one year; (4) the aggregate compensation paid to the entity or person providing the service be set in advance and be consistent with the fair market value for such services; (5) compensation must be negotiated at arm's length and not take into consideration the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under the Medicare program or state healthcare program; (6) services do not involve counseling or promotion of any activity or arrangement that violates state or federal law; and (7) the aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services. n132

n132 42 C.F.R. § 1001.952(d).

The most difficult requirement of this safe harbor concerns setting out compensation in advance, and not basing it on volume or value of referrals. For example, many PBMs receive or provide disease management programs to help deal with targeted chronic diseases. n133 For these types of arrangements, the PBM usually pays a fee to the drug manufacturer and agrees to place its drugs on the formulary in exchange for receiving the disease management program. Moreover, in an attempt to continue to develop new services, some PBMs have leveraged their large prescription claim

databases and their skill at tracking and analyzing large amounts of data to develop and market disease management programs to drug manufacturers. n134

n133 Disease management programs, which are often associated with chronic diseases, help patients better understand and manage their own medical condition. See U.S. BANCORP PIPER JAFFRAY EQUITY RESEARCH, RX HEALTH CARE: PHARMACY BENEFIT MANAGERS 15 (2001), available at www.gotoanalysts.com/piperpublic/goto/assets/pdfs/features/pbms.pdf (hereinafter PIPER ANALYSIS).

n134 See *id.* at 13.

In either case, these services could be construed as improper "remuneration," offered in return for ordering items that may be reimbursed under the federal healthcare programs. Many disease management programs, as well as other PBM contractual arrangements, are based on a fee-per-patient basis and consequently would not satisfy this requirement. One way PBMs could satisfy this specific provision would be to structure their contracts with a flat fee over the term of the contract, regardless of the patient volume received. Notwithstanding the fact that this safe harbor is often difficult to meet due to all of its specific requirements, PBMs should consider creatively structuring their contracts to fit within this safe harbor.

C. Specific PBM Guidance from the OIG

Beyond these safe harbors, the OIG has only published two pieces of guidance on how PBMs can comply with the Anti-Kickback Statute.

1. OIG Special Fraud Alert

In 1994, the OIG released its only special fraud alert that would apply to PBMs: *Special Fraud Alert on Prescription Drug Marketing Schemes*, which provided only limited guidance. n135 The alert only stated that a payment made to a patient, provider, or supplier to change a prescription from one product to another would violate the statute unless it complied with a safe harbor provision. n136 While the OIG put PBMs on notice that it was concerned about drug switching practices, it did not provide any applicable safe harbor; n137 indeed, the OIG has yet to provide PBMs with any specific guidance as to how the industry can comply with the law. Furthermore, the OIG recently has expressed the same concerns relating to drug switching practices in its *Draft OIG Compliance Program Guidance for Pharmaceutical Manufacturers (CPG)*, but again provided no meaningful guidance for compliance. n138

n135 Publication of OIG Special Fraud Alerts, 59 Fed. Reg. 65,372, 65,376 (Dec. 19, 1994).

n136 See *id.*

n137 See *id.*

n138 See Draft OIG Compliance Guidance for Pharmaceutical Manufacturers, 67 Fed. Reg. 62,057, 62,062 (Oct. 3, 2002).

2. Draft OIG Compliance Program Guidance for Pharmaceutical Manufacturers

The OIG's recent release of the *CPG* focuses specifically on drug manufacturers, but references PBMs' role in switching arrangements. n139 While the *CPG* does not have the force of law and does not provide penalties for noncompliance, there is a substantial risk that the OIG will view a violation of the *CPG* as unlawful. n140 The OIG condemned "switching arrangements" whereby a pharmacy, PBM, physician, or other arranger is paid a benefit each

time a patient's prescription is changed from a competing product to the manufacturer's product. n141 Moreover, the OIG implied it will carefully examine PBMs that contact patients or their physicians to encourage them to change a prescription, along with those that receive discounts or rebates based upon market share. n142

n139 *Id.*

n140 *Office of Inspector General Issues Draft Compliance Program Guidance for Pharmaceutical Manufacturers*, 11 Health Care Fraud Report (BNA) No. 39, Oct. 3, 2002, at 1404.

n141 *Id.*

n142 *Id.* AdvancePCS argues to the OIG that there are valid economic reasons to encourage switching arrangements. *See* Letter from Susan S. de Mars, *supra* note 97, at 7-8.

D. Examples of Suspect PBM Practices

Despite the limited OIG guidance, prosecutors and the PBM industry probably are in consensus as to certain practices that would be considered to violate the statute. First, PBMs negotiating rebates for prescription drugs that are not clinically sound would be violating the law. For example, if two drugs had the same safety and efficacy, and the PBM prescribed the much higher-priced drug, this could be deemed a violation. Similarly, the industry would likely join prosecutors in condemning a **company** that solicited a payment to place the higher-priced drug on its formulary.

In these two examples, it is easy to understand why the government would condemn the arrangements, because cost savings are not passed on to the federal healthcare programs. Many of the leading PBM **companies** claim that they do not, and would never, prescribe the higher-priced drug in such circumstances. n143 In fact, PBM **companies** have established independent pharmacy and therapeutic committees to create firewalls between the manufacturer and the PBM to prevent such practices from occurring. n144 For example, Express Scripts, a leading PBM **company**, publishes the findings of its pharmacy and therapeutic committees on its Web site. n145 AdvancePCS also has a generic drug program that notifies pharmacists of the accessibility of different drugs that are more cost-effective. n146 The investment community believes that the government's pending investigation is primarily concerned that there be an arm's-length relationship between the PBM and the drug manufacturer. n147 If this belief is accurate, the PBMs' increased disclosure of pharmacy and therapeutic committees' decisionmaking processes and divestiture of drug manufacturers' relationships to PBMs would be pivotal in demonstrating the existence of such arm's-length relationships.

n143 *See, e.g., id.* at 7-8.

n144 Lenzer, *supra* note 20.

n145 *See* www.express-scripts.com/other/company/formulary_info.htm (last visited Mar. 31, 2003).

n146 *See* PHARMACY BENEFIT MANAGEMENT & HEALTH POLICY UPDATE MANAGED CARE INSTITUTE/SAMFORD UNIVERSITY, *Health Economic Trends and Issues*, Sept. 1, 2002.

n147 Veiel Interview, *supra* note 69.

Many of these independent committees, however, may not have existed ten years ago and, under some of the

relevant laws, prosecutors can avail themselves of limitations periods ranging up to ten years. Consequently, even PBMs presently operating at arm's length face exposure for their prior practices. This exposure is greatest if a **company** did not have a process that fully documented and disclosed how it determined its formulary decisionmaking process.

There are a number of other practices that both the federal government and the PBM industry would likely agree constitute a violation of the Anti-Kickback Statute. For example, PBMs that receive payments to switch patients to higher-cost brand drugs or pay retail pharmacists to switch patients to higher-cost brand drugs would likely be considered to be in violation.ⁿ¹⁴⁸ Likewise, providing financial incentives to physicians to prescribe one drug over another would be a clear violation of the statute. Lastly, the PBM industry would agree that the payments it receives from manufacturers should not exceed the fair market value for the services it provides. Again, all of these examples go to the heart of why Congress enacted this statute. These types of arrangements could provide financial incentives that would cause overutilization at the expense of the federal healthcare programs. Likewise, in each of these arrangements, the entity would clearly be putting its economic interests ahead of the health and welfare of its customers.

ⁿ¹⁴⁸ It is important, however, to note that providing financial incentives to retail pharmacists to make a patient aware of a lower-priced generic drug is less likely to be considered a violation. In fact, some PBMs have programs that promote such a practice. See Letter from Susan S. de Mars, *supra* note 97, at 7-9, 11-13. These programs may not have been the focus of the government's concerns because they still allow the patient to make an informed decision and provide savings to the Medicaid recipient. Moreover, the AMA endorses therapeutic exchanges with the physician's permission as long as it is done within its guidelines. See HENRY J. KAISER FAMILY FOUND., *supra* note 8, at 24.

In the future, bright-line examples as to which the industry and regulators agree a violation exists will become rarer. The prescription drug market will only become more competitive, with drug manufacturers vying to produce the next blockbuster drug.ⁿ¹⁴⁹ The PBMs' role and practices will generate even more scrutiny as selecting the most cost-effective and efficacious drugs will become more difficult for certain disease states. For example, there is increasing competition in the cholesterol drug market with a number of new generation cholesterol drugs coming to market at the same time as the patents of some blockbuster drugs are expiring.ⁿ¹⁵⁰ In the case of a pending patent expiration, the drug manufacturer may try to get the PBM to switch the patient to its new generation drug to avoid being displaced by a generic substitute. The federal government may begin to look behind such arrangements to ensure that the patient's switch to the **company's** new generation drug is clinically justified over a generic drug. When feasible, it is important that PBMs be sure to document the drug switch's short and long effects on the patient. It is no wonder that many PBMs are shifting their focus to specialty distribution of biologics and injectable drugs--areas that involve less competition and higher gross margins.ⁿ¹⁵¹

ⁿ¹⁴⁹ See Barnes, *supra* note 7, at 32; Arlene Weintraub & Michael Arndt, *An Ache at Amgen?*, BUSINESS WEEK, Dec. 9, 2002, at 69.

ⁿ¹⁵⁰ See PHARMACY BENEFIT INSIDER, *Expanding Cholesterol Drug Market Leads to Increased Health Plan Costs; Get Ready for Super-Statins*, (Nov. 2002), available at www.rx.solutions.com/c/pbi_view.asp?docid=277 (last visited Mar. 5, 2003).

ⁿ¹⁵¹ PIPER ANALYSIS, *supra* note 133, at 20.

1. Medicaid Best Price Rule

The PBM industry also has faced scrutiny as to whether it has violated the Medicaid best price rule.ⁿ¹⁵²

The Omnibus Budget Reconciliation Act of 1990 established the Medicaid rebate program which requires manufacturers to pay the states and the federal government a rebate equal to at least 15.1% of the average whole acquisition cost for sales to Medicaid beneficiaries . . . Medicaid rebates may exceed

15.1% because of the "best price" provision that guarantees access to the lowest price paid by any private purchaser of a manufacturer's branded products. n153

PBMs, however, rarely receive rebates greater than 15.1% because manufacturers rarely extend their best prices to them. n154 As a result, this issue should not be a major concern of the federal government. PBMs should be attentive, however, because the federal government intends to examine this area further. n155 As a result, PBMs should be particularly careful to disclose every possible service that could be considered a rebate and seek guidance from the federal government on how to ensure full compliance with this rule. For example, the federal government will likely closely inspect educational grants, health management fees, and data sales fees to see if they are legitimate services or a means to hide an alleged rebate. n156 If a PBM provides services other than rebates, it is important to ensure that these services are negotiated by a separate department and not negotiated during the same time period in order to deflect skepticism by the federal government. The PBM should also document why it uses the same department to negotiate various contracts if it believes the use of that transaction team is justified. In addition, the PBM should be cautious to not only disclose all appropriate information, but to make sure it does not misrepresent any of its disclosures.

n152 The Medicaid Best Price is "the lowest price paid to a manufacturer for a brand name drug, taking into account rebates, chargebacks, discounts or other pricing adjustments, excluding nominal prices. Best price is a variable used in the Medicaid rebate statute to calculate manufacturer rebates owed to state Medicaid agencies." POWERS PILES SUTTER & VERVILLE, PC, *supra* note 65. A discussion of how the Medicaid price rule affects drug manufacturers is outside the scope of this Article. This Article, therefore, will not discuss in any detail the potential fraud issues that may pertain to drug manufacturers.

n153 HCFA STUDY, *supra* note 13, at 47.

n154 *Id.*

n155 *IG Sets Blueprint for 2003: Sees Nursing Homes, Pharmaceutical Fraud as Top Priorities*, 6 Health Care Fraud Report (BNA) No. 20, Oct. 16, 2002, at 752 (hereinafter *IG Sets Blueprint*).

n156 *See generally* Barnes, *supra* note 7. Rebates are not necessarily illegal. *See id.*

2. Other Concerns Regarding Rebate Arrangements

The contractual arrangements of PBMs with drug manufacturers and health plans are very complex and rarely identical. As a result, it is not possible to determine whether a specific **company's** practices violate the Anti-Kickback Statute without having full access to all the relevant contractual documents. Likewise, it is difficult to assess the allegation that rebate arrangements tied to movement of market share could be suspect. The government may choose to focus market share investigations on PBMs with mail order pharmacies. Patients who order from mail order pharmacies are more likely to be switched without consent because of the waiting and hassle costs of reordering and questioning the change in prescription. The government will also examine carefully the constraints the drug manufacturer has placed on the PBM to achieve market share movement. As in any case, the government will examine whether the patient is paying a higher copayment when purchasing this drug versus a therapeutically cheaper drug. n157

n157 It is important to note that rebates have been endorsed by the government for many years to help encourage price competition and lower drug costs. *See* Letter from LaVarne Burton, *supra* note 71, at 4. As a result, it will be more difficult for the government to bring a case where the rebate is helping spur competition among drug manufacturers and lowering drug costs to the American public.

Notwithstanding this lack of necessary information about particular contract terms, it is less likely the government would find a violation or fraud in a fee-for-service contract that is reimbursed at fair market value. This is true because it is easier to understand how much the PBM is being compensated for the services it provides in these contracts. As

such, it is imperative that PBMs are only paid fair market value for their services.

On the other hand, some **companies** such as Merck-Medco still enter into risk-sharing contracts. n158 These types of agreements are more likely to be a concern of the federal government due to the method by which rebates are structured. In these contracts, it is less clear what services the PBMs are providing and what incentives they are being paid to place the manufacturers' drugs on their formularies. Prosecutors are more likely to be concerned that these agreements inappropriately reward a PBM for the volume or market share purchased by the client MCO. It is difficult, however, to ascertain whether the government has a legitimate concern without analyzing the specific contracts at issue.

n158 See Medco Health Solutions, Inc., SEC No-Action Letter (Aug. 13, 2002), available at www.sec.gov/divisions/corpfin/cf-noaction/medco081302.htm (last visited Mar. 30, 2003).

Many health plans and states have argued with PBMs over the contractual terms of these risk-sharing agreements. n159 These arguments often occur when the state or the health plan are not paid because the contractual arrangement was unprofitable. The recent lawsuit brought by West Virginia against Merck-Medco illustrates the potential problems that can arise from a risk-sharing contract. n160 As a result, most of the leading PBM **companies** have stopped using these types of agreements, which obviates any risk that government will find them to constitute a widespread problem in the industry.

n159 See Press Release, Consumer Protection Division Press Release, State of West Virginia, Attorney General Darrell V. McGraw, Jr. and PEIA Sue PEIA's Drug Program Benefits Manager (Nov. 13, 2002), available at www.state.wv.us/wvag/press/2002/nov/13.htm (last visited Mar. 30, 2003).

n160 See *id.*

IV. PBM Industry Solutions

A. Provide Comments to OIG and Demand Compliance Guidance

The PBM industry can take several steps to help ensure that the public, policymakers, and the federal government better understand the cost-savings the PBM industry provides to the American public. First, it is imperative that the PBM industry continues to provide comments to the OIG about its problems with the draft *CPG*, and persuade the OIG to provide further clarification concerning the structure of contractual arrangements. The PBM industry's recent comments to the OIG's draft pharmaceutical guidance present a persuasive case to the government regarding the proper area of concern with rebate practices. n161

n161 See Letter from LaVarne Burton, *supra* note 71, at 3-6; Letter from Susan S. de Mars, *supra* note 97, at 5, 8-10.

Until the government provides further written clarification, it may view the current business practices of PBMs as unlawful. The mere fact that there has not been a multimillion-dollar fraud settlement involving a PBM since the government began to scrutinize this industry cannot be viewed as an escape from liability. Some fraud settlements take numerous years to come to fruition, and the OIG is continuing to focus on the pharmaceutical industry as a top priority in its 2003 work plan. n162 It is imperative, therefore, that PBMs act collectively to help influence the framework in which they operate.

n162 *IG Sets Blueprint*, *supra* note 155.

In addition, they should demand that the OIG publish a compliance program guidance that applies specifically to the PBM industry. While inferences can be drawn from the *CPG* for drug manufacturers, PBMs are a distinct type of entity. In fact, the OIG recognizes this in its recent compliance guidance. As a result, it will be very important for members of the PBM industry to understand how to structure their compliance programs to conform to the federal regulators' demands.

B. Lobby for Reform of Anti-Kickback Statute and Safe Harbors

In addition to providing comments on government guidance documents printed in the *Federal Register*, the PBM industry can lobby to reform or repeal the Anti-Kickback Statute. Repealing the statute, however, will be extremely difficult, given the current regulatory and enforcement environment. First, the nature of recent settlements, such as TAP Pharmaceutical, and the numerous smaller anti-kickback cases indicate that the statute is still needed to police certain healthcare providers and suppliers.

Further, some lawmakers do not believe the federal government has been as vigilant in prosecuting violators of healthcare laws as in the past. n163 Other lawmakers have actually recommended legislation that would add new language to the Anti-Kickback Statute to include a specific provision applying the statute to PBMs. n164 Moreover, the federal government's enforcement actions over the last few years has been responsible for restoring billions of dollars to the Medicare trust fund. n165 In a time when policymakers are concerned about paying for healthcare, it would be difficult to repeal a law that helps secure the financial stability of the Medicare trust fund.

n163 *False Claims Act--Sen. Grassley Asks Judiciary Committee To Convene Hearing on False Claims Act*, 13 Medicare Report (BNA) No. 36, Sept. 13, 2002, at 972.

n164 Press Release, Senator Robert G. Torricelli, PBM Accountability Crucial Part of Medicare Prescription Drug Bill (July 23, 2002) (on file with the author).

n165 *OIG Semiannual Report Details \$ 6.8 Billion in Savings; Unfair Trade Charges Settled*, 8 Health Law Rep. (BNA) No. 24, June 17, 1999, at 985.

Many advocates have argued that the Anti-Kickback Statute is no longer needed because fewer providers are reimbursed under a fee-for-service system. The continued implementation of the prospective payment system has the effect of making providers more cost-efficient because actual reimbursement is based upon a fixed rate rather than the actual cost of each provided service. n166 Also, while many, if not most, physicians are still reimbursed on a fee-for-service basis, those fees are set through a fee schedule that makes their charges essentially irrelevant. It also prevents them from passing through expenditures. n167 These changes in the federal reimbursement system eliminated two major concerns of the statute: increased costs and overutilization. n168 The federal government, however, is concerned that reimbursement changes will increase improper utilization of drugs because providers may turn to drug manufacturers to supplement reduced reimbursement and possibly could allow their decisions to be influenced by financial considerations. n169 As a result, this repeal argument is not as convincing when applied to drug manufacturers and PBMs.

n166 BARRY R. FURROW, ET AL., HEALTH LAW 574-75 (1995).

n167 See Bulleit & Krause, *supra* note 126, at 319-20.

n168 *Id.* For a detailed discussion of the basis for the anti-kickback statute, see FURROW, ET AL., *supra* note 166, at 574-75.

n169 See Bulleit & Krause, *supra* note 126, at 319-20.

Nonetheless, several arguments can and should be made by PBMs to demonstrate the need to reform this statute. First, PBMs and related entities were not the subject of most prior anti-kickback cases because of the limited extent to which drugs are reimbursed under the federal healthcare programs. The likely passage of a Medicare drug benefit, however, will increase their exposure to a statute that provides few examples of how to comply. Accordingly, the government should provide them with additional guidance. The establishment of relevant safe harbors would provide necessary guidance (and comfort) to the PBM industry. The industry has taken appropriate steps to facilitate the establishment of safe harbors. For example, it has submitted a proposed safe harbor for PBMs to the OIG that would largely mirror the requirements of the GPO safe harbor. n170 In addition, leading PBM **companies**, such as AdvancePCS, have submitted suggested language for a number of safe harbors. n171 The PBM industry should further lobby Congress and the OIG to ensure that other safe harbors, including a modified discount safe harbor, apply directly to them.

n170 *Anti-Kickback Statute, Stark Regulations Not Consistent, Providers Get Mixed Message*, 11 Health Law Rep. (BNA) No. 11, Mar. 14, 2002, at 391.

n171 See generally Letter from Susan S. de Mars, *supra* note 97. AdvancePCS has suggested that the OIG adopt the following language regarding the discount safe harbor:

The OIG recognizes that discounts and rebates offered by pharmaceutical manufacturers constitute an important mechanism to contain costs. To ensure compliance with the anti-kickback statute, these arrangements should be structured to comply with the discount safe harbor. Where rebates are obtained and paid to a PBM in connection with drugs utilized by its health plan customers, such rebates must be treated and accounted for as belonging to the health plans, or payors. In particular, the discounts or rebates must be passed through to the payor; appropriate documentation of the amount of the discount or rebate must be provided to each party in the transactional chain; and the payors must have authority to audit the PBMs' records to verify the rebates paid on drugs utilized by the payors' members. These assurances should be set forth in the contracts between the plans and the PBM, and in any discount or rebate agreements with pharmaceutical manufacturers.

Id. at 10.

C. Formulate PBM Industry Compliance Program Document

The PBM industry may be able to force the government to respond more quickly by releasing its own compliance requirements. For example, the Pharmaceutical Research and Manufacturers of America (PhRMA) took a proactive approach by publishing a code that addresses the industry's interactions with physicians and other healthcare professionals with respect to marketed products and related pre-launch activities. n172 The release of this document apparently prompted the OIG to comment and provide guidance as to whether it accepted the industry's recommendations. In fact, the OIG stated in its *CPG* that pharmaceutical manufacturers should, at a minimum, comply with the standards set by the PhRMA code that became effective July 1, 2002. n173 This may be viewed as an example of how the PBM industry can help influence and shape the federal government's guidance. n174 Formulating an effective compliance program that PBMs can adopt will help them better manage complaints by beneficiaries about their services. For example, if a PBM can provide a documentation log of how it has appropriately addressed all beneficiaries' complaints, it will help decrease the government's skepticism that certain PBMs' arrangements are harmful to the federal healthcare programs. Moreover, it will decrease the possibility of a qui tam lawsuit being filed against them. One of the whistleblowers in the landmark TAP Pharmaceutical fraud settlement was one of its customers--Tufts Health Plan. n175 PBMs cannot afford to have an ineffective compliance program given that other parties have incentive to join the government in monitoring their complex billing arrangements.

n172 See *In Response to Recent Fraud Enforcement of Pharmaceutical Marketing Practices, PhRMA Releases Guidelines for its*

Members, ALERT (Arent Fox, Attorneys at Law, Washington, D.C.) June 4, 2002, available at www.arentfox.com/alert2002-06-04langdon.pdf.

n173 Draft OIG Compliance Guidance for Pharmaceutical Manufacturers, 67 Fed. Reg. 62,057, 62,063 (Oct. 3, 2002). Please note, however, that the OIG cautioned that, while the PhRMA Code provides important and practicable benchmarks, compliance with the relevant sections of the PhRMA Code will not necessarily protect a manufacturer from prosecution or liability for illegal conduct. Moreover, while the OIG gives drug manufacturers a list of questions to answer to evaluate a potential illegal arrangement, it falls short of providing any specific guidance. *Id.*

n174 Notwithstanding the PBMs' own compliance initiatives, plan sponsors will likely begin to require PBMs to verify vendor performance through an audit as part of their contractual responsibilities. See *PBM Audit Update*, PBM NEWS (Pharm. Benefit Mgmt. Inst., Inc.), Fall 1999, available at www.pbmi.com/v4n3audt.htm (last visited Mar. 31, 2003). PBMs will need to take a more active role to ensure that plan sponsors' contracts with them are fair and reasonable. *Id.* Moreover, if PBMs independently conduct reliable audits as part of their own compliance program, it will provide both leverage in negotiating future contracts and build the PBM's reputation as a leader in its industry. *Id.* at 3.

n175 See TAXPAYERS AGAINST FRAUD, NEWS, *Settlement of \$ 875 Million Medicare/Medicaid Drug Fraud Yields New Funds For Trust Fund And Could Deter Overcharging*, available at www.taf.org/news.html (last visited Apr. 12, 2003).

D. Initiate Public Relations Campaign

The PBM industry also should launch an effective public-relations campaign that demonstrates to the American public that it is acting ethically and in full compliance with the law. Most Americans do not even know what a pharmaceutical benefit manager is, much less understand the type of work PBMs conduct. n176 The PBM industry should not only educate the enforcement environment and policymakers, but also inform the American public of the benefits that PBMs provide to the United States' healthcare system. This will only become more important as Congress debates a Medicare drug benefit.

n176 See Veiel Interview, *supra* note 69.

E. Seek Advisory Opinions on Questionable Arrangements

PBMs may be concerned that some of their competitors are entering into illegal contractual arrangements that allow the competitors to steal market share by providing greater financial incentives to their clients. These PBMs should seek an OIG advisory opinion to ascertain whether to offer similar arrangements.

In 1997, HIPAA required the OIG to issue written advisory opinions concerning whether a particular transaction violates the Anti-Kickback Statute. n177 This process allows healthcare entities to receive some comfort if they do not qualify under a safe harbor. To receive an opinion, the requester has to provide a significant amount of information about itself and the transaction for which it seeks guidance. n178 While the opinion provides guidance to the entire industry, it is only binding on the requester and cannot be legally relied upon by another party. n179 Furthermore, the one seeking the advisory opinion must be engaged in the business transaction it is seeking guidance on or agree to complete the transaction if a favorable opinion is received. n180

n177 Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, § 205, 110 Stat. 1936, 2000 (1996) (codified at 42 U.S.C. § 1320a-7d (2003)).

n178 See generally Medicare and State Health Care Programs: Fraud and Abuse; Issuance of Advisory Opinions by the OIG, 63 Fed. Reg. 38, 311 (July 16, 1998) (codified at 42 C.F.R. pt. 1008).

n179 OFFICE OF THE INSPECTOR GENERAL, DEPT. OF HEALTH AND HUMAN SERVS., ADVISORY OPINIONS, at oig.hhs.gov/fraud/advisoryopinions.html (last visited Mar. 30, 2003).

n180 See OIG, DHHS Advisory Opinions by the OIG, 42 C.F.R. § 1008.11 (2003).

The disadvantage of seeking an opinion is that it could put the requester at risk of a formal investigation by the OIG. This risk, however, is minimal if the PBM is forthright about its practices and intentions to the government. A more significant risk is that the OIG will issue an unfavorable opinion that prevents the **company** from entering into the proposed transaction. In this latter situation, however, the requester ultimately benefits by avoiding an arrangement that could be the basis for subsequent imposition of substantial penalties.

The OIG has frequently issued favorable advisory opinions because most parties who request one are not seeking to enter a controversial transaction that the OIG would likely determine violates the Anti-Kickback Statute. Therefore, PBMs have no insightful opinions to rely upon to better understand how the OIG may view a more complex and controversial PBM relationship. A careful and more aggressive approach to seeking advisory opinions provides another avenue a specific PBM can explore in seeking guidance. Furthermore, while an unfavorable advisory opinion would not legally prevent other PBMs from structuring a similar contractual arrangement, the issuance of the OIG's advisory opinions garner significant attention within the industry, and may deter others in the industry from entering or continuing to implement a similar arrangement.

V. Conclusion

As drug costs continue to rise and the government contemplates how best to provide a Medicare drug benefit, employers, state health plans, and the federal government will continue to scrutinize how effective PBMs are in lowering health costs. n181 The incentive for drug manufacturers to encourage PBMs to prescribe higher priced prescription drugs will only increase as health plans push more of the costs of pharmaceuticals onto consumers, who will become more educated and buy lower-priced drugs or ration their prescription amounts to save money. n182 In response, some states have banded together to obtain better prices from PBMs, and other states are developing strategies to stop using PBMs altogether. n183

n181 See DAILY HEALTH POL'Y REP., *supra* note 5.

n182 See Rhonda L. Rundle, *Drug Cost-Control Plans Push Many to Do Without*, WALL ST.J., Oct. 9, 2002, at A2.

n183 *Id.* See also *States Have 'Reservations' About PBMs' Price Breaks, Practices*, DAILY HEALTH POL'Y REP. (Henry J. Kaiser Family Found.) (Aug. 2, 2001), available at www.kaisernetwork.org/daily_reports/print_report.cfm?DR_ID=6157&dr_cat=3 (last visited March 30, 2003).

Accordingly, PBMs need to remain proactive in persuading the government to provide more guidance on how they should be complying with the law, and better communicate their benefits to enforcement agencies. With the recent release of the OIG's CPG draft, PBMs have an opportunity to comment on how they believe they should be able to structure transactions with drug manufacturers. In fact, AdvancePCS and other PBMs have filed extensive comments to the OIG concerning this matter. n184 PBMs must remain proactive, as the regulatory and enforcement environment will only become more complex as the drug manufacturers' environment becomes more competitive and consumers scramble to find ways to reduce healthcare costs. PBMs have the opportunity now to shape the method by which millions of Americans could receive a Medicare drug benefit. They must take a more active approach in defining their role in the delivery of pharmaceuticals.

n184 *See generally* Letter from Susan S. de Mars, *supra* note 97.

As the PBMs' role in administering the Medicare drug benefit takes center stage, it is crucial that the PBM industry develop a strategy that clearly articulates the benefits it provides to the American public in lowering prescription drug costs. To ensure that PBMs are not relegated to a purely administrative role in administering Medicare drug benefits, they will need to change their image. At a minimum, PBMs need to do a better job at conducting studies to show how they help health plans and other parties pick the most efficacious and cost-effective drug for patients, resulting in savings to the federal healthcare programs and its beneficiaries. It is just as important that the PBM industry spend the necessary resources to ensure that these studies reach the appropriate audiences.

Most importantly, PBMs must educate the public and the government. The recent comments by the PBM's industry association and AdvancePCS will help inform the government of the benefits provided by the industry, as well as of its compliance with the law. n185 As the public gains a more favorable perception of the PBMs' role in the delivery of healthcare, it will be more difficult for federal prosecutors to question the PBM industry's practices. The PBM industry's recent efforts have resulted in favorable reports by the Centers for Medicare & Medicaid Services, as well as by the investment community. n186 These reports will help the PBM industry build credibility and respond to critics who are skeptical of its benefits. n187

n185 *See generally id.*; Letter from LaVarne Burton, *supra* note 71.

n186 *See generally* HCFA STUDY, *supra* note 13; PIPER ANALYSIS, *supra* note 133.

n187 PBMs should also try to better promote some of their other benefits to the public. For example, the PBM industry could emphasize how it helps ensure the safety of patients through drug utilization and safety monitoring programs. According to the National Academy of Sciences' Institute of Medicine (IOM), "Outpatient deaths due to medication errors rose 8.48-fold [from 1983 to 1993], compared with a 2.37-fold increase in inpatient deaths." INSTITUTE OF MEDICINE, TO ERR IS HUMAN: BUILDING A BETTER HEALTH SYSTEM 32-33 (Linda T. Kohn et al. eds., 2000). The IOM also reported that drug complications were the most common type of adverse event among hospitalized patients--accounting for 19% of such errors. *Id.* at 30. Both types of error could be substantially reduced through PBM services.

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LENGTH: 10996 words**TITLE:** Practice Resource: Religious Accommodations for Employees in the Health Care Workplace

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TEXT:

Introduction

Patients occasionally seek health care services that doctors, nurses, and hospitals object to providing for moral or religious reasons. n1 Over the last 40 years, health care providers' legal privilege to refuse such care has dramatically expanded due to a proliferation of "conscience clause" legislation across the country. n2 Conscience clauses, or rights of refusal laws, allow health care providers to refuse to provide or participate in health care services against their religious or moral beliefs, or for other personal reasons, n3 by stipulating that refusal will not be grounds for disciplinary action or liability. n4 This Practice Resource provides an overview of this legislation in all 50 states and discusses practical considerations for drafting a conscience clause policy that balances employee rights and the provision of timely patient care.

n1 Kent Greenawalt, *Objections in Conscience to Medical Procedures: Does Religion Make a Difference?*, 2006 U. Ill. L. Rev. 799, 818 (2006) [hereinafter *Greenawalt*].

n2 Lynn D. Wardle, *Protection of Health-Care Providers' Rights of Conscience in American Law: Present, Past and Future*, 9 Ave Maria L. Rev. 1, 27 (2010) [hereinafter *Wardle*].

n3 Kristin M. Roshelli, Note, *Religiously Based Discrimination: Striking a Balance Between a Health Care Provider's Right to Religious Freedom and a Woman's Ability to Access Fertility Treatment Without Facing Discrimination*, 83 St. John's L. Rev. 977, 986 (2009) [hereinafter *Roshelli*] (citing Lynn D. Wardle, *Protecting the Rights of Conscience of Health Care Providers*, 14 J. LEGAL MED. 177, 178 (1993)).

n4 Elizabeth Sepper, *Taking Conscience Seriously*, 98 Va. L. Rev. 1501, 1509 (2012).

Legal Background

The first modern conscience clause emerged in the 1970s shortly after the Supreme Court's landmark ruling in *Roe v. Wade*,ⁿ⁵ which mandated legalization of abortion proceduresⁿ⁶ and compelled hospitals receiving federal funds to perform abortion and sterilization procedures.ⁿ⁷ To protect the conscience rights of health care providers in the wake of *Roe*, Congress passed the Church Amendment, which stated that individuals and institutions that received federal funding cannot be required to perform sterilization or abortion procedures that are contrary to moral or religious convictions.ⁿ⁸ By 1979, over 40 states had enacted conscience clauses permitting health care providers to refuse performing abortion or sterilization procedures for reasons of conscience.ⁿ⁹ Conscience protections have since expanded to numerous health care services, procedures, and providers.ⁿ¹⁰ States have, however, enacted these laws with varying degrees of protectionⁿ¹¹ as state conscience laws are neither required nor forbidden by the Constitution's Free Exercise Clause and Establishment Clause.

n5 *Roe v. Wade*, 410 U.S. 113 (1973), *overruled in part by Planned Parenthood v. Casey*, 505 U.S. 833 (1992) and *Gonzales v. Carhart*, 550 U.S. 833 (2007) [hereinafter *Roe*]; *Wardle*, at 28.

n6 *See Roe*, at 154 ("[T]he right of personal privacy includes the abortion decision . . .").

n7 *See Wardle*, at 28-29 (discussing the impact of *Roe*).

n8 *Id.* at 29. *See also* 42 U.S.C. § 300a-7(b).

n9 Melissa Duvall, Comment, *Pharmacy Conscience Clause Statutes: Constitutional Religious "Accommodations" or Unconstitutional "Substantial Burdens" on Women?*, 55 AM. U. L. REV. 1485, 1491 (2006) [hereinafter *Duvall*].

n10 *See* Maxine M. Harrington, *The Ever-Expanding Health Care Conscience Clause: The Quest for Immunity in the Struggle Between Professional Duties and Moral Beliefs*, 34 FLA. ST. U. L. REV. 779, 784 (2007) [hereinafter *Harrington*]; *Roshelli*, at 986-87.

n11 *Roshelli*, at 986.

Physicians, nurses, and other health care providers

In most states, conscience laws apply to particular groups of providers, such as nurses and physicians,ⁿ¹² to protect them from being fired, demoted, or sanctioned for declining to provide or participate in certain medical services or procedures.ⁿ¹³ These laws typically cover services associated with reproduction and end-of-life issues.ⁿ¹⁴ A few states permit hospital workers to refuse influenza vaccinations.ⁿ¹⁵

n12 *Wardle*, at 27-28.

n13 *See Roshelli*, at 986.

n14 *Id.* at 986, 990.

n15 *See, e.g.*, ILL. ADMIN. CODE TIT. 77, § 956.30(c)(1)(B); 10-144-264 ME. CODE R. § 3(B); 105 MASS. CODE REGS. CODE 130.325(F)(1)(b).

Pharmacists are the newest group of health care employees to receive conscience protections against laws and regulations that require them to dispense prescriptions.ⁿ¹⁶ For example, an Arkansas statute specifies that pharmacists may refuse to provide contraception.ⁿ¹⁷ South Dakota permits pharmacists to refuse filling any prescription the pharmacist reasonably believes will be used to cause an abortion.ⁿ¹⁸ Other states, such as Georgia and New Jersey, broadly protect pharmacists' moral and ethical beliefs.ⁿ¹⁹

n16 *See Duvall*, at 1492.

n17 ARK. CODE ANN. § 20-16-304(4).

n18 S.D. CODIFIED LAWS § 36-11-70.

n19 *See, e.g.*, Ga. Comp. R. & Regs. 480-5-.03(n) (stating pharmacists may "refuse to fill any prescription based on his/her . . . ethical or moral beliefs."); N.J. Stat. Ann. § 45:14-67.1(a) ("A pharmacy site has a duty to properly fill lawful prescriptions . . . despite any conflicts of employees to filling a prescription and dispensing a particular prescription drug or device due to sincerely held moral, philosophical or religious beliefs.").

The institutional provider

Conscience clauses can also extend to health care institutions such as public, private, or religious hospitals, n20 relieving them from obligations to perform or permit the performance of objectionable procedures. n21 Importantly, some state laws differentiate between public and private facilities by declining to extend protection to those that are publicly funded, n22 while courts in other states have found clauses intended to protect conscience rights of all institutions unconstitutional as applied to publicly funded institutions. n23 Other laws, such as California's abortion conscience clause, are limited to religious or denominational institutions only. n24

n20 *Roshelli*, at 986-87.

n21 *Id.*

n22 *See, e.g.*, IND. CODE § 16-34-1-3; IOWA CODE § 146.2; MASS. GEN. LAWS CH. 272, § 21B; MONT. CODE ANN. § 50-20-111(1); OR. REV. STAT. § 435.475(3); S.C. CODE ANN. § 44-41-40; TEX OCC. CODE ANN. § 103.004; WYO. STAT. ANN. § 35-6-105.

n23 *See Hodgson v. Anderson*, 378 F. Supp 1008, 1017-18 (D. Minn. 1974), *aff'd in part, rev'd in part* by *Hodgson v. Lawson*, 542 F.2d 1350, 1356 (8th Cir. 1976) (finding conscience clause unconstitutional as applied to private institutions); *Doe v. Bridgeton Hosp. Ass'n*, 366 A.2d 641, 647 (N.J. 1976) (stating refusal to participate in abortion by non-sectarian nonprofit hospitals would be unconstitutional state action).

n24 CAL. HEALTH & SAFETY CODE § 123420(c).

States' varying treatment of the conscience clause

Conscience clauses are typically narrowly drafted to cover specific medical procedures performed by certain providers or at certain institutions, n25 but Illinois, Mississippi, and Washington have enacted conscience clauses that are broadly applied to all health care procedures. n26 Some conscience laws state that no person can be required to participate in a particular procedure, while refusal under others must be based on moral, religious, or conscientious objections. n27 In a number of states, conscience clauses exempt providers and institutions from civil, criminal, or administrative liability for refusing to perform a particular procedure n28 or any procedure that violates a conscience belief. n29

n25 *See Wardle*, at 27-28.

n26 745 ILL. COMP. STAT. 70/3-70/4; MISS. CODE ANN. §§ 41-107-3 to -7; WASH. REV. CODE ANN. § 70.47.160(2)(a).

n27 *Greenawalt*, at 820.

n28 *See, e.g.*, HAW. REV. STAT. § 453-16(e); ARK. CODE ANN. § 20-16-601(a)-(b); CAL. HEALTH & SAFETY CODE § 123420(a).

n29 *See, e.g.*, 745 ILL. COMP. STAT. 70/4.

Practical Considerations

Given the variations in state law, it is difficult to draft a model conscience clause policy. There are, however, general considerations that may be useful in drafting such clauses. For example, although signed, written objections are required by a number of state conscience clauses, n30 not all laws require employer notification. As a result, a patient's care may be disrupted until he or she can find a new, willing provider. To prevent this delay, health care facility objection policies may consider requiring employees to notify the facility, in writing, of the procedures they will not participate in or provide. This will allow health care facilities to accommodate the providers' refusal request while minimizing disruptions to patient care. In states where a written objection is not required, however, a policy requiring mandatory written objections may cause an employee to fear discrimination based on his or her documented objections. An alternative approach may be to have policies and procedures in place to ensure that, in the event an employee does raise an objection, the facility can ensure adequate patient care while honoring the employee's refusal.

n30 *See, e.g.*, ARIZ. REV. STAT. ANN. § 36-2154(A); KY. REV. STAT. ANN. § 311.800(4); MASS. GEN. LAWS CH. 112, § 12I.

Although a provider may not have a duty to transfer a patient if the patient will not be harmed by temporary delay, n31 refusing to cooperate with patient transfers or referrals may inappropriately interfere with the patient's ability to obtain care elsewhere. n32 Facility policies should ensure that patients are not prevented from obtaining health care from another provider, whether within or outside the facility, as a result of the objection. n33 Some states that have enacted conscience clauses for pharmacists have included similar protections in the prescription drug context. For example, Georgia requires objecting pharmacists to find a pharmacist willing to fill the prescription and immediately return the prescription if an alternate pharmacist cannot be identified. n34 Other states, however, place the burden on the employer to balance accommodating an employee's rights of conscience and ensuring prescriptions are dispensed to prescription holders. For example, pharmacies in New Jersey have a duty to fill prescriptions despite employee objections. n35

n31 *Harrington*, at 822-23.

n32 Nancy Berlinger, *Conscience Clauses, Health Care Providers, and Patients*, THE HASTINGS CENTER, www.thehastingscenter.org/Publications/BriefingBook/Detail.aspx?id=2266 (last visited Mar. 22, 2015).

n33 *Id.*

n34 GA. CODE ANN. § 16-12-142(b).

n35 N.J. STAT. ANN. § 45:14-67.1(a).

Right of Refusal Basics

Conscience clause policies require organizations to balance the rights of their employees with the organization's duty to its patients. A conscience clause policy should be carefully drafted to take into account applicable state law, as well as Constitutional and employment law considerations. Table 1 provides a checklist of questions or issues to consider when analyzing a state's "right of refusal" provisions, followed by a 50-state survey of certain conscience clause laws, regulations, and guidance, as well as pending legislation.

Table 1. Basic Questions with State Law Examples

Questions to	State Law Examples
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Consider Is the right of refusal limited to certain types of providers?	<p>(Click state for more detailed summary and citation)</p> <p>Health Care Provider</p> <p>This is a common term, used in many states' right of refusal/conscience clauses, including: Alabama, Alaska, California, Delaware, Hawaii, Michigan, Mississippi, New Hampshire, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Tennessee, Utah, Vermont, Washington, and Wyoming.</p>
	<p>Physicians</p> <p>Several states specifically mention physicians in their right to refuse/conscience clauses, including: Colorado, Florida, Georgia, Illinois, Iowa, Kentucky, Louisiana, Massachusetts, Minnesota, New Hampshire (attending physician or APRN), New Mexico, North Dakota, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, West Virginia, and Wisconsin.</p>
	<p>Pharmacists</p> <p>Some states' laws include provisions specifically applicable to pharmacists, in addition to other categories of covered individuals and entities. These include Alabama, California, Delaware, Georgia, New Jersey, North Carolina, Pennsylvania, and South Dakota.</p>
	<p>Note: Some states, including Colorado, Florida, Illinois, Maine, and Tennessee, have broad refusal clauses that do not specifically mention pharmacists. Mississippi does not have a provision in its conscience clause specific to pharmacists, but allows health care providers such as pharmacists and pharmacy employees to refuse medical services, including counseling and referral, on religious or ethical grounds. See www.ncsl.org/research/health/pharmacist-conscience-clauses-laws-and-information.aspx (last visited April 13, 2015).</p>
Questions to Consider Is the right of refusal limited	<p>State Law Examples</p> <p>(Click state for more detailed summary and citation)</p> <p>Hospital Workers</p> <p>. Texas (physician, nurse, staff member, or employee of</p>

to certain types
of providers?
(continued)

a hospital or other health care facility).

Genetic Counselor

. Virginia (genetic counselor may refuse to provide counsel if such counsel would conflict with his or her religious or moral beliefs).

Freestanding Urgent Care Center

. Utah (such centers not required to provide emergency contraception if the center is located within 30 miles of a hospital).

City, County, State Employees

. Colorado (city/county employees may refuse to offer family planning and birth control services).

. Georgia (employees of state agencies may refuse to offer family planning services).

Any person

. Kansas (right of any person to refuse to participate in an abortion or sterilization procedure).

Is the right of
refusal limited to
certain types of
care?

Abortion

. Connecticut (any phase of an abortion that violates the person's judgment, philosophical, moral, or religious beliefs).

. Delaware (procedures resulting in the termination of a pregnancy).

. Florida (termination procedure unless to deliver a live child).

. Georgia (abortion-related services).

. Kentucky (general prohibition on abortion except to save the life of the pregnant woman).

Questions to
Consider

State Law Examples

(Click state for more detailed summary and citation)

. Massachusetts (privately controlled hospitals and facilities not required to admit patients for termination of a pregnancy).

. Nebraska (providers not required to admit patients for abortions).

. Nevada (unlawful to require participation in abortion unless a medical emergency).

Sterilization

- . Georgia (hospital staff permitted to object based on moral or religious grounds).
- . Massachusetts (privately controlled hospitals and facilities not required to admit patients for sterilization procedures).
- . Pennsylvania (health care facilities not required to permit sterilization procedure contrary to its stated ethical policy).
- . West Virginia and Wisconsin (hospital or medical facility not required to admit patient for sterilization procedure).

Contraception

States generally address the issue of emergency contraception (below) more frequently than contraception in general. Arkansas's right of refusal statute allows a provider to refuse to provide contraceptive procedures, supplies, and information in general, and includes a provider's right to not inform a sexual assault victim of emergency contraception. Tennessee law contains a right of refusal clause pertaining to contraception services generally, in the context of a private institution and based on religious or conscience grounds.

Questions to Consider

State Law Examples

(Click state for more detailed summary and citation)

Emergency Contraception

- . Arkansas (health care provider can refuse to inform sexual assault victim of emergency contraception).
- . Colorado (health care provider may refuse to inform sexual assault survivor of emergency contraception on basis of religious or moral beliefs).
- . Massachusetts (patient bill of rights includes right of sexual assault victims to be promptly offered emergency contraception).
- . New Mexico (hospitals that provide emergency care for sexual assault survivor must inform of option to receive emergency contraception and provide if survivor

- requests it).
- . New York (hospitals providing emergency treatment to rape survivors must inform about emergency contraception and provide upon request).
- . Pennsylvania (hospital not required to provide emergency contraception contrary to its stated religious or moral beliefs).
- . Texas (health care facility, employees, and contractors can refuse to provide information about emergency contraception based on religious or ethical beliefs).
- . Utah (freestanding urgent care center not required to provide emergency contraception if center is within 30 miles of hospital).
- . Wisconsin (hospital may refuse to provide emergency contraception if sexual assault victim is pregnant).

Questions to Consider
Is the right of refusal limited to certain types of

State Law Examples
(Click state for more detailed summary and citation)
Life-Sustaining and Life-Ending Decisions

- . Iowa (patient declarations regarding life-sustaining procedures).
- . New Hampshire (terms of a patient's advance directive or surrogate).
- . Oklahoma (acts that intentionally cause the death of an individual and similar acts and procedures).
- . Oregon (medication to end a patient's life).
- . Pennsylvania (withholding or withdrawing life-sustaining treatment).
- . South Dakota (medication the pharmacist believes will be used to cause the death of any person).
- . Washington (provision of medication to a patient to end his or her life).

Family Planning

Several states' right of refusal/conscience clauses allow providers, both individual and institutional, the right to refuse provision of family planning services, supplies, or information, including Colorado, Florida, Georgia, Maine, Massachusetts, New Mexico, Oregon, Virginia, West Virginia, and Wisconsin.

All Procedures

Many states allow health care providers to refuse to comply with a patient's living will, health care instruction, or health care decision, including Alaska, Arkansas, California, Delaware, Hawaii, Maine, Mississippi, New York, North Dakota, Pennsylvania, Tennessee, Utah, Vermont, West Virginia, and Wyoming. New Hampshire's language refers to terms of an advance directive or surrogate.

Questions to Consider
Do rules vary for public, private, or religious employers?

State Law Examples

(Click state for more detailed summary and citation)

Public

State laws vary in their treatment of public providers, particularly with regard to abortion. Kentucky, for example, generally prohibits abortions in publicly-owned hospitals and health care facilities, except to save the life of the pregnant woman. In contrast, Oregon hospitals are generally not required to admit patients for the purpose of terminating pregnancy, but this right of refusal does not apply to hospitals operated by the state or political subdivision.

Private

Some state laws focus on the right of refusal in the context of private hospitals and health care facilities. For example, in Massachusetts, privately controlled hospitals and health care facilities are not required to admit patients for abortion, sterilization, contraception, and family planning services. Other examples of state laws

applicable to private providers in the context of abortion include those in Montana, Nevada, South Carolina, Texas, Washington, and Wyoming.

Religious

State laws rights of refusal may be limited to employers with a religious affiliation or established religious beliefs, as in New York (private hospitals not required to honor health care decisions contrary to formally adopted policy based on sincerely held religious beliefs or moral convictions central to operating principles) and Virginia (hospitals operated under a religious institution may refuse on religious grounds to provide family planning information).

Note: Case law may make a state's right of refusal statute inapplicable to quasi-public hospitals.

See Alaska.

Questions to Consider
Must the provider object in writing?

State Law Examples

(Click state for more detailed summary and citation)

Some states require an objection to be in writing, with a subset specifying certain grounds for the refusal.

. California (employee written statement indicating a moral, ethical, or religious basis for refusal, and a pharmacist may refuse to dispense a prescription if he or she previously notified employer in writing).

. Kentucky (providers may object in writing based on moral, religious, or professional grounds).

. Massachusetts (providers may object in writing based on moral or religious grounds).

. New York (refusal to perform an abortion must be in writing in advance of the procedure).

. Oklahoma (written statement required for refusal

to participate in activities on moral or religious grounds).

. Rhode Island (written statement by physician, medical staff, or health care facility employee for refusal to participate based on moral or religious grounds).

. South Carolina (written statement by hospital, clinic, employee to refuse to participate in procedure).

. Virginia (written statement by persons objecting to procedures based on ethical, moral, religious, or personal grounds).

. Wisconsin (written statement by physicians and hospital staff to object to participating in procedures based on moral or religious grounds).

Questions to Consider
What are the state law duties of transfer and continuing care?

State Law Examples

(Click state for more detailed summary and citation)

As the following examples illustrate, many states require certain objecting providers to provide for alternative sources of care:

. Alabama (refusing pharmacist must make concerted effort to inform customer where Plan B may be obtained).

. Hawaii (refusing provider must provide continuing care until patient can be transferred to another facility).

. Idaho (objecting provider must provide treatment in life-threatening situation--until an alternate provider is located--when no other health care provider is capable of treating patient).

. Iowa (refusing provider must take steps to transfer

patient to another physician or facility).

. New Hampshire (attending physician or APRN must, without delay, make necessary arrangements to transfer patient, and while transfer is pending, cannot deny health care treatment if such denial would hasten or result in patient's death against patient's express will).

. New Jersey (pharmacy has duty to fill lawful prescription without regard to employee conflicts).

. New York (patient must be promptly transferred to another hospital willing to honor patient's decision, and transferring hospital must continue to provide certain care while transfer is pending).

. North Carolina (refusing pharmacist should take proactive measures to avoid obstructing patient's right to receive medication, including emergency contraception).

Questions to Consider
What are the state law duties of transfer and continuing care?

State Law Examples

(Click state for more detailed summary and citation)

. North Dakota (refusing provider must take all reasonable steps to transfer care to another provider willing to honor the health care decision, and shall provide continuing care until the transfer).

. Pennsylvania (refusing hospital must arrange for sexual assault victim to be transferred to facility where emergency contraception is available, and pharmacies must make reasonable accommodations to ensure delivery of services to patients).

. Tennessee (refusing provider must provide continuing care until patient can be transferred to another facility).

. Utah (refusing provider must provide continuing care until patient can be transferred).

. Vermont (health care provider or facility must inform the patient of the conflict and provide continuing care until the patient can be transferred).

. Wyoming (must promptly inform patient and provide continuing care until patient can be transferred to another facility).

Is the right to refuse this type of care limited to certain grounds?

Reasons of Conscience

Several states, including California, Delaware, Hawaii, Maine, Mississippi, New Mexico, Tennessee, Utah, and Wyoming have provisions in which a provider may refuse to comply with an individual's health care instruction or health care decision for reasons of conscience. Note, however, that Alaska's provision does not apply to Do Not Resuscitate Orders.

Questions to Consider
Is the right to refuse this type of care limited to certain grounds?

State Law Examples

(Click state for more detailed summary and citation)

Moral or Religious Grounds

At least half of all states include a provision allowing health care providers to refuse to inform, supply medications, or perform or participate in a procedure (usually related to family planning, abortion, or termination of pregnancy) based on moral, ethical, or religious grounds, including California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Kentucky, Maine, Maryland, Massachusetts, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, Texas, Utah, Virginia, West Virginia, and Wisconsin. Of note:

. Colorado (provider may refuse to inform sexual assault victim of emergency contraception based on religious or moral beliefs).

- . Delaware (pharmacies must establish procedures regarding refusal to dispense based on religious, moral, or ethical beliefs of dispensing pharmacist).
- . Florida (Florida's Family Planning Act permits providers to refuse to furnish contraceptive or family planning services, supplies, and information based on medical or religious reasons).
- . Georgia (participation in sterilization procedure).
- . Maine (institutions and provider may refuse to provide family planning services based on religious or conscientious objection).
- . New Jersey (pharmacies have duty to fill lawful prescriptions without regard to conflicts of employees due to moral, philosophical, or religious beliefs).

Questions to Consider	State Law Examples (Click state for more detailed summary and citation)
Is the right to refuse this type of care limited to certain grounds?	<p>Moral or Religious Grounds</p> <ul style="list-style-type: none"> . New Mexico (hospital and hospital staff who object on moral or religious grounds not required to perform abortions). . North Carolina (provider may refuse to participate in an abortion, and pharmacist may refuse to provide medication). . North Dakota (health care institutions or private agencies may refuse to participate in health care services that violate its religious or moral policies). . Oregon (employees of the Oregon Health Authority may refuse to offer family planning services). . West Virginia (health care facility may establish policy based on sincere religious or moral beliefs). <p>Reason for Refusal not Specified</p> <ul style="list-style-type: none"> . Colorado (sterilization, contraceptive procedures,

supplies, and information).

Any Reason

- . Minnesota (abortion).

What is a provider's liability exposure for refusing to provide or participate in a procedure or service?

A few states extend protection of a provider's right to refuse to include immunity from damages.

- . Alabama (Health Care Rights of Conscience Act gives providers civil, administrative, and criminal immunity for exercising right of refusal).
- . Alaska (hospital or person not liable under abortion statute for refusing to participate; note, however, case law regarding quasi-public hospitals).
- . Illinois (health care providers not held civilly or criminally liable for refusing to perform or participate in service or procedure contrary to their conscience).

Questions to Consider	State Law Examples (Click state for more detailed summary and citation)
<p>What is a provider's liability exposure for refusing to provide or participate in a procedure or service?</p>	<ul style="list-style-type: none"> . Maine (immunity for refusal to participate in an abortion). . Minnesota (no person or institution shall be held liable or discriminated against for exercising right of refusal, and shall not be held liable for related damages). . Wisconsin (medical practitioners exempt from civil liability for refusing based on religious or moral precepts to participate in sterilization or removal of embryo or fetus).

Health Care Worker Rights of Refusal: A 50-State Survey

This is an informal survey. Local counsel should be consulted to determine the full scope of requirements and restrictions in each state.

Alabama

- . 2014 Ala. H. B. No. 31: This bill, known as the Health Care Rights of Conscience Act, permits health care providers to refuse to perform or participate in health care services that violate their conscience; provides such providers with civil, administrative, and criminal immunity for such refusal; and makes it unlawful for a person to discriminate against any health care provider that declines to participate in services that violate the provider's conscience.

- . Guidance from the 24 Alabama State Board of Pharmacy News 1 (Feb. 2007), *available at*

www.nabp.net/publications/assets/AL022007.pdf : "Alabama pharmacists have the right to refuse to fill any prescription; however, if there is a customer in need of Plan B, and [the] pharmacy has chosen not to carry the product, there should be a concerted effort to let the customer know where this product may be obtained to ensure the delivery of complete pharmaceutical service to the community."

Alaska

. Health Care Decisions Act, Alaska Stat. §§ 13.52.010-.090. This Act includes a provision permitting a health care provider to refuse to comply with an individual's health care instructions for reasons of conscience. This provision does not apply to Do Not Resuscitate orders. *See, e.g.*, Alaska Stat. § 13.52.060.

. Alaska Stat. § 18.16.010: Alaska's abortion statute states that a hospital or person is not liable for refusing to participate in an abortion. Note, however, that there is case law stating that this does not apply to quasi-public hospitals. *See, e.g.*, Valley Hosp. Ass'n v. Mat-Su Coal. for Choice, 948 P.2d 963 (Alaska 1997).

Arizona

. Ariz. Rev. Stat. § 36-2154: Hospitals and health care providers may refuse to participate in an abortion.

Arkansas

. Ark. Code Ann. § 20-16-304(5): Health care providers and certain health care institutions may refuse to provide contraceptive procedures, supplies, and information.

. Ark. Code Ann. § 20-16-601: Health care providers may refuse to participate in an abortion.

. Ark. Code Ann. § 20-6-109: Health care providers and institutions may refuse to comply with individual instructions or health care decisions.

. Ark. Code Ann. § 20-10-1305(2): Employees of **nursing home** facilities may refuse influenza vaccine based on religious beliefs.

. Ark. Code Ann. § 20-13-1403(b)(1): Health care providers may refuse to inform sexual assault victim of emergency contraception.

California

. Cal. Bus. & Prof. Code § 733(b)(3): Pharmacists may not refuse to dispense a prescription unless they have previously notified the employer, in writing, of the drugs or classes of drugs to which he or she objects. The employer may provide reasonable accommodation to the objection.

. Cal. Health & Safety Code § 123420: Employer cannot require employee to participate in abortion if employee has filed written statement with employer indicating a moral, ethical, or religious basis for refusal.

. Cal. Prob. Code § 4734: A health care provider may refuse to comply with an individual's health care instruction for reasons of conscience. A health care institution may also decline to comply with an individual's health care instruction if contrary to a policy of the institution that is expressly based on reasons of conscience, and provided that the policy was timely communicated to the patient or his or her representative.

. Cal. Health & Safety Code § 1288.7: Hospital employee permitted to decline influenza vaccine.

Colorado

. Colo. Rev. Stat. § 25-6-207: City/county employees may refuse to offer family planning and birth control services.

. Colo. Rev. Stat. § 25.5-10-235(2): Hospitals and health care providers may refuse to participate in sterilization.

. Colo. Rev. Stat. § 25-6-102: Physicians and private institutions may refuse to furnish contraceptive procedures, supplies, and information.

. Colo. Rev. Stat. § 25-3-110(3)(a): Health care professionals may refuse to inform a sexual assault survivor of the availability of emergency contraception on the basis of religious or moral beliefs.

Connecticut

. Conn. Agencies Regs. § 19-13-D54(f): A person cannot be required to participate in any phase of an abortion that violates the person's judgment, philosophical, moral, or religious beliefs.

Delaware

. Del. Code Ann. tit. 24, § 1791: A person cannot be required to participate in procedures resulting in the termination of a pregnancy. A hospital may refuse to permit termination of a human pregnancy within the institution.

. Del. Code Ann. tit. 16 § 2508(e) & (g): A health care provider may refuse to comply with an individual's health care instruction for reasons of conscience. A health care institution may also decline to comply with an individual's health care instruction if such instruction is contrary to a policy of the institution that is based on reasons of conscience, and provided that the policy was timely communicated to the patient or his or her representative.

. Del. Code Ann. tit. 24 § 2500(3.0): Pharmacies must establish procedures regarding refusal to dispense pharmaceuticals based on the religious, moral or ethical beliefs of the dispensing pharmacist.

Florida

. Fla. Stat. § 381.0051(5): This statute, referred to as the Comprehensive Family Planning Act, permits a physician or other health care provider to refuse to furnish contraceptive or family planning services, supplies, or information for medical or religious reasons.

. Fla. Stat. § 390.0111(8)-(9): No person or hospital can be required to participate in a termination procedure. This statute does not apply to a procedure that terminates a pregnancy in order to deliver a live child.

Georgia

. Ga. Code Ann. § 16-12-142: Physicians, hospitals, other medical facilities, and pharmacists have a right to object to providing abortion-related services.

. Ga. Code Ann. § 49-7-6: Employees of state agencies may refuse to offer family planning services based on personal religious beliefs. The directors or supervisors of such agencies must reassign the duties of any such employees.

. Ga. Code Ann. § 31-20-6: Hospitals are not required to admit a patient for a sterilization procedure; physicians and other hospital staff can object to participating in a sterilization procedure based on moral or religious grounds.

. Ga. Comp. R. & Regs. § 480-5-03(n): Pharmacists may refuse to fill prescriptions based on professional judgment or ethical or moral beliefs.

Hawaii

. Haw. Rev. Stat. § 453-16(e): A hospital or person may refuse to participate in an abortion.

. Haw. Rev. Stat. § 327E-7(e) & (g): A health care provider may refuse to comply with an individual's health care instruction for reasons of conscience. A health care institution may also decline to comply with an individual's health care instruction if such instruction is contrary to a policy of the institution that is expressly based on reasons of conscience, and provided that the policy was timely communicated to the patient or his or her representative. The health care provider must provide continuing care until the patient can be transferred to another facility.

Idaho

. Idaho Code Ann. § 18-611(2), (5), (6): A health care professional is not required to provide health care services that violate his or her conscience. The statute expressly prohibits a health care provider from refusing to provide services based on a patient's race, color, religion, sex, age, disability, or national origin. If the right is invoked in a life-threatening situation and no other health care provider capable of treating the patient is available, then the objecting health care provider must provide treatment until an alternate provider is located.

. Idaho Code Ann. § 18-612: A health care provider has a right to refuse to perform abortions.

. Idaho Code Ann. § 39-3915: A health care provider has a right to refuse to participate in sterilization.

Illinois

. 745 Ill. Comp. Stat. 70/1: This Act, known as the Health Care Right of Conscience Act, states that physicians and other health care personnel are not civilly or criminally liable for refusing to perform or participate in a form of health care service that is contrary to their conscience.

. Ill. Admin. Code tit. 77, § 956.30(c)(1)(B): Health care employees may refuse to receive the influenza vaccine based on religious beliefs.

Indiana

. Ind. Code § 16-34-1-6: Prohibits hospitals and other persons from discriminating against or disciplining an individual because of their moral beliefs concerning abortion.

Iowa

. Iowa Code §§ 146.1-.2: A health care provider or hospital not controlled, maintained, and supported by a public authority has a right to refuse to perform abortions.

. Iowa Code § 144A.8: Physicians and providers not willing to comply with patient declarations regarding the use of life-sustaining procedures must take steps to transfer the patient to another physician or facility.

Kansas

. Kan. Stat. Ann. §§ 65-443-47: Right of any person to refuse to participate in termination of human pregnancy or in sterilization procedure.

Kentucky

. Ky. Rev. Stat. Ann. § 311.800: General prohibition on abortions in publicly-owned hospitals and health care facilities except to save the life of the pregnant woman; physicians and other providers may object, in writing, to performing or participating in abortions on moral, religious, or professional grounds.

Louisiana

. La. Rev. Stat. Ann. § 40:1299.35.9(A)(1): A health care worker is permitted to refuse to participate in a health care service that violates his or her conscience to the extent that patient access to health care is not compromised.

. La. Rev. Stat. Ann. § 40:1299.31(A): Physicians, nurses, and other persons may refuse to participate in an abortion.

. La. Rev. Stat. § 40:1299.32: Hospitals, clinics, and other facilities may refuse to permit abortions in their facilities.

Maine

. Me. Rev. Stat. tit. 22, § 1591: Immunity for health care providers, hospitals, and health care facilities for refusing to participate in an abortion.

. Me. Rev. Stat. tit. 22, § 1592: Prohibition against discrimination for refusal to participate in an abortion.

. Me. Rev. Stat. tit. 22, § 1903(4): Institutions and providers may refuse to provide family planning services based on religious or conscientious objection.

. Me. Rev. Stat. tit. 34-B, § 7016: Hospitals and other persons are not required to participate in sterilization procedures.

. Me. Rev. Stat. tit. 18-A, § 5-807(E): A health care provider may refuse to comply with an individual's health care instruction for reasons of conscience. A health care institution may also decline to comply with an individual's health care instruction if such instruction is contrary to a policy of the institution that is expressly based on reasons of conscience, and provided that the policy was timely communicated to the patient or his or her representative.

Maryland

. Md. Code Ann., Health-Gen. § 20-214(a)(1): Cannot require persons to participate in medical procedure resulting in artificial insemination, sterilization, or termination of pregnancy.

. Md. Code Regs. 10.07.01.34(F)(5): Hospitals must document reason for employee refusal of influenza vaccine.

. Md. Code Regs. 10.06.01.12(D)(2)(b): Worker may object to measles immunization on grounds that it conflicts with his or her bona fide religious beliefs and practices.

. Md. Code Regs. 10.06.01.15(A)(2)(b): Worker may object to rubella immunization on grounds that it conflicts with his or her bona fide religious beliefs and practices.

Massachusetts

. Mass. Gen. Laws ch. 112, § 12I: Physicians and other providers may object to performing an abortion or sterilization procedure on moral or religious grounds. Objection must be in writing.

. Mass. Gen. Laws ch. 272, § 21B: Privately controlled hospitals and health care facilities are not required to admit patients for the purpose of performing abortions or sterilization procedures or receiving contraceptive devices or information. Privately controlled hospitals and health care facilities are not required to permit abortion or sterilization procedures or furnish family planning services or make referrals to other facilities for such services where such services are contrary to the hospital's or facility's religious or moral principles.

. Mass. Gen. Laws ch. 111, § 70E: Massachusetts' patient bill of rights includes the right of victims of sexual assault to be promptly offered emergency contraception.

. 105 Mass. Code Regs. 130.325(F)(1)(b): Hospital personnel may refuse to receive the influenza vaccine based on religious beliefs.

Michigan

. Mich. Comp. Laws §§ 333.20181-84: Hospitals, other facilities, and health care providers may refuse to participate in an abortion.

Minnesota

. Minn. Stat. § 145.414(a): No person or hospital or institution shall be held liable or discriminated against for refusing to perform, accommodate, assist, or submit to an abortion for any reason.

. Minn. Stat. § 145.42: No physician, nurse, or other person who refuses to perform or assist with an abortion, and no hospital that refuses to permit an abortion to be performed upon its premises, shall be liable for damages related to such refusal. Hospitals are prohibited from demoting, suspending, or otherwise taking adverse action against a physician, nurse, or other person who refuses to perform or assist in the performance of an abortion.

Mississippi

. Miss. Code Ann. § 41-107-5(1): A health care provider may refuse to participate in health care services that violate the provider's conscience. Refusal may not be based on a patient's race, color, national origin, ethnicity, sex, religion, creed, or sexual orientation.

. Miss. Code Ann. § 41-107-7(1): A health care institution may refuse to participate in health care services that violate the institution's conscience. Refusal may not be based on a patient's race, color, national origin, ethnicity, sex, religion, creed, or sexual orientation.

. Miss. Code Ann. § 41-41-215(5): A health care provider may refuse to comply with an individual's health care instruction for reasons of conscience. A health care institution may also decline to comply with an individual's health care instruction if such instruction is contrary to a policy of the institution that is expressly based on reasons of conscience, and provided that the policy was timely communicated to the patient or his or her representative.

Missouri

. Mo. Rev. Stat. § 197.032: Right of providers and hospitals to refuse to perform an abortion.

. Mo. Rev. Stat. § 188.105(1)-(2): An employer is generally prohibited from discriminating against an employee because of the employee's failure to participate in an abortion. Employers are, however, permitted to take certain actions with respect to such employees if there is an inability to reasonably accommodate the employee's refusal without undue hardship on the employer, or in instances where participation is a bona fide occupational qualification reasonably necessary to the normal operation of the employer's business.

Montana

. Mont. Code Ann. § 50-20-111: Right of private hospitals, health care facilities, and providers to refuse to participate in an abortion.

. Mont. Code Ann. § 50-5-501-50-5-505: Right of private hospitals, health care facilities, and individuals to refuse

to participate in sterilization.

Nebraska

. Neb. Rev. Stat. § 28-337-28-338: Hospital, clinics, institutions, or other facilities not required to admit patients for abortions. Right of persons to refuse to perform or participate in an abortion.

Nevada

. Nev. Rev. Stat. § 449.191(1): Right of a hospital or other medical facility that is not operated by the state or a local government to refuse to allow abortions, except in medical emergencies.

. Nev. Rev. Stat. § 632.475(1) & (3): Unlawful to require participation in abortion. Does not apply to medical emergencies.

New Hampshire

. N.H. Rev. Stat. Ann. § 137-J:7(I)(d), (II), (IV): A patient's physician or Advanced Practice Registered Nurse (APRN) may refuse to comply with the terms of an advance directive or surrogate. In such an event, the physician or APRN must immediately inform the patient, the patient's family, or the patient's agent, who may request transfer to another physician or APRN. The attending physician or APRN must, without delay, make necessary arrangements to transfer the patient. While the transfer is pending, the physician or APRN cannot deny health care treatment, nutrition, or hydration if within a reasonable degree of medical certainty such denial would hasten or result in the patient's death against his or her express will or against the will of the agent or surrogate. Health care providers and residential care providers must allow a patient to be transferred if the agent's direction or instruction of the patient's living will is contrary to the health care provider or residential care provider's moral or ethical principles.

New Jersey

. N.J. Stat. Ann. § 45:14-67.1(a): Duty of pharmacy to fill lawful prescriptions without regard to any conflicts of employees due to moral, philosophical, or religious beliefs.

. N.J. Stat. Ann. § 2A:65A-1-:65A-2 : Hospitals, other health care facilities, and persons not required to perform or assist in the performance of an abortion or sterilization services or procedures.

New Mexico

. N.M. Stat. Ann. § 30-5-2: Hospital and hospital staff who object on moral or religious grounds are not required to perform abortions.

. N.M. Stat. Ann. § 24-8-6(A)(1): Health facilities may not include in its bylaws or other governing documents a statement that interferes with the physician-patient relationship with respect to family planning services. *See also* N.M. Stat. Ann. § 24-8-5.

. N.M. Stat. Ann. § 24-7A-7(E): A health care provider may refuse to comply with an individual's health care instruction for reasons of conscience. A health care institution may also decline to comply with an individual's health care instruction if such instruction is contrary to a policy of the institution that is expressly based on reasons of conscience, and provided that the policy was timely communicated to the patient or his or her representative.

. N.M. Stat. Ann. § 24-10D-3(A)(1)-(3): Hospitals that provide emergency care for sexual assault survivors must (i) inform the survivor orally and in writing of her option to receive emergency contraception and (ii) provide such contraception to any sexual assault survivor who requests it.

New York

. N.Y. Civ. Rights Law § 79-i: Right to refuse to perform an abortion. The refusal must be in writing in advance of the procedure and must set forth the reasons for the refusal.

. N.Y. Comp. Codes R. & Regs. tit. 10, § 405.9(b)(10): Hospitals are not required to admit any patient for termination of pregnancy. The hospital must inform the patient of its decision and provide appropriate resources for services or information.

. N.Y. Pub. Health Law § 2805-p(2): Hospitals providing emergency treatment to rape survivors must provide survivors with both oral and written information regarding emergency contraception and must provide such contraception to survivors upon request.

. N.Y. Pub. Health Law § 2994-n: Private hospitals are not required to honor health care decisions if they contradict a formally adopted policy based on sincerely held religious beliefs or moral convictions that are central to the hospital's operating principles. The hospital must inform the patient or the patient's representative of the policy before or at the time of admission, if possible. The patient must be promptly transferred to another hospital that is willing to honor the patient's decision. The hospital must provide certain care while the transfer is pending. This law also permits individual health care providers to refuse to honor a patient's health care decision if it is contrary to the health care provider's sincerely held religious beliefs or moral conviction and the health care provider has promptly informed the patient and the hospital of such refusal. In such an event, the hospital is required to promptly transfer the patient to another individual who is willing to honor the patient's decision. The refusing health care provider must continue to provide care while the transfer is pending.

. Letter from Lawrence H. Mokhiber, N.Y. State Educ. Dept., Office of the Professions, to Supervising Pharmacists, Policy Guideline Concerning Matters of Conscience (Nov. 18, 2005), *available at* www.op.nysed.gov/prof/pharm/pharmconscienceguideline.htm : If a pharmacist objects to filling a prescription based on religious, moral, or ethical grounds, the pharmacist must take steps to avoid abandoning or neglecting a patient, which may include notifying the pharmacist's supervisor and/or the owner of the pharmacy. The owner of the pharmacy should seek to accommodate the pharmacist's choice while assuring delivery of services to patients. The objecting pharmacist should not interfere with another pharmacist who is seeking to fill the prescription, and should avoid confrontation with the patient.

North Carolina

. N.C. Gen. Stat. § 14-45.1(e): Health care providers may refuse to participate in abortion on moral, ethical, or religious grounds.

. N.C. Bd. of Pharmacy Policy, *Conscience Concerns in Pharmacist Decisions* (Rev. Apr. 2005), *available at* www.ncbop.org/LawsRules/ConscienceClause.pdf : A pharmacist may object to providing a medication to a patient on moral or ethical grounds but "should take proactive measures" to avoid obstructing a patient's right to receive the medication. If the prescription is for emergency contraception, the pharmacist must get the patient and the prescription to a pharmacist who is able to provide the medication in a timely manner.

North Dakota

. N.D. Cent. Code § 23-16-14: Hospitals, physicians, nurses, hospital employees, or any other person may refuse to participate in an abortion if they object.

. N.D. Cent. Code § 14-02.4-15.1: Governmental entities may not discriminate against health care institutions or private agencies as a result of the institution's or agency's refusal to participate in a health care service that violates the

institution's or agency's religious or moral policies.

. N.D. Cent. Code § 23-06.5-09(2): A provider may refuse to comply with a health care decision due to conscience or other conflict but must take all reasonable steps to transfer care to another provider who is willing to honor the patient's decision, and shall provide continuing care until the transfer becomes effective.

Ohio

. Ohio Rev. Code Ann. § 4731.91(A), (B), (D): No private or public hospital is required to permit an abortion. No person is required to perform a medical procedure that will result in an abortion.

Oklahoma

. Freedom of Conscience Act, Okla. Stat. tit. 63, § 1-728a--f: Health care providers may refuse, in writing, to participate in activities on moral or religious grounds; health care facilities may refuse to admit patients or allow facilities to be used for abortions, procedures affecting in vitro human embryos, acts that intentionally cause the death of an individual (e.g. assisted suicide), and similar acts and procedures. *See also Okla. Stat. tit. 63 § 1-741.*

Oregon

. Or. Rev. Stat. § 435.475: Hospitals are not required to admit a patient for the purpose of terminating a pregnancy. This does not apply to hospitals operated by the state or a political subdivision.

. Or. Rev. Stat. § 435.485: A physician is not required to participate in or give advice about a termination procedure. The physician must advise the patient of the refusal. A hospital employee is not required to participate in termination of a pregnancy if the employee notifies the hospital of the refusal.

. Or. Rev. Stat. § 435.225: Employees of the Oregon Health Authority may refuse to offer family planning/birth control services based on personal or religious beliefs. The employee must notify his or her immediate supervisor so that alternate arrangements may be made.

. Or. Rev. Stat. § 127.885(4): No health care provider has a duty to provide a patient with medication to end his or her life. The provider must transfer the patient's medical records to a new provider upon request.

Pennsylvania

. 18 Pa. Cons. Stat. § 3213(d): Medical personnel and facilities may refuse to participate in abortion procedures or dispense abortifacients if it is against the provider's or facility's conscience. This does not apply to facilities devoted exclusively to the performance of abortions.

. 49 Pa. Code § 27.103: Pharmacists may decline to fill prescriptions based on professional judgment or religious, moral, or ethical beliefs by taking steps that may include notifying the owner and pharmacist-manager if the pharmacist's beliefs will limit the drug products that the pharmacist will dispense. Pharmacies must make reasonable accommodations that assure the delivery of services to patients in need.

. 43 Pa. Stat. Ann. § 955.2(a): Health care facilities are not required to permit abortion or sterilization procedures contrary to stated ethical policy. Physicians and other hospital staff may refuse to participate in abortion and sterilization procedures based on moral, religious, or professional grounds.

. 16 Pa. Code § 51.44: Hospitals and other health care facilities must make reasonable accommodations for staff members who refuse to participate in abortion and sterilization procedures based on moral, religious, or professional grounds.

. 16 Pa. Code § 51.32: Nonpublic hospitals or other nonpublic health care facilities that object to the performance of abortion or sterilization procedures on moral, religious, or professional grounds are not required to perform or permit abortion or sterilization procedures. Such policies must be in writing, must be made known to all patients and employees, and must be conspicuously posted for public inspection.

. 20 Pa. Cons. Stat. § 5424: An attending physician or other health care provider may refuse to comply with a living will or health care instruction for reasons of good conscience, and they cannot be required to participate in the withholding or withdrawal of life sustaining treatment. The health care provider must assist in the transfer of the patient.

. 28 Pa. Code § 117.57: A hospital is not required to provide emergency contraception contrary to its stated religious or moral beliefs. The hospital must notify the Department of Health Division of Acute and Ambulatory Care in writing. The hospital must also inform the victim that emergency contraception services are not provided due to the stated religious or moral beliefs of the hospital and provide the victim with oral and written notice of the hospital's obligation to arrange for the victim to be transferred to a facility where emergency contraception is available.

Rhode Island

. R.I. Gen. Laws § 23-17-11: A physician, the medical staff, or employee of a health care facility may refuse, in writing, to participate in abortion and sterilization procedures based on moral or religious grounds.

. R.I. Gen. Laws § 23-17.19-6(2): Residents and employees of long term care facilities may refuse an influenza or pneumococcal vaccine based on religious beliefs.

South Carolina

. S.C. Code Ann. § 44-41-50(a): A physician or other employee of a hospital or clinic may refuse to participate in abortion procedures. Such refusal must be in writing.

. S.C. Code Ann. § 44-41-40: Private and non-governmental hospitals and clinics are not required to admit patients for the purpose of terminating a pregnancy if the institution has adopted a policy not to admit patients for such purposes. Such facilities may not, however, refuse an emergency admittance.

South Dakota

. S.D. Codified Laws § 36-11-70: A pharmacist is not required to dispense medication if he or she believes it will be used to cause an abortion, destroy an unborn child, or cause the death of any person through assisted suicide, euthanasia, or mercy killing.

. S.D. Codified Laws §§ 34-23A-12, -14: Providers and hospitals are not required to perform or admit patients for the purpose of terminating a pregnancy. For a hospital to be exempt from liability, it must have adopted a policy not to admit patients for such purposes.

Tennessee

. Tenn. Code Ann. § 39-15-204: Physicians may refuse to participate in abortion procedures. Hospitals may refuse to permit abortion procedures.

. Tenn. Code Ann. § 39-15-205: Hospitals may refuse to admit a patient for an abortion.

. Tenn. Code Ann. § 68-34-104(5): A private institution and its employees may refuse to provide contraceptive procedures, supplies, and information for reasons of religion or conscience.

. Tenn. Code Ann. §§ 68-11-1808(c), (d)(1), (f); 32-11-108(a): A health care provider may refuse to comply with an individual instruction, health care decision, or living will for reasons of conscience. A health care institution may also refuse to comply with a living will or health care instruction contrary to the institution's policies. The health care institution must promptly inform the patient or his or her representative of the refusal and provide continuing care until the patient can be transferred to another facility.

. Tenn. Comp. R. & Regs. 1200-8-1-.06(2)(f)(2): Hospital staff members may refuse an influenza vaccination for non-medical reasons.

Texas

. Tex. Occ. Code Ann. § 103.001: Hospital or other health care facility employees may refuse to participate in abortion procedures.

. Tex. Occ. Code Ann. § 103.004: Private health care facilities may refuse to perform abortion procedures, unless the mother's life is in danger.

. Tex. Health & Safety Code § 323.005(c): Health care facility employees or contractors may refuse to provide emergency contraception information based on religious or ethical beliefs. The facility must ensure that patients receive the information from another individual.

Utah

. Utah Code Ann. § 76-7-306(2)--(3): Health care providers may refuse on moral or religious grounds to participate in abortions or other procedures that may terminate a pregnancy. Except where required by law, health care facilities may refuse on moral or religious grounds to admit a person for or perform a procedure to terminate a pregnancy.

. Utah Code Ann. § 75-2a-115(4)(b)(ii), (4)(c), (4)(e): A health care provider may refuse to comply with a health care decision for reasons of conscience. A health care facility may also decline to comply with a health care decision if such decision is contrary to a conscious-based policy of the facility, provided that the policy is timely communicated to the patient or his or her representative. The health care facility must provide continuing care until the patient can be transferred to another facility.

. Utah Code § 26-21b-201: Freestanding urgent care centers are not required to provide emergency contraception if the center is within 30 miles of a hospital. The freestanding urgent care center must provide the patient with the name and address of such hospital(s) and unbiased written and oral information regarding emergency contraception.

Vermont

. Vt. Stat. Ann. tit. 18, § 9707(b)(3): A health care provider or facility may refuse to comply with a health care instruction based on a moral, ethical, or other conflict, and must inform the patient or his or her representative of the conflict and provide continuing care until the patient can be transferred to another facility.

Virginia

. Va. Code Ann. § 18.2-75: Health care facilities may refuse to admit a patient for an abortion. Persons may object in writing to abortion procedures based on ethical, moral, religious, or personal grounds.

. Va. Code Ann. § 32.1-134: A hospital operated under a religious institution may refuse on religious grounds to provide family planning information.

. Va. Code Ann. § 54.1-2957.21: A genetic counselor may refuse to participate in counseling that conflicts with his

or her deeply-held moral or religious beliefs.

Washington

. Wash. Rev. Code § 9.02.150: No person or private medical facility can be required to participate in an abortion.

. Wash. Rev. Code § 70.245.190(1)(d): No person or health care provider has a duty to participate in the provision of medication to a patient to end his or her life.

West Virginia

. W. Va. Code § 16-2B-4: State employees may refuse to offer family planning services based on personal religious beliefs.

. W. Va. Code § 16-11-1: A medical facility is not required to admit a patient for a sterilization procedure; physicians and other hospital staff are permitted to object to participating in sterilization procedures.

. W. Va. Code § 16-30-12: A health care facility may establish policies based on sincere religious or moral beliefs. A provider may refuse to honor a health care decision based on the provider's sincere moral or religious beliefs. The provider must promptly inform the facility and the patient and cooperate in the transfer of the patient.

Wisconsin

. Wis. Stat. § 253.09(a): Hospitals are not required to admit a patient for a sterilization procedure or procedure to remove a human embryo or fetus. Physicians and other hospital staff may object to participating in such procedures based on moral or religious grounds. An objection must be in writing.

. Wis. Stat. § 448.03(5)(a): A medical practitioner who refuses to participate in a sterilization procedure or procedure to remove a human embryo or fetus based on religious or moral precepts is exempt from civil liability.

. Wis. Stat. § 253.07(3)(b): Employees of state agencies may refuse to offer family planning services based on personal religious beliefs. The directors or supervisors of such agencies must reassign the duties of any such employees.

. Wis. Stat. § 50.375(4): Hospitals may refuse to provide emergency contraception to a sexual assault victim who is pregnant.

Wyoming

. Wyo. Stat. Ann. § 35-6-105: Private hospitals, clinics, institutions, and other private facilities may refuse to admit a patient for the purpose of performing an abortion. These facilities must inform the patient of such policy.

. Wyo. Stat. § 35-6-106: Persons are not required to perform abortions or similar procedures.

. Wyo. Stat. § 35-22-408(e): A health care provider may refuse to comply with a patient's health care decision for reasons of conscience. A health care institution may also refuse to comply if the patient's decision is contrary to the institution's written conscience policy and the policy was timely communicated to the patient. The institution must promptly inform the patient or his or her representative and provide continuing care until the patient can be transferred to another facility.

REFERENCE: CITATION: Pamela H. Del Negro and Stephen W. Aronson, Religious Accommodations for Employees in the Health Care Workplace, J. Health & Life Sci. L., June 2015 at 72, (c) 2015 American Health Lawyers Association, www.healthlawyers.org/JHLSL . All rights reserved.

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TITLE: ARTICLE: Application of the HIPAA Privacy Rule to Employer Benefit Plans and A Compliance Theory of Statutory Interpretation

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TEXT:

ABSTRACT: The application of the federal privacy regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to employer benefit plans is arguably the most conceptually difficult area of a complex law. A purely textual reading of the Rule, when applied to employer plans, results in varying interpretations on some significant issues and puzzling results on others. This Article offers a practical approach for interpreting the rule when clear-cut answers are not provided by the text and DHHS guidance is nonexistent or unclear. In addition, this approach can be applied to the interpretation of other statutes and regulations.

The application of the federal privacy regulations (Privacy Rule or Rule) n1 promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) n2 to employer benefit plans is arguably the most conceptually difficult area of a complex law. A purely textual reading of the Rule, when applied to employer plans, results in varying interpretations on some significant issues and puzzling results on others. The Department of Health and Human Services (DHHS), which issued the Rule, and the Office for Civil Rights (OCR), which is responsible for its enforcement, n3 failed to clarify most of these issues n4 in the preamble and various other guidance accompanying the final Rule. n5

n1 Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462 (Dec. 28, 2000).

n2 Health Insurance Portability and Accountability Act (HIPAA) of 1996, Pub. L. No. 104-191, 110 Stat. 1936. The Privacy Rule is one of a set of regulations mandated under title II, subtitle F, §§ 261-264 of HIPAA, and titled "Recommendations with Respect to Privacy of Certain Health Information."

n3 See Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,472 (Dec. 28, 2000) (to be codified at 45 C.F.R. pts. 160, 164) ("The Secretary has decided to delegate her responsibility under these regulations to the Department's Office for Civil Rights.").

n4 Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,472; Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 14, 776 (Mar. 27, 2002) (to be codified at 45 C.F.R. pts. 160, 164); Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 53,182 (Aug. 14, 2002) (to be codified at 45 C.F.R. pts. 160, 164); Dep't of Health

and Human Servs., *Office for Civil Rights--HIPAA: Medical Privacy--National Standards to Protect the Privacy for Personal Health Information*, at www.hhs.gov/ocr/hipaa/ (last visited Apr. 5, 2004).

n5 Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,472.

This Article offers a practical approach for interpreting the Rule when clear-cut answers are not provided by the text and DHHS guidance is nonexistent or unclear. In addition, this approach can be applied to the interpretation of other statutes and regulations. The Article also addresses the relationship between the proposed approach to the ongoing lively debate and dynamic development of the jurisprudence of statutory interpretation. Further, it discusses the usefulness of the approach for businesses and their lawyers struggling with current corporate governance compliance issues.

Commentators already have begun to proffer paradigms for judging HIPAA's effectiveness that may offer courts some philosophical bases for resolving HIPAA interpretation conundrums. In point-counterpoint articles published in the *Minnesota Law Review* June 2002 symposium issue on *Modern Studies in Privacy Law*, n6 Professors Lawrence Gostin and James Hodge suggest a balancing test between individual and communal interests as the proper backdrop for the Rule. n7 Meanwhile, Professor Peter Jacobson proposes a modified rule of reason approach with a presumption for privacy. n8 While each approach has its philosophically appealing attributes, both articles offer their tests as ones against which the Rule itself should be evaluated rather than as specific guidance for resolving ambiguities in that Rule. These approaches are tailored specifically to evaluate HIPAA, rather than for use generally to evaluate statutes or regulations. Moreover, the tests offer policy-based balancing more appropriate for judicial application or theoretical academic analyses, as opposed to the type of specific direction that is helpful to **companies** implementing compliance.

n6 Dale Carpenter, *Keeping Secrets*, 86 MINN. L. REV. 1097, 1110-11 (2002).

n7 Lawrence O. Gostin & James G. Hodge, Jr., *Personal Privacy and Common Goods: A Framework for Balancing Under the National Health Information Privacy Rule*, 86 MINN. L. REV. 1439, 1470 (2002).

n8 Peter D. Jacobson, *Medical Records and HIPAA: Is It Too Late To Protect Privacy?*, 86 MINN. L. REV. 1497, 1499 (2002).

Unlike the symposium articles, the framework offered in this Article provides direction for interpreting statutes and regulations for purposes of required compliance when varying interpretations appear possible. The framework proposes the analysis of each possible interpretation under four factors: (1) the extent to which the interpretation is consistent with the text of the law (Textual Test); (2) the extent to which the interpretation is consistent with the legislative history or official agency guidance (Commentary Test); (3) the extent to which the interpretation furthers the stated purposes of the law (Purposes Analysis); and (4) the extent to which, when applied to actual facts, the interpretation avoids producing an absurd result (Absurdity Analysis). The last prong of the approach, avoiding an absurd result, is used in this Article as a shorthand reference to the entire analytical framework (Absurdity Avoidance).

The Absurdity Avoidance framework, when applied to the HIPAA Privacy Rule, provides the philosophical underpinnings for judging the effectiveness of the Rule. Reality has an ability to "zero in" on the absurd that is often missed by academics and government bureaucrats dealing with issues in the abstract.

Part I of this Article sets forth the general Privacy Rule requirements for employer-sponsored health plans. Part II analyzes the impact of those requirements on the most common forms of employer plans. Part III describes the Absurdity Analysis, including how the analysis relates to other theories of statutory interpretation and to current corporate governance developments. Part IV identifies and analyzes two areas of application and interpretation issues with respect to the impact of the Privacy Rule on employer health plans. These issues merit further discussion because they were left unclear or were unanticipated by the provisions of the Rule. Specifically, the areas addressed are: the

application of the Rule to healthcare flexible spending accounts, employee assistance programs, and to "other health plans" in the employer context; and the limits on the use of enrollee authorization by employers to avoid certain Privacy Rule compliance requirements. Within these areas, the specific issues addressed include: (1) whether, and to what extent, employee assistance programs (EAPs) are subject to the Rule; (2) whether, in the employer context, the Rule applies only to employee welfare benefit plans regulated under the Employee Retirement Income and Security Act of 1974 (ERISA);ⁿ⁹ (3) how certain plans, such as healthcare flexible spending accounts and EAPs, that are ERISA plans, but do not meet the definition of "insured" or "self-insured" are regulated under the Rule; (4) whether employers may utilize authorizations to avoid the Rule's compliance requirements dealing with receipt of protected health information for final appeals determinations; and (5) whether employers may circumvent the Rule's prohibition on the use of protected health information from a covered health plan for purposes of administering other benefit plans. ⁿ¹⁰ Finally, Part V evaluates reasonable interpretations for each issue addressed in Part IV under the Absurdity Avoidance framework, resulting in guidance for resolution of these issues and providing an example of the analysis that may be applied generally to other laws.

ⁿ⁹ 29 U.S.C. § 1002(1) (2004).

ⁿ¹⁰ Indeed, many other unsettled issues have arisen in the application of the Privacy Rule to employer group health plans, including: (1) whether sponsor workforces who provide plan administration functions for self-insured plans administered by third parties are subject to the health plan workforce compliance requirements, such as training, or only to the partially overlapping requirements specifically set forth in the Rule as applicable to plan sponsors performing plan administration functions; (2) whether employers with "wrap-around" plans must count all benefits under the wrap-around plan, which may include medical, dental, vision, cafeteria plans, and others, as one covered entity health plan for Privacy Rule compliance purposes; and (3) to what extent the state law preemption analysis under the Privacy Rule applies to Group Health Plans. These issues and others merit discussion but are beyond the scope of this Article. Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,508.

I. Privacy Rule Background

A. Definition of Health Plans Under the Privacy Rule

While employers are not Covered Entities under the Privacy Rule, ⁿ¹¹ certain health plans sponsored by employers are Covered Entities and, in many cases, are subject to the full spectrum of Privacy Rule compliance requirements. ⁿ¹² A health plan that is a Covered Entity under HIPAA (Health Plan) ⁿ¹³ is an individual or group plan that provides, or pays the cost of, medical care.

ⁿ¹¹ HIPAA applies only to "covered entities," which are defined as (1) a health plan, (2) a healthcare clearinghouse, and (3) a healthcare provider who transmits any health information in electronic form in connection with a transaction governed by HIPAA. 45 C.F.R. § 160.103 (2004). The Privacy Rule governs uses and disclosures by Covered Entities of protected health information. The Rule provides certain rights for individuals with respect to their protected health information, and imposes certain administrative requirements on Covered Entities. *See generally* Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462.

ⁿ¹² 45 C.F.R. § 160.104 (2004).

ⁿ¹³ *See id.* § 160.103.

The Rule cites Section 2791(a)(2) of the Public Health Service Act (PHS Act) for the definition of "medical care" and specifically includes items and services paid for as medical care. ⁿ¹⁴ The PHS Act defines medical care as: (A) amounts paid for diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of effecting any structure or function of the body; (B) amounts paid for transportation that is primarily for and essential to medical care referred to in (A); and (C) amounts paid for insurance covering medical care referred to in (A) and (B) (Medical Care). ⁿ¹⁵

n14 See Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,772.

n15 42 U.S.C. § 300gg-91(a)(2) (2004).

This definition of a Health Plan specifically includes employee welfare benefit plans as defined in ERISA n16 to the extent they provide or pay for Medical Care (Group Health Plans) n17 and "any other individual or group plan . . . that provides or pays the cost of" Medical Care (Catchall Category). n18

n16 See 45 C.F.R. § 160.103 (2004). An employee welfare plan includes any plan, fund, or program that is established or maintained for the purpose of providing medical, surgical, or hospital care or benefits or benefits in the event of sickness.

n17 The Privacy Rule defines a Group Health Plan as:

an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income and Security Act of 1974 (ERISA), 29 U.S.C. § 1002(1)), including insured and self-insured plans to the extent the plan provides medical care (as defined in section 2791(a)(2) of the Public Health Service Act (PHS Act)) . . . to employees or their dependents directly or through insurance, reimbursement, or otherwise, [and that h]as 50 or more participants . . . or is administered by an entity other than the employer that sponsors the plan.

45 C.F.R. § 160.103 (2004) (defining Health Plan).

n18 *Id.* § 160.103 (including in the definition of Health Plan: HMOs, health insurance issuers, issuers of long term care policies (excluding **nursing home** fixed indemnity policies), certain government programs, and any other individual or group plan that provides or pays for the cost of medical care).

Health Plans specifically exclude plans or programs that provide or pay for excepted benefits listed in Section 2791(c)(1) of the PHS Act (Excepted Benefits). n19 These Excepted Benefits include accident or disability income insurance, liability insurance, worker's compensation, and coverage for on-site medical clinics. n20 An exception exists, however, under the Privacy Rule for Group Health Plans that are administered by a third party and have fewer than fifty participants. n21 In addition, plans with annual receipts of \$ 5 million or less are considered "small health plans" n22 and were not required to comply with the Privacy Rule until April 14, 2004. n23 All other Health Plans were required to comply by April 14, 2003. n24

n19 *Id.* § 160.103 (excluding from the definition of Health Plan "any policy, plan or program to the extent it provides, or pays the cost of, excepted benefits listed in section 2791(c)(1) of the PHS Act, 42 U.S.C. § 300gg-91(c)(1).").

n20 See 42 U.S.C. § 300gg-91(a)(2) (2004). It is important to note that while on-site clinics are not health plans covered by the Privacy Rule, these clinics may be subject to the Rule as covered providers.

n21 See 45 C.F.R. § 160.103 (2004).

n22 *Id.* § 160.103. CMS has issued guidance on how to determine annual receipts for this purpose that in part provides:

Health plans that do not report receipts to the IRS--for example, ERISA welfare plans that are exempt from filing income tax returns--should use proxy measures to determine their annual receipts. Fully insured health plans should use the amount of total premiums which they paid for health insurance benefits during the plan's last full fiscal year. Self-insured plans, both funded and unfunded, should use the total amount paid for health care claims by the employer, plan sponsor or benefit fund, as applicable, on behalf of the plan during the plan's last full fiscal year. Those plans that provide health benefits through a mix of purchased insurance and self-insurance should combine the proxy measures to

determine their total annual receipts.

Ctrs. for Medicare and Medicaid Servs., "HIPAA 101" Video Script, May 12, 2003, at www.cms.hhs.gov/hipaa/hipaa2/education/May12videoscript.doc (last visited Apr. 5, 2004).

n23 45 C.F.R. § 164.534(b)(2) (2004).

n24 *Id.* § 164.534(b)(1).

Group Health Plans usually do not have a separate corporate presence and are dependent on the plan sponsor or another third party for administration and operations support. In addition, due to its dual nature as both employer and plan administrator, an employer often provides plan administration functions and, thus, has a legitimate need for information, including protected health information, n25 from its Group Health Plans. The relationship between an employer and the Group Health Plans it sponsors creates two main categories of issues for the employer under the Privacy Rule. With respect to any Group Health Plan, the categories are:

- (i) Ensuring compliance with the Privacy Rule by the Group Health Plan itself; and
- (ii) Ensuring compliance with the Privacy Rule by the employer in its role as sponsor with respect to its receipt of protected health information from the Group Health Plan.

n25 Protected health information is defined in the Rule to mean individually identifiable health information that is transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form of medium, except for "(i) education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g; (ii) records described at 20 U.S.C. 1232g(a)(4)(B)(iv); and (iii) employment records held by a covered entity in its role as employer." *See* 45 C.F.R. § 160.103 (2004).

B. Privacy Rule Requirements for Health Plans

Compliance by Health Plans with the Privacy Rule can be quite burdensome and compels such Covered Entities to comply with a long list of requirements. Thus, Health Plans must: (i) use and disclose protected health information only as permitted under the Rule, limited by the "minimum necessary" requirements, n26 and subject to the numerous exceptions and qualifications applicable to Covered Entities; n27 (ii) obtain special authorization for any other uses and disclosures not permitted under the Rule; n28 (iii) provide a written notice of privacy practices to plan beneficiaries; n29 (iv) enter into Business Associate Agreements with entities that create or receive protected health information in the course of providing certain services to or on behalf of the plan; n30 (v) appoint a privacy officer and establish a contact for privacy-related complaints by plan beneficiaries and a complaint mechanism; n31 (vi) create and implement policies and procedures allowing beneficiaries to access and copy their protected health information, request restrictions on or confidential communications of their protected health information, request amendments to the information, and request an accounting of certain types of disclosures (Individual Rights); n32 (vii) develop and implement policies and procedures to ensure compliance with the Rule, including the minimum necessary requirements; (viii) provide appropriate training to all members of the plan's workforce; (ix) implement appropriate administrative, physical, and technical safeguards to protect the privacy of protected health information; (x) adopt and apply appropriate sanctions against workforce members for violations of the Rule or the plan's policies and procedures; (xi) mitigate any known, harmful effects caused by any violation of the Rule or the plan's policies and procedures; (xii) refrain from taking intimidating or retaliatory actions against individuals who exercise their rights under the Rule; (xiii) refrain from requiring individuals to waive their rights under the Rule as a condition of treatment, payment, enrollment, or eligibility; and (xiv) document adherence to these requirements as provided in the Rule. n33 These obligations are referenced in this Article collectively as "Health Plan Requirements."

n26 Except for uses and disclosures made pursuant to an authorization, disclosures made to a provider for treatment purposes, and certain other disclosures specified by the Rule, a covered entity may use or disclose only the minimum amount of protected health information necessary to accomplish the intended purpose. 45 C.F.R. §§ 164.502(b)-164.514(d) (2004).

n27 *See generally id.*

n28 *See id.* § 164.508.

n29 *See id.* § 164.520. "A Group Health Plan that provides benefits solely through an insurance contract with a health insurance issuer or HMO and that creates or receives protected health information in addition to summary health information as defined in § 164.504(a)" or enrollment or disenrollment information must maintain its own notice, separate from the notice provided by the HMO or issuer, and provide it upon request to any person. The issuer or HMO is required to actually send its notice to enrollees as specified in the Rule. In most cases, compliance can be structured such that two separate notices are not required. Specifically, if the plan itself receives no protected health information but the HMO or issuer instead provides protected information to the sponsor to perform the administrative functions on behalf of the plan, then it need not comply with the notice and other requirements of the Rule, but must amend the plan documents and otherwise comply with the Privacy Rule requirements. *Id.* § 164.520.

n30 *See* 45 C.F.R. §§ 164.502(c)-164.504(e) (2004).

n31 *See id.* § 164.530(a)(1).

n32 *Id.* §§ 164.524-164.528.

n33 *See id.* § 164.530.

Health maintenance organizations (HMOs) and other insurance issuers are Health Plans and must themselves comply with the Privacy Rule. As such, if a Group Health Plan contracts with an HMO or insurance issuer to fully insure its benefits and does not create or receive protected health information (except for summary health information n34) or enrollment or disenrollment information, n35 the Group Health Plan can avoid most of these burdensome Health Plan Requirements. n36

n34 The Rule provides that

Summary health information means information . . . : (1) that summarizes the claims history, claims expenses, or type of claims experienced by individuals for whom a plan sponsor has provided health benefits under a Group Health Plan; and (2) from which the identifiers described in § 164.514(b)(2)(i) have been deleted, except that the geographic identifier described in § 164.514(b)(2)(i)(B) need only be aggregated to the level of a five digit zip code.

Id. § 164.504(a). Essentially this definition requires that the information be de-identified except for the ZIP code and geographic subdivisions (*e.g.*, city) that are larger than the ZIP code.

n35 The Rule describes enrollment and disenrollment information as information on whether the individual is participating in the Group Health Plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan. 45 C.F.R. § 164.530(k)(1).

n36 The Rule provides that in these circumstances the Group Health Plan is subject only to the requirements set forth in three subsections: (g) (refraining from intimidating or retaliatory acts against individuals exercising their rights under the Rule); (h) (refraining from conditioning benefits on a waiver of rights); and sometimes (j) (documentation requirements in the case of amendments to plan documents). *Id.* § 164.530(k)(2).

On the other hand, to the extent that the Group Health Plan is self-insured or creates or receives protected health information (other than summary health information or enrollment and dis-enrollment information), it retains ultimate

compliance responsibility and must meet all the Health Plan Requirements. A Group Health Plan can try to negotiate with third-party administrators to transfer contractually all or part of the administrative burden of compliance. n37

n37 *See generally* Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,627-28 (Dec. 28, 2000) (to be codified at 45 C.F.R. pts. 160, 164); Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 53,182, 53,248 (Aug. 14, 2002) (to be codified at 45 C.F.R. pts. 160, 164). The contractual transfer of a Health Plan's obligations to a TPA is separate and apart from the Business Associate obligations a Health Plan is required to impose on certain third parties.

C. Privacy Rule Requirements for Health Plan Sponsors

The Privacy Rule does not apply directly to employers, but it indirectly requires compliance by employers in certain instances. n38 Thus, in addition to ensuring that Group Health Plans comply with the Health Plan Requirements, an employer in many instances must comply with the Privacy Rule in its role as plan sponsor and employer. It will be prudent for employers to focus on this compliance because of the potential criminal penalties under HIPAA associated with knowingly receiving improperly disclosed protected health information. n39

n38 The Rule requires that Group Health Plans require sponsors to comply with certain requirements as a condition of receiving protected health information from the plan. As a practical matter, for self-insured plans, the sponsor is the one who must ensure the plan's compliance with the Rule by requiring of itself compliance with the sponsor requirements. This circle is just one example of the conceptually confusing compliance structure created for employer health plans by the Privacy Rule.

n39 Civil money penalties for failure of a Covered Entity to comply with HIPAA regulations may be imposed in a fine of up to \$ 100 for each violation, not to exceed \$ 25,000 in any calendar year for violations of the same requirement. *See* 42 U.S.C. § 1320d-5 (2004). Criminal penalties for any person who knowingly obtains or discloses individually identifiable health information in violation of the HIPAA regulations start with fines of not more than \$ 50,000 and imprisonment up to a year, or both, and can increase, depending on intent factors, up to a fine of not more than \$ 250,000 and imprisonment up to ten years, or both. *See id.* § 1320d-6.

Absent an authorization from the affected individual, the Privacy Rule allows for the disclosure of protected health information by a Group Health Plan, including HMOs or insurance issuers with respect to the Group Health Plan, n40 to the plan sponsor for the purpose of carrying out plan administration functions. n41 This disclosure is allowed provided that the sponsor amends the plan documents to include: (i) a description of the permitted uses and disclosures of enrollee protected health information by sponsor employees providing plan administration functions; n42 (ii) adequate separation between the Health Plan and employer; n43 and (iii) a provision that the Health Plan shall disclose enrollee protected health information to the employer only upon receipt of a certification that the plan documents have been amended to incorporate the provisions described in the following paragraph and that the employer, in its capacity as plan sponsor, shall comply with the numerous sponsor requirements mandated by the Rule. n44

n40 Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,507. Throughout this discussion, when reference is made to disclosure of information by a Group Health Plan, that reference includes disclosure by an HMO or insurance issuer with respect to the Group Health Plan.

n41 *See* 45 C.F.R. § 164.504(a) (2004). Plan administration functions are defined in the Rule as administration functions performed by the plan sponsor on behalf of the Group Health Plan and exclude functions performed in connection with any other benefit or plan.

n42 *Id.* § 164.504(f)(2)(i).

n43 This is accomplished by providing a description of the workforce members or classes of workforce members who shall be given access to the enrollee protected health information and assurance that this access shall be restricted to the plan administration functions that the employer performs for the Health Plan. In addition, it requires a provision that describes a mechanism for resolving any issues of

noncompliance by any workforce member or other person who is given access to enrollee protected health information. *Id.* § 164.504(f)(2)(iii).

n44 *Id.* § 164.504(f)(2)(ii) (discussing that in addition to amending the plan documents to provide these terms, the plan sponsor must also make this certification to the Health Plan).

Specifically, the sponsor shall: (i) not use or further disclose enrollee protected health information other than as permitted or required by the plan document or as required by law; (ii) ensure that any contractors, including a subcontractor, to whom the employer or workforce members provide enrollee protected health information received from the Health Plan, agree to the same restrictions; (iii) not use or disclose enrollee protected health information for employment-related actions and decisions unless authorized by an individual enrollee; (iv) not use or disclose enrollee protected health information in connection with any other benefit or employee benefit plan of the employer unless authorized by an individual enrollee; (v) report to the Health Plan privacy officer any enrollee protected health information use or disclosure that is inconsistent with the uses or disclosures provided for; (vi) make enrollee protected health information available to an individual in accordance with 45 C.F.R. § 164.524; (vii) make enrollee protected health information available for amendment and incorporate any amendments to enrollee protected health information in accordance with 45 C.F.R. § 164.526; (viii) make available the information required to provide an accounting of disclosures in accordance with 45 C.F.R. § 164.528; (ix) make internal practices, books, and records relating to the use and disclosure of enrollee protected health information received from the Health Plan available to the Secretary of DHHS for the purposes of determining the Health Plan's compliance with the Privacy Rule; and (x) where possible, return or destroy all enrollee protected health information received from the Health Plan that the employer or workforce members still maintain in any form, and retain no copies of such enrollee protected health information when no longer needed for the purpose for which disclosure was made. n45 These obligations to amend plan documents and to certify compliance with requirements (i) through (x) are the "Sponsor Requirements."

n45 *Id.* § 164.504(f)(2)(ii).

It is important to note that the Privacy Rule allows a Group Health Plan to share certain limited protected health information with the plan sponsor in two situations without the plan or the sponsor having to meet these Sponsor Requirements. Specifically, a Group Health Plan may, without individual authorization, amend the plan documents or by provision of the Certification by the plan sponsor share with the sponsor: (i) summary health information for the limited purposes of obtaining premium bids for health insurance coverage or modifying, amending, or terminating the Group Health Plan; and (ii) enrollment and disenrollment information. n46

n46 *See id.* §§ 164.504(f)(1)(ii), 164.504(a), 164.530(k)(1)(B).

II. Impact of Privacy Rule on Employer Group Health Plans

Employers typically sponsor one or more of the following employee benefit plans: medical, including prescription and behavioral health benefits; dental; vision; smoking cessation and other wellness plans; an EAP; an executive health program; travel/ accident plan; life insurance; short- and long-term disability; healthcare and dependent-care flexible spending accounts (FSAs); and worker's compensation.

The disability programs, life insurance programs, dependent care FSA, and worker's compensation insurance coverage are not Health Plans and, thus, are not subject to the Privacy Rule. n47 Disclosure by Health Plans or covered providers of PHI to these other programs or their sponsors, however, is subject to the Privacy Rule and may be done only in compliance with the Rule. n48

n47 These programs are either Excepted Benefits or they do not provide or pay for the cost of Medical Care. Programs such as pre-employment physicals and annual testing of healthcare workers also are considered employer functions rather than Health Plan functions, and information held by an employer with respect to these and other employer activities is not subject to the Privacy Rule. Issues related to the limits on and separation of these employer functions, however, must be addressed in the context of Privacy Rule compliance efforts. *See* 42 U.S.C. § 300gg-91(a)(2) (2004); 45 C.F.R. § 160.103 (2004); Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,567 (Dec. 28, 2000) (to be codified at 45 C.F.R. pts. 160, 164).

n48 An exception is made for disclosures of protected health information by a covered entity as authorized by and to the extent necessary to comply with laws relating to worker's compensation or similar programs established by law that provide benefits for work-related injuries or illness without regard to fault. *See* 45 C.F.R. § 164.512(1) (2004).

The remaining plans typically sponsored by employers are medical, dental, vision, healthcare FSA, EAP, and other wellness programs. Benefits under medical, dental, and vision plans are either fully insured or self-insured by the employer. n49 The applicability of the Privacy Rule to these benefit plans and programs is analyzed in this section. The application of the Rule to FSAs, EAPs, and other wellness programs, which commonly are not provided under the same types of "fully-insured" or "self-insured" mechanisms, offer one of the three interpretation issues analyzed in Part III.

n49 *See infra* notes 75-81 and accompanying text (discussion of the meaning and difference between insured and self-insured plans).

A. Insured Plans

Group Health Plans with insured benefits are subject to the Privacy Rule. n50 Although, if these benefits are provided by an insurance issuer or HMO and if:

(i) The plans (or the sponsor on the plans' behalf) do not create or receive any protected health information other than summary health information or enrollment or disenrollment information; and

(ii) The sponsor does not receive from the insurance issuer or HMO any protected health information other than summary health information or enrollment or disenrollment information, n51

then the statutory obligations under the Privacy Rule will be only for the plans to:

(i) Refrain from any retaliatory or intimidating acts if an individual seeks to exercise rights under the Privacy Rule with respect to these plans; n52 and

(ii) Refrain from requiring individuals to waive their rights under the Privacy Rule as a condition of treatment, payment, enrollment in these plans, or eligibility for benefits. n53

n50 *See* 45 C.F.R. § 160.103 (2004).

n51 *See id.* § 164.530(k)(1)(B) (defining summary health information and enrollment and disenrollment information).

n52 *Id.* § 164.530(g). Specifically, the Privacy Rule provides as follows:

A covered entity may not intimidate, threaten, coerce, discriminate against, or take other retaliatory action against: (1) Individuals. Any individual for the exercise by the individual of any right under, or for participation by the individual in any process established by this subpart, including the filing of a complaint under this section; (2) Individuals and others. Any individual or other person for: (i) Filing of a complaint with the Secretary under subpart C of part 160 of this subchapter; (ii) Testifying, assisting or participating in an investigation, compliance review, proceeding, or hearing under Part C or Title XI; or (iii) Opposing any act or practice made unlawful by this subpart, provided the individual or person has a good faith belief that the practice opposed is unlawful, and the manner of opposition is reasonable and does not

involve a disclosure of protected health information in violation of this subpart.

Id. § 164.530(g).

n53 *Id.* § 164.530(h). As a practical matter, however, the sponsor may be advised to do the following: (1) ensure its insurance agreements address HIPAA compliance issues; (2) confirm that an authorization has been obtained from any employee whose protected health information is disclosed by the insurance issuer or HMO to the sponsor; (3) educate its employees to recognize cases in which protected health information may be improperly disclosed to them and also to facilitate compliance with the statutory obligations to refrain from retaliation and/or requiring a waiver; and (4) adopt policies and procedures for dealing with both improper disclosures and proper disclosures made pursuant to authorizations, including policies and procedures designed to prevent the use or disclosure of any protected health information disclosed to the sponsor pursuant to an authorization, as well as policies and procedures to facilitate compliance with the statutory obligations to refrain from retaliation and requiring a waiver.

If the sponsor of a plan for which the benefits are provided by an insurance issuer or HMO does receive additional protected health information from the insurance issuer or HMO, then the sponsor will be required to amend the plan documents and comply with the Sponsor Requirements.

B. Self-Insured Plans

The Privacy Rule provides that Self-Insured Group Health Plans must comply with all the Health Plan Requirements. Further, if the sponsor receives additional protected health information with respect to these plans, the sponsor will be required to amend the plan documents and comply with the Sponsor Requirements. In most cases, sponsors of self-insured plans receive additional protected health information in connection with their duties as plan fiduciaries to hear final appeals related to denial of enrollee benefits. In addition, because employers bear the ultimate costs of claims under these plans, they often need more detailed claims data for purposes of utilization review and disease management.

Most employers contract with third-party administrators (TPAs) n54 to handle the administrative functions of managing self-insured plans, including claims processing and payment. The Privacy Rule requires that Health Plans enter into Business Associate Agreements with any such TPAs that will receive or create protected health information on behalf of the Health Plan. The Business Associate Agreement requires the TPA to safeguard the protected health information and limits the TPA's use and disclosure of that information. n55 This contracting process n56 has resulted in some plans and sponsors transferring some of the plan's compliance responsibilities to the TPA, such as direct administration of Individual Rights or issuance of a privacy notice. At the same time, some TPAs are using the Business Associate Agreement as a vehicle for adding burdensome provisions not required by the Rule. n57

n54 *See generally* Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,627-28 (Dec. 28, 2000) (to be codified at 45 C.F.R. pts. 160, 164); Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 53,182, 53,248 (Aug. 14, 2002) (to be codified at 45 C.F.R. pts. 160, 164). TPAs are service **companies** that provide one or more management and/or administrative services to a Health Plan, performing these services on behalf of the plan but not assuming any of the insurance risk associated with the Medical Care. When TPA services are provided by an entity that is also an insurance issuer or HMO for other purposes, the arrangement typically is referred to as an "administrative services only" or ASO arrangement, but the relationship is essentially the same.

n55 *See* 45 C.F.R. §§ 164.502(b)-164.514(d) (2004). Under the Rule, these Business Associate Contracts must establish the permitted and required uses and disclosures of protected health information by the Business Associate, and provide generally that the Business Associate will: (i) not use or further disclose the information other than as permitted or required by the contract; (ii) use appropriate safeguards to prevent unauthorized use or disclosure of that information; (iii) report to the Health Plan any unauthorized use or disclosure of which the Business Associate becomes aware; (iv) ensure that any agents or subcontractors to which it provides the information agree to the same restrictions and conditions; (v) make available the information as necessary for the Health Plan to respond to the exercise by an individual of his or her rights under the Rule with respect to that information and comply with certain of those rights if directed by the Health Plan; (vi) make its books or records available to the DHHS Secretary; (vii) authorize termination of the contract if the Health Plan believes the Business Associate has violated a material term; and (viii) upon termination of the contract, return or destroy all the information if feasible and, if not feasible, extend the protections of the contract to that information and limit uses and disclosures to those that made the return or destruction infeasible. *Id.* § 164.504(e).

n56 *See id.* §§ 164.502(b)-164.514(d). When entering into a Business Associate Agreement with a TPA, a sponsor is contracting on behalf of the Health Plan, which is the Covered Entity. An interesting dichotomy is raised by this requirement. This is true because a sponsor that receives protected health information for the performance of administration functions for the plan and has complied with the Sponsor Requirements also has the option of contracting on behalf of itself as a sponsor with a third party to perform those administration functions on behalf of the sponsor (who is performing them on behalf of the plan) rather than contracting directly on behalf of the plan. The interesting issues raised are that if a sponsor contracts on behalf of the plan, it may then limit its technical receipt of protected health information. The Business Associate obligations imposed on the TPA are onerous and numerous. On the other hand, if the sponsor takes on the responsibility of performing all administration functions for the plan and subcontracts those out to the TPA, technically the sponsor is in receipt of substantial protected health information. As such, the obligations the Rule requires the sponsor to put on the TPA are much more general and less onerous. As a result, the advisable route for sponsors is to contract with the TPA on behalf of the plan, although this distinction in practice is often missed.

n57 *See* Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. at 53,248. Some TPAs have attempted to negotiate rights that go beyond those provided by the Rule, such as obtaining representations and warranties of compliance by the Health Plan or obtaining the right to use protected health information for research. Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. at 53,248. Some even attempt to wholly circumvent the Business Associate obligations by requiring the Health Plan to assume the responsibility for compliance by the TPA of those obligations. Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. at 53,248.

The Privacy Rule requires that Health Plans impose Business Associate obligations on a TPA. Practically, it is also possible for a plan, through its sponsor, to contractually transfer the administrative burden for virtually all of the Health Plan Requirements to a willing TPA. In addition, if the TPA agrees to assume the sponsor's fiduciary responsibility under ERISA and serve as final claims adjudicator, the sponsor can decide not to receive any additional protected health information from or with respect to the plan. Thus, the sponsor avoids all the Sponsor Requirements. n58

n58 The risk for a sponsor associated with transferring fiduciary responsibility under a self-insured plan to a third-party contractor and not having access to any individual level claims data is that the sponsor is the party financially responsible for paying the claims, yet would have no role in determining which claims will be paid nor access to data relating to large dollar claims.

No employer, however, can escape the burden of carefully analyzing its benefit plans and programs. This burden includes identifying Health Plans, determining its compliance responsibilities, and developing and implementing a compliance program. In developing this compliance program, each employer and its counsel will be faced with the need to make interpretation decisions concerning the Rule's application to that employer's operations where the issues are not clearly defined under the Rule. The following section describes the Absurdity Avoidance approach as a framework for making those decisions.

III. Practical Jurisprudence and the Case for Avoiding Absurdity

The analysis proposed in this Article consists of four tests to apply serially when evaluating various statutory or regulatory interpretations for compliance purposes. The analysis provides a structured way for individuals and entities to make a compliance decision when faced with ambiguous, vague, or incomplete rules of law. Courts and enforcement authorities also may find the analysis useful in determining violations. If a person has documented a decision or drafted a compliance plan based on this analysis, and a court or other authority finds the application of the analysis to be rational and in apparent good faith, no liability should exist. This remains true if the court or enforcement authority disagrees with the actual result. This approach is consistent with the contemporary development of compliance and the enforcement standards that consider compliance plans, training, and review systems to be key factors in determining liability. n59

n59 *See, e.g.,* Sentencing Reform Act, 18 U.S.C. § 3551 (2004).

The Absurdity Avoidance approach is more practical and less lofty than other principles of statutory interpretation recently debated and discussed in the literature. Those theories are meant for legislators and judges who have the luxury

of authority and discretion when making their decisions. For businesses faced with current deadlines and little real guidance--yet very real penalties--a different, more pragmatic approach is needed and warranted.

A. The Absurdity Avoidance Approach

1. The Textual Test

Scholars have dueled about the significance of legislative history to statutory interpretation,ⁿ⁶⁰ but no author has argued with the primary importance of the text. No interpretation of a statutory or regulatory provision will or should survive scrutiny if that interpretation is not consistent with the text of that law. Despite one's motivation in molding a particular result, if that result is born of an interpretation contrary to the clear meaning of the rule of law at issue, the result is doomed. When making decisions about interpretations of law for compliance, careful thought and attention should be directed to the precise wording of that law. Under the Absurdity Avoidance approach, interpretations that are consistent with the text of the law survive the Textual Test and move on to be measured against the second prong--the Commentary Test.

ⁿ⁶⁰ Compare *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 388-91 (2000) (Scalia, A., concurring in the judgment) with Stephen Breyer, *On the Uses of Legislative History in Interpreting Statutes*, 65 S. CAL. L. REV. 845 (1992).

It may seem obvious that an issue would not reach the Commentary Test if it did not pass the Textual Test. In other words, an interpretation should be unclear only when more than one interpretation will fit the text of the Rule, and technically this is true. Sometimes, however, the tendency in making compliance interpretations is to read the Rule in the context of other considerations or one's own judgment. It is helpful to isolate the text and evaluate its application in a vacuum in order to identify the reasons and process for making any decision.

2. The Commentary Test

In a lawsuit, a party may legitimately take a position that is consistent with the text of a regulation and its enabling statute, but is contrary to the legislative history or an interpretation published by the promulgating body. When determining compliance policy, making a decision that is contrary to published commentary that was clearly meant to apply to the facts at hand entails too much risk and is unrealistic. Thus, the Commentary Test measures the consistency of any interpretation that survives the Textual Test against the legislative history, guidance, or interpretations issued by the executive or legislative body that promulgated the statute or regulation. This guidance serves as an expression of the intent of those who adopted or promulgated the law.

Violation of many rules and regulations carries civil and criminal penalties. Criminal penalties require intent, which can be inferred from a position contrary to that taken by published interpretations of the promulgating agency. It makes sense, therefore, to require in the case of textual vagueness or ambiguity that any resolution be consistent with interpretations published by the promulgating body. Indeed, even in cases in which the Textual Test produces what appears to be one clear result, failing to review the commentary can be risky. Thus, this second prong is a necessary step in all instances. If commentary exists relevant to the issue and if only one interpretation passes this second test, however, the inquiry can end at this point. The third and fourth prongs--the Purposes Analysis and the Absurdity Analysis--are more subjective tests that involve interpretation and balancing. They are appropriate only for cases in which multiple interpretations of the same law meet both the Textual Test and the Commentary Test.

3. The Purposes Analysis

If, after application of the Textual Test and the Commentary Test, multiple possible interpretations of the text continue to exist, each interpretation should be examined to determine to what extent it furthers the stated purposes of the relevant statute or regulation. The Purposes Analysis is the second, less direct and more subjective step toward attempting to determine the drafter's intent. If the intent is not spelled out in the commentary, perhaps it can be gleaned

from the stated purposes of the law as applied to the application being studied.

If one or more interpretations are substantially consistent with the furtherance of one or more of the primary purposes of the law, then these interpretations survive. Stated another way, any interpretation that does not serve those purposes or is contrary to the furtherance of one or more of those purposes is conditionally eliminated. The elimination is conditional because the Purposes Analysis and the Absurdity Analysis are by their nature subjective balancing tests and, in the end, must be considered in concert.

4. The Absurdity Analysis

If one or more interpretations meet the Purposes Analysis, the next and final prong requires that any result not be absurd. If more than one result is obtained and neither is absurd, the least absurd is chosen. If all results are absurd, then one must reconsider any result that failed to pass the Purposes Analysis. If one of the discarded interpretations leads to a significantly less absurd result than the interpretations that passed the Purposes Analysis, a more complex balancing of these two prongs is required and a leap of faith is necessary. Nonetheless, the process will narrow the instances in which this must occur and, thus, reduce the overall compliance risk.

One may ask why absurdity must enter the equation at all when the reliable and ubiquitous concept of reasonableness stands as ready soldier to the task. The answer lies in the reasonable nature of reasonableness itself. When one thoughtfully considers the issue, the absurd is simply the obviously, unmistakably unreasonable. It is so unreasonable that it is more likely than not to prompt the reaction, "that's absurd!" The measuring of one statutory interpretation against another, based on which is the more reasonable, carries with it the assumption that each is a reasonable result. If more than one interpretation is reasonable, it makes more sense to revert to the Purposes Analysis and evaluate the intent of the drafters rather than to substitute one's own values to determine the more reasonable result.

B. Integration with Enforcement Standards

Despite recent frenetic activity surrounding corporate governance issues, n61 the current federal organizational sentencing guidelines actually were established by the Sentencing Reform Act of 1991 n62 (Sentencing Guidelines). These guidelines offer a business the possibility of reduced fines or penalties for wrongdoing if it can demonstrate it has diligently designed and implemented an effective compliance program. The Sentencing Guidelines attempt to set the tone in corporate America for dealing with governance issues related to legal and ethical compliance. n63

n61 See, e.g., Sarbanes-Oxley Act of 2002, 15 U.S.C. § 7201 (2004); Press Release, U.S. Sec. and Exch. Comm'n, Summary of SEC Actions and SEC Related Provisions Pursuant to the Sarbanes-Oxley Act of 2002 (July 30, 2003), available at www.sec.gov/news/press/2003-89a.htm (last visited Apr. 5, 2004).

n62 See *supra* text accompanying note 58.

n63 See Kirk S.Jordan & Joseph E. Murphy, *Ethics and Compliance Programs: What the Government Really Wants*, Integrity Interactive, at www.integrity-interactive.com/compliance/mkt_expertise_pg6.htm (last visited Apr. 5, 2004) (a thoughtful discussion of the Sentencing Guidelines and a review of cases settled subsequent to adoption of those guidelines to show empirical evidence of specific measures governmental agencies expect in an organization's compliance program).

Unfortunately, there is no apparent guidance addressing how a business should implement compliance programs for laws that are vague or ambiguous when applied. n64 Counsel advising these businesses are without consistent direction not only on how to protect their clients but, in light of recent developments surrounding ethical rules for lawyers, how to protect themselves. On August 12, 2003, the American Bar Association adopted proposed revisions to the *Model Rules of Professional Conduct* that include obligations for a lawyer to report potential illegal activity to higher authorities within a client organization and potentially outside that organization. n65 Such an obligation may apply if the lawyer knows facts from which a reasonable lawyer under the same circumstances would conclude that an organizational

representative intends to violate a legal obligation to the organization or a law that could lead to substantial injury to the organization. n66

n64 Jordan & Murphy state that no reported cases exist interpreting what is meant by an "effective" program under the Sentencing Guidelines. *Id.* at 2.

n65 News Release, American Bar Association, ABA Adopts New Lawyer Ethics Rules, Urges Fairness in Military Commission Trials (Aug. 12, 2003), available at www.abanet.org/media/aug03/081203_1.html (last visited Apr. 5, 2004).

n66 *Id.*

The adoption of a rational and consistent framework such as the Absurdity Avoidance approach provides an objective, good-faith process to which businesses and their counsel can point as evidence of due diligence when designing and implementing compliance programs.

C. Other Approaches to Statutory Interpretation

Uniform principles or rules on statutory interpretation or, as suggested by Nicholas Rosenkranz in a recent article, n67 the adoption of a set of federal rules of statutory interpretation, n68 may provide much-needed guidance for Congress and the courts. These rules, however, are unlikely to be as helpful to businesses that are subject to compliance obligations imposed by statutes and regulations. Even if such rules were to prove helpful for compliance purposes, agreement on these principles or even agreement that uniform rules should be adopted is years away. Meanwhile, laws continue to be enacted and enforced and businesses and their counsel continue to face daily compliance decisions that cannot be postponed.

n67 Nicholas Quinn Rosenkranz, *Federal Rules of Statutory Interpretation*, 115 HARV. L. REV. 2085 (2002).

n68 *See generally id.* at 2086.

The current debate around statutory interpretation issues is lively and diverse, n69 but is largely directed at the courts and Congress. n70 In his article, Rosenkranz suggests that Congress adopt federal rules of statutory interpretation much akin to those that exist for civil procedure or evidence. He argues persuasively that, in most cases, Congress has the constitutional power to prescribe definitions, canons of interpretation, and the impact of legislative history on subsequent interpretations of its legislation. Furthermore, he suggests that this prescription is desirable given the lack of any "generally accepted and consistently applied theory of statutory interpretation." n71

n69 To a certain extent, Rosenkranz reports on the more germane and significant participants and theories of this debate in his article, from the new textualism championed by Justice Scalia and by Judge Easterbrook to the dynamic statutory interpretation theories of Professor William N. Eskridge. *Id.* The fabric of the discourse, however, is being woven even more richly than reported by Rosenkranz. *See* Harold P. Southerland, *Theory and Reality in Statutory Interpretation*, 15 ST. THOMAS L. REV. 1 (2002). Professor Southerland passionately and beautifully presents a humanistic philosophical critique of Justice Scalia's new textualism, which Southerland contends "ignores the inexactitude of language generally and American English in particular" as well as taking "no account of the failings and foibles of the human beings who people [the world.]" *Id.* at 12, 14. *See also* Joseph A. Grundfest & A. C. Pritchard, *Statutes With Multiple Personality Disorders: The Value of Ambiguity in Statutory Design and Interpretation*, 54 STAN. L. REV. 627 (2002). The latter article proffers the view that the adoption of any consistent rule of statutory interpretation is bound to fail because it would "seek to impose a degree of uniformity in interpretation that is inconsistent with the equilibrium relationship between the legislative and judicial branches." *Id.* at 636. Grundfest and Pritchard argue that legislators have a vested interest in ambiguity because it can credibly be argued to support opposing viewpoints and garner more widespread constituent support. They also argue that judges have a vested interest in ambiguity because it leaves them more room to exercise judicial discretion. *Id.* at 628-29. As if that argument alone is not enough, the authors perform a statistical analysis of

appellate opinions relating to a specific statutory standard to determine which interest wins out. They conclude that the congressional ability to obscure prevails over the judiciary's ability to interpret at the appellate level. *Id.* at 634, 671.

n70 Rosenkranz notes that his article, which proposes that Congress adopt federal rules, questioned the "central, unquestioned premise" in the field of statutory interpretation "that the judiciary is the proper branch to design and implement tools of statutory interpretation." *See* Rosenkranz, *supra* note 67, at 2086.

n71 *Id.*

In each instance, whether the solution proffered is directed at Congress or at the courts, the target audience has the discretion to make interpretative decisions. In drafting legislation, Congress on the front end has the discretion to define and interpret, n72 or require certain interpretations, as it sees fit, subject to constitutional limitations and few reprisals. n73 On the "back end," courts may use judicial discretion and the facts of the case at issue to interpret a statute or regulation for which more than one possible interpretation exists, and sometimes when it does not.

n72 *See* Grundfest & Pritchard, *supra* note 69, at 636-39 (arguing that Congress often favors ambiguity over clarity).

n73 *See* Rosenkranz, *supra* note 67 (Rosenkranz's treatment generally of the constitutional limitations on congressional authority to legislate interpretive rules and standards).

Those businesses that must comply with the adopted text of a statute or regulation are caught square in the middle, insofar as they are without either authority or discretion. If they guess wrong, civil and criminal penalties can apply. n74 Moreover, the negative effects on public relations that often follow prosecution or just an investigation are arguably worse than the statutory penalties.

n74 *See, e.g.*, 42 U.S.C. § 1320d (2004).

Existing rules and canons of interpretation that may offer tools for courts and legislators offer little to businesses interpreting statutes or regulations for compliance purposes. Compliance is a high-risk proposition and it is in a business' interest to document its interpretations in detail. The Absurdity Avoidance approach set forth in this Article is designed to provide guidance for these businesses and their counsel. It suggests a largely objective standard for statutory and regulatory interpretation for compliance purposes.

IV. Selected Privacy Rule Interpretation Issues

A. Other Health Plans

Employers sponsor certain Health Plans that do not fit neatly into the categories of self-insured or fully-insured, as those terms are used in the Rule. This causes conflicting interpretations of the application of the Privacy Rule in the industry. Two of the most common conflicting interpretations involve healthcare FSAs and certain EAPs. n75 In addition, DHHS guidance appears inconsistent with respect to the application of the "other health plans" Catchall Category to employer plans and programs. n76 It is unclear whether an employer plan or program that falls into the Catchall Category, but is not a Group Health Plan, is subject to the Rule.

n75 Most healthcare FSAs and EAPs qualify as small health plans under HIPAA and thus had until April 14, 2004, to comply with the Privacy Rule. 45 C.F.R. § 164.534(b)(2) (2004).

n76 *See infra* notes 93-96 and accompanying text (discussion of Catchall Category plans).

While DHHS issued subsequent guidance clarifying the Rule's application to the healthcare FSA, n77 no guidance has been issued with respect to EAPs, and the guidance with respect to FSAs, although instructive, remains incomplete.

n77 Dept. of Health and Human Servs., *Questions and Answers: Is a flexible spending account or a cafeteria plan a covered entity?* (April 24, 2003) (addressing whether a flexible spending account or a cafeteria plan is a Covered Entity), at tinyurl.com/2tbuh (last visited Apr. 25, 2004) [hereinafter *Questions and Answers*].

1. Insured vs. Self-Insured

The definition of insurance, when used to determine which entities will be subject to state regulation as insurance **companies**, is a complex analysis that is beyond the scope of this Article. The generally accepted, as opposed to technical, meaning in the employer health plan context relates to the use of the terms "insured" and "self-insured" as applied to Group Health Plans. Insured employer plans are those plans for which the risk of the ultimate cost of the benefit is borne and paid by a third party in exchange for a set premium. A self-insured plan is one for which the employer or other sponsor ultimately bears the risk for, and pays, the costs of providing the benefits. Self-insured employer plans may be administered through a TPA, which processes and pays the claims, but the TPA is reimbursed by the employer for the costs of those claims and is usually paid an administrative fee for the TPA services. Some Group Health Plans may be a combination of insured and self-insured.

The Privacy Rule uses the terms "insured" and "self-insured" in its definition of Group Health Plans to indicate that the Rule applies to both categories of employer health plans. n78 The Rule neither references nor admits to the existence of any Group Health Plans that are neither insured or self-insured. As discussed, the Rule has significantly reduced compliance requirements for employer plans for which benefits are fully-insured by an insurance issuer or HMO. Moreover, the Rule carefully defines both "insurance issuer" n79 and "HMO," n80 leaving no doubt that these terms refer to entities that are licensed by states as insurance **companies**, health maintenance organizations, or other similar entities that are regulated for solvency.

n78 See 45 C.F.R. § 160.103 (2004).

n79 The Rule provides as follows:

Health insurance issuer (as defined in section 2791(b)(2) of the PHS Act, 42 U.S.C. 300gg-91(b)(2) and used in the definition of health plan in this section) means an insurance **company**, insurance service, or insurance organization (including an HMO) that is licensed to engage in the business of insurance in a State and is subject to State law that regulates insurance. Such term does not include a group health plan.

Id. (emphasis added).

n80 The Rule provides as follows:

Health maintenance organization (HMO) (as defined in section 2791 (b)(3) of the PHS Act, 42 U.S.C. 300gg-91(b)(3) and used in the definition of health plan in this section) means a federally qualified HMO, an organization recognized as an HMO under State law, or a similar organization regulated for solvency under State law in the same manner and to the same extent as such an HMO.

Id. (emphasis added).

In the Rule's preamble, DHHS appears to use the term "insured" or "fully-insured" to refer to these plans for which the benefits are fully-insured by an insurance issuer or HMO. The reasoning provided for substantially exempting these plans from the Rule's requirements in cases in which the insurance issuer or HMO does not disclose any protected health information to the Group Health Plan or to the sponsor is that insurance issuers and HMOs themselves are covered entities under the Privacy Rule. Thus, they are already subject to the requirements of the Rule. n81 To the

extent that the only party that will use or disclose protected health information on behalf of the plan is already subject to the Rule, imposition of the Rule's requirements on the plan itself makes little sense. Moreover, for benefits provided fully by an insurance issuer or HMO, employees enroll directly with the insurance issuer or HMO, creating contractual privity and an obligation between those entities and the individuals whose information they handle.

n81 See Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,645 (Dec. 28, 2000) (to be codified at 45 C.F.R. pts. 160, 164).

It appears that DHHS fails to recognize, however, that there are employer health plans that do not fit neatly into either definition--fully-insured or self-insured--and are not "insured" at all. Specifically, certain plans, such as healthcare FSAs, certain EAPs, smoking cessation programs, and wellness programs, offer benefits for which the employer bears no financial risk and that are typically not fully-insured by an insurance issuer or HMO. Thus, the extent of the Rule's application to these plans is unclear.

2. Healthcare FSAs

A healthcare FSA is different from other Group Health Plans because it does not provide traditional insurance benefits. Employees designate an amount of money, up to an annual cap, to pay for healthcare that is not covered by other plans. This amount is deducted from that employee's salary, usually in equal installments throughout the year. The total amount, however, is available throughout the year for reimbursement to the employee for these noncovered healthcare expenses. The employee does not receive this FSA amount as income and does not pay income taxes on it. The amount set aside is available on a "use it or lose it" basis; any excess at the end of the year reverts to the employer. The employer pays the cost of administering this benefit and technically provides the funds for the medical care but has no additional out-of-pocket costs or other financial risk for the medical care.

A healthcare FSA qualifies as a Group Health Plan because it meets the definition of an employee welfare benefit plan under ERISA. n82 The healthcare FSA is often one benefit among others, such as a dependent-care FSA. In some cases, an employer "wrap-around" plan includes the FSAs and other benefit plans in one ERISA filing, and this filing may combine both Health Plans and Excepted Benefits. Whether and how the wrap-around plan structure affects Privacy Rule compliance is unsettled. n83 Whether structured as a separate Covered Entity or as the healthcare component of a hybrid entity, the FSA clearly is subject to the full spectrum of compliance requirements under the Privacy Rule. This is true unless the FSA meets the definition of providing or paying the cost of an Excepted Benefit.

n82 See 45 C.F.R. § 160.103 (2004). If an FSA did not meet the definition of an ERISA plan, employers would be faced with the question whether it was captured by the Catchall Category of "other health plans." See *infra* notes 93-96 and accompanying text.

n83 Some industry participants have interpreted a wrap-around plan as requiring a hybrid entity structure, but in reality the structure does not seem to make much difference in compliance, particularly with the definition of Health Plans having the same sponsor as an organized healthcare arrangement.

In addition, if a sponsor intends to receive any protected health information with respect to its healthcare FSA, n84 it will need to comply with and certify compliance with the Sponsor Requirements. Most plan sponsors currently receive protected health information with respect to their FSAs, if only in the form of debit reports. While these reports may contain only names and dollar amounts, they nevertheless meet the definition of protected health information because they identify the individual and relate to payment for the provision of healthcare. Any use or disclosure of protected health information by or on behalf of a covered entity implicates the Privacy Rule, and the reports fail to meet the definition of summary health information or enrollment or disenrollment information. Thus, a sponsor's receipt of these reports involves a disclosure of protected health information that will trigger the Sponsor Requirements.

n84 It is possible that a sponsor can avoid most of these compliance requirements by restructuring its arrangement with its TPA such that: (i) the TPA agrees to assume the Health Plan compliance responsibilities described in Part I.B on behalf of the FSA; and (ii) the TPA agrees to assume the ERISA fiduciary responsibility for final claims adjudication and the sponsor provides the TPA with the right to draw on accounts maintained by the sponsor for the purpose of claims payment. In this case, the TPA will manage the accounting for the funds in a way that protected health information is never disclosed to sponsor. The TPA simply reports in the aggregate to the sponsor the total amounts reimbursed to enrollees without allocating the total to the participating individuals. Transferring the accounting responsibilities to the TPA could involve some modest additional financial risk for the sponsor in that the sponsor would not be able to audit the TPA's claims payment or accounting.

While a healthcare FSA is not listed in the Privacy Rule as an Excepted Benefit, in a limited context it was found to qualify as an excepted benefit under the same overall section of the PHS Act that includes Excepted Benefits. The Internal Revenue Service, the Department of Labor (DOL), and DHHS issued a notice on December 29, 1997, stating that for purposes of applying the HIPAA rules with regard to pre-existing conditions under both the Internal Revenue Code and ERISA, excepted benefits included healthcare FSAs. n85

n85 *See Application of HIPAA Group Market Portability Rules to Health Flexible Spending Arrangements*, 62 Fed. Reg. 67,688 (Dec. 29, 1997) (to be codified at 29 C.F.R. pt. 2590, 45 C.F.R. subtit. A, pts. 144, 146; 26 C.F.R. pt. 54).

The unusual nature of the FSA benefit and the classification of the FSA as excepted from other portions of HIPAA led lawyers and their clients initially to believe that the FSA may qualify as an Excepted Benefit under the Privacy Rule. Most healthcare FSAs qualify as small health plans under the Rule, pushing their compliance date to April 14, 2004. Thus, taking a "wait-and-see" attitude with respect to these small plans posed little risk to employers. In sparsely worded guidance issued on April 24, 2003, DHHS confirmed that healthcare FSAs are subject to the Privacy Rule.

A "group health plan" is a covered entity under the Privacy Rule and the other HIPAA, Title II, Administrative Simplification standards. A "group health plan" is defined as an "employee welfare benefit plan," as that term is defined by the Employee Retirement Income Security Act (ERISA), to the extent that the plan provides medical care. . . . Thus, to the extent that a flexible spending account or a cafeteria plan meets the definition of an employee welfare benefit plan under ERISA and pays for medical care, it is a group health plan, unless it has fewer than 50 participants and is self-administered. Employee welfare benefit plans with fewer than 50 participants and that are self-administered are not group health plans. Flexible spending accounts and cafeteria plans are not excluded from the definition of "health plan" as excepted benefits. n86

n86 *Questions and Answers, supra* note 77 (citations omitted). Some discussion on industry listserves has tried to characterize the DHHS answer as not being definitive because it essentially states that an FSA is a Health Plan that is an ERISA plan and begs the questions whether an FSA is an ERISA plan. It is difficult to imagine, however, a convincing argument that an FSA is not an ERISA plan.

While the DHHS guidance provided little explanation, its conclusion is consistent with a more detailed analysis of whether the FSA is an Excepted Benefit.

The reasoning underlying the prior determination that FSAs were excepted benefits for purposes of defining pre-existing conditions does not easily extend to the Privacy Rule application. The December 29, 1997, notice determined that certain healthcare FSAs should be included in the excepted benefits identified under Section 2791(c) of the PHS Act. The Privacy Rule defines Excepted Benefits as only those listed under Section 2791(c)(1) of that act. In earlier guidance unrelated to the FSA issue, The Centers for Medicare & Medicaid Services (CMS) noted that the excepted benefits as defined in Section 2971(c)(2) of the act, such as limited scope dental or vision benefits, were not explicitly excepted from the Rule and could be considered Health Plans. CMS explained that "such plans, unlike the programs and plans listed at Section 2971(c)(1), directly and exclusively provide health insurance, even if limited in scope." n87

n87 See Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,577 (Dec. 28, 2000) (to be codified at 45 C.F.R. pts. 160, 164).

A healthcare FSA directly and exclusively pays for the cost of Medical Care. It does not, however, provide what is typically identified as health insurance, because no financial risk-bearing is involved. The implied principle that the benefit provided is primarily for Medical Care purposes is a generally consistent distinction between the health plans that are covered by the Rule and those that are Excepted Benefits. n88 Disability insurance, worker's compensation, and, to some extent, life insurance, are primarily to compensate a person for lost income or other expenses incurred because of death, injury, or disability. Their primary purpose is not to pay for Medical Care. Even though all or part of the money derived from those benefits may be used by beneficiaries for that purpose and, with respect to worker's compensation benefits, may be calculated partially on the basis of those expenses, the programs are not purposed on dollar-for-dollar reimbursement for those expenses.

n88 The one Excepted Benefit that is not consistent with this principle is the on-site medical clinic.

This reasoning is consistent with the Rule's application to Group Health Plans "to the extent that the plan provides Medical Care" through insurance, reimbursement, or otherwise. n89 The FSA is an ERISA plan. Thus, if it does not provide an Excepted Benefit, it is subject to the Rule to the extent it provides Medical Care through insurance, reimbursement, or otherwise. The healthcare FSA provides Medical Care through reimbursement, and this reimbursement for Medical Care is its primary purpose.

n89 See 45 C.F.R. 160.103 (2004).

What the DHHS guidance does not clarify, however, is how the healthcare FSA is regulated under the Rule. The FSA does not fit neatly into the category of either insured or self-insured plan as those terms are used in the Rule.

3. Employee Assistance Programs

Many employers offer their employees an EAP. Although some disagreement exists on whether and to what extent EAPs are Group Health Plans, the DOL has issued at least one opinion holding that an EAP which provided counseling qualifies as an ERISA plan. n90 The DOL concluded that an EAP under which coverage was provided for services addressing mental or physical health was an employee welfare benefit plan because the program provided "benefits in the event of sickness." The letter noted that ERISA Section 3(1) defines the term employee welfare benefit plan as:

any plan, fund or program . . . established or maintained by an employer . . . to the extent that such . . . was established or is maintained for the purpose of providing for its participants or their beneficiaries, through the purchase of insurance or otherwise, (A) medical, surgical, or hospital care or benefits, or benefits in the event of sickness, accident, disability, death or unemployment, or vacation benefits. n91

n90 Dep't of Labor Employee Benefits Security Admin. (formerly PWBA), Opinion Letter 88-04A (Mar. 11, 1988), available at 1988 WL 360954.

n91 *Id.*

While some EAPs are solely referral services, many provide several counseling sessions before referring an employee to a third-party provider. A distinction between EAPs that provide less than three or four counseling sessions and those that provide more than three or four sessions has been adopted by some benefits consultants and organizations as the benchmark for determining whether an EAP is a welfare benefit plan under ERISA. This distinction does not appear to be based on any official judicial or governmental opinion or pronouncement.

In many cases, the counseling and referral functions are provided by a third-party EAP services entity that is not a licensed insurance issuer or HMO. Such entities are not themselves subject to the Privacy Rule.ⁿ⁹² Moreover, the benefits commonly are provided on behalf of employers for a set per-member per-month charge. In other words, an employer pays the set fee each month for each employee, whether or not and to whatever extent the employee uses the benefit. This payment methodology transfers the risk of the ultimate cost of providing the benefit to the EAP services entity because the employer's costs are fixed, yet the extent of services that will be required to be provided each month is uncertain.

ⁿ⁹² Some entities have argued that an EAP provider may meet the Catchall Category definition as a plan or program that pays for the cost of Medical Care because the EAP provider bears some financial risk for providing the care and pays the counselors or care providers directly. This argument appears to be misguided because the Catchall Category is defined as an individual plan or program that provides or pays for certain benefits. An EAP provider has no contractual privity with the beneficiaries of its services, thus it is not an individual or group plan or program—it simply administers a plan or program provided by the employer, and that plan or program does have contractual privity with, and obligations to, the beneficiaries.

Some confusion exists concerning the application of the Privacy Rule to plans for which benefits are provided by an insurance issuer or HMO. This results from the Rule's use of the term "insured" and the reasonable interpretation that EAPs that function on the per-member per-month model are more akin to insured rather than self-insured plans. Some employers have concluded that the plans fit the definition of insured plans. As such, as long as the employer as sponsor receives no protected health information from the EAP services entity, the EAPs are exempt from the requirements of the Privacy Rule as if the benefits were provided by an insurance issuer or HMO.

Thus, at issue is whether an EAP is a Health Plan and whether it is subject to the full spectrum of compliance requirements imposed on self-insured plans.

4. Catchall Category Plans

Employers sponsor a variety of other plans or programs that provide or pay for the cost of Medical Care. These plans appear to be plans captured by the Catchall Category in the definition of Health Plans. Programs such as smoking cessation programs, wellness programs, health fairs, free flu vaccines, and the like (collectively, Other Programs) may or may not be Group Health Plans under ERISA. To the extent these Other Programs are ERISA plans, the issue becomes, as with FSAs or EAPs, whether they are to be regulated as an insured or self-insured plan under the Rule. None of these Other Programs fit well within the definition of either an insured or self-insured plan. To the extent any of these Other Programs are not ERISA plans, the question raised is whether they are subject to the Rule under the Catchall Category or not subject to the Rule at all.

While the definition of a Health Plan under the Rule and the definition of an ERISA plan are similar, they are not identical.ⁿ⁹³ The Rule provides no guidance as to whether a plan or program that is paid for by an organization for its employees and is not a Group Health Plan but meets the Catchall Category definition was intended to be captured by that definition.

ⁿ⁹³ Compare 45 C.F.R. § 160.103 with ERISA § 3(1), 29 U.S.C. § 1002(1) (2004).

In the preamble to the Rule and in response to a public comment asking whether employer discount programs,

membership incentive programs, and other "unfunded" employee benefits are Health Plans, DHHS replied that:

Only those special employee discounts or membership incentives that are "employee welfare benefit plans" . . . and provide "medical care" . . . are health plans for the purposes of this rule. Discount or membership incentive programs that are not group health plans are not covered by the rule. n94

n94 See Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,577 (Dec. 28, 2000) (to be codified at 45 C.F.R. pts. 160, 164).

This comment admittedly supports the proposition that only employee benefits that qualify as ERISA plans are Health Plans. That support is weakened, however, by the nature of the discount programs and membership incentives that are the subject of the comment, the absence of a reference to the Catchall Category in the reply, and the broad language elsewhere with respect to the Catchall Category.

Discount programs, membership incentive programs, and other "unfunded" benefits for which no cost is incurred by the employer, and that usually are offered to organizations by vendors as a marketing effort, do not meet the definition of Health Plan for other reasons. Specifically, those programs do not involve the employer providing or paying the cost of Medical Care. Rather, they simply involve the employer giving access to vendors who have agreed to offer employees a discount or incentive. Thus, these programs are not akin to the Other Programs at issue in this discussion.

A public comment urged the DHHS Secretary to clarify that the Catchall Category includes "24-hour coverage plans" that integrate traditional employee health benefits with workers compensation coverage. In response to this comment, DHHS clarified "that to the extent that the 24-hour coverage plans have a health care component that meets the definition of 'health plan' in the final rule, such component must abide by the provisions of the final rule." n95 This response is ambiguous because even though the question references the Catchall Category, the response does not because the healthcare portion of a 24-hour coverage plan is an ERISA plan that otherwise meets the definition of a Health Plan.

n95 *Id.* at 82,576.

Finally, in the preamble, DHHS responded to public comments asking the DHHS Secretary to clarify the Catchall Category and to specify which plans would meet the criteria for this category:

This statutory language is general, not specific, and as such, we are leaving it general in the final rule. However, as described above, we add explicit language which excludes certain "excepted benefits" from the definition of "health plan" in an effort to clarify which plans are not health plans for the purposes of this rule. Therefore, to the extent that a certain benefits plan or program otherwise meets the definition of "health plan" and is not explicitly excepted, that program or plan is considered a "health plan" under . . . the final rule. n96

n96 *Id.* at 82,578.

This comment implies that benefit plans other than Group Health Plans are Health Plans if they are not Excepted Benefits and they satisfy the Catchall Category definition.

B. Enrollee Authorizations

The Privacy Rule provides that a covered entity may use or disclose protected health information pursuant to and in compliance with an authorization signed by the individual to whom the protected health information relates or the individual's personal representative. n97 Authorizations under the Rule are valid if they meet a set of requirements that includes a prohibition on a covered entity conditioning the provision of treatment, payment, enrollment, or eligibility for benefits on the provision of an authorization. n98 Other than this prohibition and specific content requirements, the Rule imposes no specific limits on the use of authorizations. n99

n97 45 C.F.R. § 164.502(a)(1)(iv) (2004).

n98 *See generally id.* § 164.508 (general requirements for, and core elements of, a valid authorization under the Rule). The instances in which a Covered Entity is allowed to condition the provision of services or benefits on the provision of an authorization include cases in which the treatment or benefit is for the sole purpose of creating protected health information for disclosure to a third party, such as pre-employment physicals and employer drug testing. *Id.* § 164.508(b)(4)(iii). The other two exceptions to this general prohibition relate to research-related treatment and health plan initial enrollment and eligibility determinations. *Id.* § 164.508(b)(4)(i)-(ii).

n99 *See generally id.* § 164.508(b)(4).

For self-insured Group Health Plans, often the only protected health information an employer or sponsor receives is the information necessary to hear final appeals on denials of claims. This final appeals adjudication is the sponsor's role as the ERISA plan fiduciary. A sponsor may contractually transfer this fiduciary responsibility to the plan TPA, but many TPAs will not agree to assume the duty and associated liability. Moreover, because the sponsor of a self-insured plan is the party that ultimately will pay the costs of all approved claims, many sponsors are reluctant to transfer this adjudication authority to a third party that has no financial stake in the decision.

Claims are rarely appealed to the fiduciary. To avoid the Sponsor Requirements imposed by the Privacy Rule, some sponsors have adopted the use of enrollee authorizations as a way to gain access to the necessary protected health information on an ad hoc basis for final appeals. n100 These sponsors avoid receiving protected health information for any other purpose and represent to plan enrollees that they do not use or disclose protected health information without individual authorization. n101 If or when an enrollee appeals a claim denial to the plan fiduciary, the sponsor requires the enrollee to sign an authorization allowing disclosure to the sponsor of the protected health information necessary for the sponsor to decide the appeal.

n100 For a list of these requirements, *see supra* text accompanying notes 38-46.

n101 A Health Plan is required under the Rule to disclose in its notice of privacy practices provided to enrollees. *See* 45 C.F.R. §§ 164.502(b)-164.514(d), 164.520(b)(1)(iii)(C) (2004).

Some sponsors have adopted a policy of obtaining employee authorizations for the use of Group Health Plan data for the administration of other benefit plans, such as disability plans. This is a use that otherwise is prohibited by the Privacy Rule. n102 Generally, an employer must obtain protected health information directly from the affected employee or his physician for purposes of disability benefit plans, which themselves are not covered entities under the Rule. When the information is disclosed by the physician, an authorization under the Privacy Rule is required for the physician to be able to disclose the information. This authorization may be required by the sponsor as a condition to access disability benefits. This falls under the specific exception in the Rule for cases in which the treatment or benefit is for the sole purpose of creating protected health information for disclosure to a third party, such as pre-employment and disability physicals.

n102 *Id.* § 164.504(f)(2)(ii)(C).

While not obvious, a distinction can be made between: (1) requiring an employee to sign an authorization that allows an employer to use the employee's protected health information from a disability physical for purposes of a disability benefit determination; and (2) requiring an employee to sign an authorization that allows the disability plan, for purposes of that disability benefit determination, to access all the employee's protected health information maintained by the employer's Health Plan. In the second case, the authorization would allow access to a much broader category of information. This information may be related to prior or separate treatment by other providers and may be used by the employer to contradict or interpret the information provided by the physician who is selected by the employee or employer for the disability determination. In addition, the authorization in the second case does not appear to meet the specific exception in the Rule for cases in which the treatment or benefit being conditioned is for the sole purpose of creating the protected health information for disclosure to the third party. In the case of the broader Health Plan authorization, the provided treatment was almost certainly for a purpose other than disclosure to a third party for the disability determination.

At issue is the prohibition on conditioning payment or eligibility for benefits on the provision of an authorization, and whether this prohibition prevents the use of authorizations in the two types of situations discussed below.

V. Analysis and Conclusions

A. Other Health Plans

This section applies the Absurdity Avoidance analysis to two issues left unclear in the Privacy Rule with respect to the FSA and EAP plans. These analyses illustrate the importance, in the context of compliance, of following the prongs of the approach in order. The first analysis is whether the EAP is a Health Plan under the Privacy Rule. The second analysis is whether the FSA and/or EAP should be treated by employers as self-insured or fully-insured plans. The analysis also addresses whether the Catchall Category applies to all employer programs or only those employer programs that are Group Health Plans.

The results of these analyses also apply to the Other Programs that provide or pay the cost of Medical Care but do not fit neatly into the insured or self-insured category.

1. Whether an EAP is a Health Plan

The Textual Test indicates that an EAP which provides counseling is a Health Plan because it is an ERISA plan that provides Medical Care. n103 This conclusion is supported by a DOL opinion rather than judicial ruling and possibly could be subject to legal challenge. The conclusion, however, is consistent with the definition of an ERISA plan and appears to be accurate. An EAP that does not provide counseling but simply consists of a referral hotline has been found not to be an ERISA plan. Thus, such an EAP is not a Health Plan unless it meets another part of the Health Plan definition.

n103 *See* 42 U.S.C. § 300gg-91(a)(2) (2004).

As noted, the only other aspect of the definition that could be applicable is the Catchall Category of "other plan or program" that provides or pays the cost of Medical Care. Medical Care is broadly defined. From a purely textual perspective, it is not certain that a hotline, through which someone listens to a caller's problems and recommends a resource, could never be found to be a service that mitigates or prevents disease or effects any structure or function of the body. n104

n104 *See id.* § 300gg-91(a)(2).

The Commentary Test reveals no specific government guidance on the EAP, but related guidance is relevant. The OCR guidance that provided FSAs are Health Plans because they are ERISA plans, n105 and the absence of any relevant contrary guidance, supports the result of the Textual Test that the EAP providing counseling is indeed a Health Plan. No reasonable argument to the contrary appears to exist. Thus, the application of the first two tests produces a result sufficiently clear to end the inquiry.

n105 *See Questions and Answers, supra* note 77.

As discussed, contradictory DHHS guidance exists that categorizes an EAP hotline, which is not an ERISA plan, as a Health Plan. DHHS categorized EAP hotlines in this way because they fit the Catchall Category. An EAP hotline is a service for which an employer pays. As such, it does not fall into the category of examples listed in the DHHS guidance that excepts discount programs and the like. n106 Its status as a non-ERISA plan that makes the commentary potentially applicable is, however, contradicted by the commentary with respect to the Catchall Category. While it may not be unreasonable to determine the EAP hotline is not a Health Plan, based on the tenuous application of the Catchall Category, an argument still exists that it could be a Health Plan. When any arguable doubt exists, proceeding with the remaining two tests is indicated, particularly given that the application of those tests does not require much in the way of time or resources.

n106 Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,577 (Dec. 28, 2000) (to be codified at 45 C.F.R. pts. 160, 164).

The Purposes Analysis first requires the identification of the purpose or purposes of the statute or regulation at issue. The Privacy Rule implements portions of the administrative simplification provisions of HIPAA that relate to a person's individually identifiable health information. n107 Section 264 of HIPAA provides that the Secretary of DHHS shall recommend standards with respect to the privacy of individually identifiable health information that would address at least the following: the rights that an individual should have with respect to his or her individually identifiable health information; the procedures that should be established to exercise those rights; and the uses and disclosures of that information that should be authorized or required.

n107 Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 53,182, 53,182 (Aug. 14, 2002) (to be codified at 45 C.F.R. pts. 160, 164).

The administrative simplification provisions of HIPAA were enacted to improve the efficiency and effectiveness of the healthcare system by encouraging the development of a health information system. n108 DHHS established standards and requirements for the electronic transmission of certain health information to facilitate such a system. n109 It identified three major purposes for the Privacy Rule: (1) to protect and enhance consumer rights to access and control appropriate use of their health information; (2) to restore trust in the healthcare system; and (3) to improve the efficiency and effectiveness of that system through the establishment of a national framework for health privacy protection. n110 The DHHS Secretary also noted that the Rule "seeks to balance the needs of the individual with the needs of society." n111 The DHHS Secretary explained in detail the "legitimacy of various uses and disclosure of health information," n112 the necessary "balance between the burden on covered entities and need to protect privacy," n113 and the need to achieve that balance "in a way that is also workable for the varied stakeholders" n114 and "track[s] current practices." n115 The purposes of the Privacy Rule involve a balancing of the competing interests of individual

privacy and societal needs. As such, the Purposes Analysis is less determinative of the overall outcome of the Absurdity Avoidance framework but, nonetheless, is still significant.

n108 *Id.* at 53,182.

n109 *Id.*

n110 Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82, 463.

n111 *Id.* at 82,464.

n112 *Id.* at 82,471.

n113 *Id.*

n114 *Id.* at 82,472.

n115 *Id.*

If an EAP hotline were found to be a Health Plan, the protected health information that would be subject to the Rule's protections would be the name of the callers, any details concerning the problems for which the call was made, and any referrals to a third-party resource provided by the hotline. If the hotline were not a Health Plan, in the absence of applicable state law, this information would not be subject to any consistent protection or restrictions on use and disclosure. **Protecting** that information at first blush seems consistent with the purpose of **protecting** individual privacy. Most EAP hotlines, however, currently cost employers little and operate in a way that employers are never provided the identity of callers. In fact, many times the caller's identity is not requested by or required to be disclosed to the hotline. Ironically, imposition of the Rule's compliance requirements would increase the likelihood of disclosure of the information to employers if employers were responsible for hotlines' compliance with the Rule.

Trying to determine which entity would be responsible for the program's compliance provides the line of analysis that, under the Absurdity Analysis, finally clarifies the result produced by the application of the four tests. These EAP hotlines do not meet the definition of a Group Health Plan under ERISA. Thus, if they are Health Plans, it is unclear who is responsible for the programs' compliance with the Rule or the role of the employer. The employer would not be a sponsor because that role is defined in the Rule solely in terms of the ERISA plan definition. n116 The employer is paying for the program, but the program is administered by a third party. The program itself is not a separate legal entity, as is the case with an ERISA plan. Thus, it is unclear what entity is the "Covered Entity."

n116 *See* 45 C.F.R. § 164.103 (2004) (defining "plan sponsor").

If the program is a Health Plan, some legal entity must be a Covered Entity or a hybrid entity. It makes no sense to designate the hotline provider as the Covered Entity because the hotline provider is not providing or paying for the cost of the benefit and, thus, by definition does not meet the definition of a Health Plan unless one argues that bearing the risk under a per-member, per-month payment scheme qualifies. In any event, that argument fails because the hotline provider, like other EAP service providers, is not an individual or group plan or program because it has no contractual privity with or obligation to any individual or group. Its contractual privity is with the employer or the employer's plan. The beneficiaries of its services derive the benefit from the employer plan, and the obligation to provide the benefit to

the beneficiary rests with the employer plan. Thus, the hotline provider is a service provider to the covered entity plan and not a Health Plan in its own right. If the employer is the Covered Entity, then by definition any employer offering an EAP hotline automatically becomes a Covered Entity subject to the Privacy Rule, another absurd result.

Finally, the interpretation that the EAP hotline is not a Health Plan, and that any other employer program that does not meet the definition of a Group Health Plan under ERISA is not a Health Plan, is not an absurd result. These programs are small benefits that do not cost an employer great sums, participation by employees is voluntary, and burdening the programs with substantial compliance requirements is likely to discourage their availability. The inconsistency in **protecting** an employee's health information with respect to Group Health Plans and not with respect to these benefits that are not Group Health Plan benefits is not an inconsistency in the context of the Rule. The Rule excepts from its reach many programs, such as disability plans and pre-employment physicals, through which an employer collects employee health information.

In summary, with respect to EAPs that provide counseling and are Group Health Plans, the Textual Test provides a clear result that those plans are subject to the Rule. This result is supported by the Commentary Test. With the EAP hotlines, the Textual Test provides no guidance on the issue and the Commentary Test offers conflicting support as to whether employer programs that are not Group Health Plans can be subject to the Rule under the Catchall Category. One could argue both ways as well with the Purposes Analysis. When the application of each interpretation undergoes the Absurdity Analysis, however, the interpretation that these programs are subject to the Rule as covered entities produces an absurd result. The exception of these programs from regulation under the Rule produces a result that is not absurd. Thus, for compliance purposes, it seems reasonable for businesses and their counsel to determine that these programs that are not Group Health Plans are not Health Plans subject to the Rule.

2. Regulation of FSAs and EAPs

The next step is to apply the Absurdity Analysis to the issue of whether the FSA and EAP, and other non-traditional Group Health Plans, are subject to regulation by the Rule as insured or self-insured plans. Under the Textual Test, if the employer contracts with an insurance issuer or HMO to fully insure the plan benefits, then the plans meet the definition, and the insured exemption may be applied. While it is not the norm, it is possible to contract with an insurance issuer or HMO to fully insure an EAP program. This is anathema to an FSA, however, because the benefits are never insured, but rather are paid for by the money set aside from the employee's defined salary. Thus, only a small subset of these two types of plans meet the textual definition of insured.

Applying the Textual Test with respect to the self-insured category is more complex because the Rule does not provide a specific definition for this term or category of plans. The Rule's use of the term "self-insured" fails to shed any light on the issue, but is not inconsistent with the inclusion of the FSA or the EAP in the case in which the benefit is not insured by an insurance issuer or HMO. Thus, for this category of plans, the Textual Test provides no direction.

For the small subset of EAPs for which the benefit is fully-insured by an insurance issuer or HMO and for which the Textual Test provides a clear result, application of the Commentary Test supports that resultⁿ¹¹⁷ and concludes the analysis. For the remainder of EAPs and all FSAs, the Commentary Test provides no additional information. As such, the Textual Test and Commentary Test each support the conclusion that these EAPs and FSAs do not meet the definition of insured plans under the Rule and that determination may be made with confidence. These first two tests are not inconsistent with the determination that these plans are self-insured, but they provide no real support for that conclusion other than it appears to be the only choice remaining.

ⁿ¹¹⁷ See generally *id.* § 164.508

While the inquiry could stop at this point, the absence of another good option is more of a subjective determination than an objective application of the Textual and Commentary Tests. As such, it is more appropriate for the second set of

tests. Also, the Rule may simply not have contemplated these unique plans and, thus, failed to provide an appropriate regulatory structure for them. It is not unreasonable, therefore, to continue with the analysis. The Purposes Analysis provides minimal additional assistance. It is consistent with the purposes of the Rule for these plans to be Health Plans and placed into a category of Health Plans for which regulatory requirements are provided. Consequently, a conclusion that these EAPs and FSAs are to be regulated as self-insured plans is consistent with the Rule's purposes. Alternatively, to conclude that the plans were neglected by the drafters of the Rule and pose an issue that requires promulgation of additional regulations is hardly inconsistent with the Rule's purposes. Those purposes, however, may be frustrated during the waiting period for further regulation or guidance.

The Absurdity Analysis in this case produces a result less than satisfying, but the result is practical. If the EAPs that are not insured by an insurance issuer or HMO and the FSAs are regulated as self-insured plans, then they are subject to the full panoply of Health Plan Requirements. If the sponsor receives any protected health information in administering these plans, which is usual for FSAs, then those sponsors are subject to the Sponsor Requirements as well. This is not an absurd result judged under the proposed standard--notwithstanding the fact that the cost of compliance may far outweigh the cost of providing the underlying benefit.

Further, the exception of these EAPs and FSAs from any regulation under the Privacy Rule produces a result that makes little sense and could be termed absurd. Employers may not receive much health information in the provision of the FSA or EAP because in most cases claims are administered by a TPA and claims level detail is not provided to the employer. The health information received and used by the TPA, however, is similar to that received and used by other Group Health Plans. Such information concerns Medical Care that typically is prescribed by a physician and not voluntarily accessed in the same sense that participating in a free flu-vaccine program is voluntary. If the TPA is not an insurance issuer or HMO, the Rule would not apply to its activities if not through its application to the FSA or EAP as a self-insured plan. If these FSAs or EAPs are not subject to the Privacy Rule, the information will receive protection when the claims are submitted for reimbursement by traditional insurance and not receive protection for purposes of FSA reimbursement. This is a difference with no apparent justification. Thus, these plans should be regulated as self-insured plans.

The result may not be completely satisfying because it does not take into account what could truly be the case--that the Rule's drafters neglected to consider these unique plans and their differences from typical Group Health Plans and that special rules would have been developed to deal with those differences. While this reasoning is attractive, it borders on the absurd to expect a business to decide not to comply with the Rule with respect to its FSA or EAP for that reason.

In summary, with respect to EAPs that are fully insured by an insurance issuer or HMO, the Textual Test produces a clear result supported by the Commentary Test, which settles the issue. With respect to other FSAs and EAPs, and other nontraditional programs that are Group Health Plans and are regulated under the Rule, neither the Textual Test nor the Commentary Test provides any direction. The Purposes Analysis produces an inconclusive result. The Absurdity Analysis, however, highlights and supports the judgment issues apparent from the beginning: (1) it makes no sense for these plans not to be regulated because they clearly are Group Health Plans subject to the Rule; (2) they are clearly not fully-insured by an insurance issuer or HMO; and (3) to regulate them as self-insured plans, though perhaps burdensome, is not an absurd result.

B. Enrollee Authorizations

Two issues concerning whether an employer may utilize enrollee authorizations remain unclear under the Privacy Rule. First, it is unclear whether enrollee authorizations may be used rather than implementing the full panoply of Sponsor Requirements for gaining access to protected health information in the rare cases of final appeals of denials of benefits. Second, it is unclear whether their use is proper when using Health Plan data in administering other benefit plans, such as disability plans.

The Textual Test indicates the Rule provides that a covered entity may use and disclose protected health

information with an authorization that provides for that use or disclosure. The only limitation is that a covered entity may not require an authorization as a condition to receiving treatment, payment, enrollment, or eligibility for benefits. n118 The Rule seems clear that access to the final appeal of an enrollee denial of benefits and, as a consequence, the benefits, may not be conditioned on the requirement that the enrollee sign an authorization. Instead, the sponsor must implement the Sponsor Requirements for access by the sponsor to protected health information. Similar reasoning does not apply to an employer requiring an employee to sign an authorization for access to Health Plan data as a condition of receiving a disability benefit. This is true because the employer is not a Covered Entity and is not acting on behalf of a Covered Entity when acting on behalf of the disability plan.

n118 *See generally id.*

The disclosure of Health Plan data for use by the sponsor in administering other benefit plans that are not covered entities, such as disability plans, implicates another provision of the Rule. A sponsor that receives protected health information from a Group Health Plan for administration of that plan is prohibited from using that protected health information for any other plan or benefit. n119 Thus, the issue is whether a sponsor can circumvent this prohibition by obtaining specific authorization from the enrollee to allow the use or disclosure. The text of the Rule supports an employer's ability to do just that. Authorizations are for the purpose of authorizing otherwise prohibited uses and disclosures. n120

n119 *Id.* § 164.504(f)(2)(ii)(C).

n120 "Except as otherwise permitted or required . . . a covered entity may not use or disclose protected health information without an authorization that is valid under this section." *Id.* § 164.508(a)(1).

While other laws may apply in the context of use of health information in determining disability, the Textual Test supports an employer's ability under the Privacy Rule to require and use an authorization in this circumstance. Moreover, the text also supports the ability of an employer to request a voluntary authorization for these purposes, which may blunt any criticism or other legal issues associated with an absolute requirement.

While not determinative, DHHS guidance is not inconsistent with the results obtained under the Textual Test for these issues. Policy reasons may exist, however, that support contrary results. One may argue that employees sign whatever employers provide to them to sign. Thus, the unequal bargaining positions create an unfair result. Employees may not realize the impact of authorizing the use of their Health Plan data for other benefit program purposes.

In addition, a persuasive argument exists that employers, as fiduciaries to all ERISA plans, may not decide when they are acting on behalf of one plan that is not a Covered Entity versus a plan that is a Covered Entity. This argument, however, is neither based on nor supported by the Privacy Rule, which clearly provides for a sponsor to wear two hats--sponsor and employer. It also clearly provides that an employer acting as an employer may use authorizations to obtain protected health information. For instance, an employer may assist an employee in investigating a claim submitted to a fully-insured plan from which the sponsor otherwise receives no protected health information. Other laws may affect the outcome in any given case. The textual and commentary support for these issues is not ambiguous with respect to the Privacy Rule's impact. The inquiry under the Rule ends at this point.

In summary, the Textual Test and Commentary Test are clear and consistent in producing a result that an employer may use an employee authorization to access protected health information about that employee for use in making a determination with respect to another plan or benefit.

VI. Conclusion

The absence of a rational framework for making statutory and regulatory interpretation decisions for compliance purposes leads to inconsistent interpretations that are difficult to support when questioned by government authorities or the courts. This is especially true in light of the contrary clarity that hindsight often produces. The application of the Privacy Rule to employer Health Plans provides a good example of the myriad of compliance decisions that must be made by businesses and their counsel in the face of unclear statutory or regulatory guidance.

The Absurdity Avoidance framework proffered in this Article provides a rational, practical framework to use with respect to the Privacy Rule and other statutes and regulations for which compliance interpretations are required. The application of the framework can be documented and provides a solid basis to support decisions made in good faith in the context of the time and circumstances in which they were made.

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LENGTH: 23705 words**TITLE:** Articles: Consumer Voice and Representation in Managed Healthcare**AUTHOR:** Marc A. Rodwin *

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TEXT:

ABSTRACT: The author examines the potential role for the public and, more specifically, for plan participants, in making managed care organizations ("MCOs") respond to their wishes by means other than market exit. "Market exit," or simply choosing an alternative means of procuring healthcare, is not an option for most plan participants--and even when available, sends a message that is muted at best. Moreover, the author reasons that MCOs are imbued with a variety of quasigovernmental qualities; thus, it is appropriate that they should be more responsive to the requirements of their customers than, say, a retailer. Professor Rodwin describes and analyzes various ways that public policy and law could enhance the ability of consumers to help shape the policies of MCOs and discusses the pros and cons of differing means by which Consumer Voice can be represented.

Preface: The Concept of Consumer Exit, Voice, and Representation

This Article examines the potential role for the public in making managed care organizations ("MCOs") respond to their wishes--by means other than choosing to enroll in one MCO rather than another, i.e., market exit. It describes various ways consumers can become involved in shaping the policies of MCOs and differing ideas about how the public's views can be represented. I begin with a brief definition of key terms.

Market proponents believe that the best way to control healthcare spending and increase the availability and quality of services is to give consumers a choice among competing MCOs. For them, the engines driving change are financial incentives for individuals to shop for the health plan that offers the best value. If the performance of an organization declines, its customers or members will become dissatisfied, and their defections will signal the firm to clean up its act. In short, consumers can express their dissatisfaction by *exiting*, purchasing their services elsewhere.

For Albert Hirschman, author of the classic, *Exit, Voice, and Loyalty: Responses to Decline in Firms, Organizations and States*, there are two choices: not just *exit* but *voice*--complaints, grievance, protests, and political pressures. n1 Consumers may express their voice horizontally, among themselves and potential consumers, or vertically, to authorities. They may express themselves individually or collectively. Voice takes many forms. Individuals can state their views when asked, complain, file grievances, protest, bargain collectively, participate in organizational governance, appeal to higher authority, or become active in politics. They may express their concerns to physicians, managers, policymakers, or influential outsiders--such as the press or activists--who may take up their cause. Voice can be exercised episodically as special circumstances arise, or continuously through established

consultative mechanisms. Sometimes exit and voice reinforce each other, while at other times they may be at cross-purposes. Each has strengths and limitations. Exit, for example, sends a powerful signal that something is wrong, but reveals little or none of the information that voice can provide about the problem or possible remedies. n2

n1 ALBERT O. HIRSCHMAN, EXIT, VOICE AND LOYALTY: RESPONSES TO DECLINE IN FIRMS, ORGANIZATIONS, AND STATES (ed., Harvard University Press 1970). See Albert O. Hirschman, *Some Uses of the Exit-Voice Approach*, 66 AM. ECON. REV. 386 (1976); Albert O. Hirschman, *Exit, Voice, and Loyalty: Further Reflections and a Survey of Recent Contributions*, 13 SOC. SCI. INFO. 7 (1980), reprinted in 58 MILBANK MEMORIAL FUND Q./HEALTH AND SOC'Y 431 (1980); Albert O. Hirschman, *Exit and Voice: An Expanding Sphere of Influence*, in RIVAL VIEWS OF MARKET SOCIETY AND OTHER RECENT ESSAYS (Viking 1980); see also A. H. Birch, *Economic Models in Political Science: The Case of 'Exit, Voice, and Loyalty'*, 5 BRIT. J. POL. SCI. 69 (1975); Brian Barry, *Review Article: "Exit, Voice, and Loyalty"*, 4 BRIT. J. POL. SCI. 79 (1974).

n2 Carl M. Stevens, *Voice in Medical-Care Markets: Consumer Participation*, 13 SOC. SCI. INFO. 33, 33 (1974). For discussion of Hirschman's ideas in healthcare outside of managed care, see Rudolf Klein, *Models of Man and Models of Policy: Reflections on Exit, Voice, and Loyalty Ten Years Later*, MILBANK MEMORIAL FUND Q./HEALTH AND SOC'Y 416 (1980); Paul Starr, *Changing the Balance of Power in American Medicine*, 58 MILBANK MEMORIAL FUND Q./HEALTH AND SOC'Y 166 (1980); Severino Sterpi, *"Exit" and "Voice" in the Italian National Health Service*, 33 CAHIERS DE SOCIOLOGIE ET DE DEMOGRAPHIE MEDICALES 169-82 (1993).

Individuals can express their voice by participating in decisionmaking. At its fullest, participation can mean consumer or citizen control. n3 It may also be something less, such as delegated power in a specified area or a partnership between producers and consumers. Participation can also be merely a device for informing those who make decisions, a form of consultation. Organizations can also use token participation as a means of co-optation or manipulation.

n3 Sherry Arnstein, *A Ladder of Citizen Participation*, 35 J. AM. INST. PLANNERS 216, 216 (1969); see EUGENE FEINGOLD, *CITIZEN PARTICIPATION: A REVIEW OF THE ISSUES, THE CITIZENRY AND THE HOSPITAL* 12 (Duke University 1974); Cathy Charles & Suzanne DeMaio, *Lay Participation in Health Care Decision Making: A Conceptual Framework*, 18 J. HEALTH POL. POL'Y & L. 881, 893 (1993).

Most individuals do not have the time to participate in decisionmaking or to express their voice on every issue that arises. However, their views or interests can be *represented* by an intermediary that speaks or acts for the groups they represent. n4 How the views of the consuming public are best represented is a major challenge in making voice effective.

n4 HANNA FENICHEL PITKIN, *THE CONCEPT OF REPRESENTATION* 2 (University of California Press 1967).

One can distinguish three different kinds of representation: (1) *Formal Representation*, the institutional mechanisms by which representatives are selected and controlled; n5 (2) *Substantive Representation*, the process of acting in the interests of constituencies; and (3) *Descriptive Representation*, choosing representatives to mirror the represented group's ethnic or social makeup or other characteristics.

n5 See 2 JAMES A. MORONE, *IOM, MODELS OF REPRESENTATION: CONSUMERS AND THE HSAs. HEALTH PLANNING IN THE UNITED STATES: SELECTED POLICY ISSUES* 237 (National Academy Press 1981); Paul E. Peterson, *Forms of Representation: Participation of the Poor in the Community Action Program*, 64 AM. POL. SCI. REV. 491, 491 (1970).

Consumer representatives can play various roles. These range from directing or controlling policy, exercising delegated power for defined tasks, being a partner with producers, providing advice, or participating without power as a token or symbolic gesture. n6

n6 See *supra* note 3.

I. The Interplay of Consumer Voice and Exit in Managed Care

A. How Consumer Voice Became an Issue

Once called "an alternative delivery system" and considered a means of reform, managed care has now become the predominant vehicle through which the public receives healthcare services. Yet the public now views MCOs as a source of problems to be addressed, and the issues surrounding MCOs figure prominently on the national political agenda. In the last five years, there have been successive waves of state and federal legislation and regulation of managed care that aim to protect the public and bolster the authority of doctors and other providers in relation to MCOs. n7

n7 Marc A. Rodwin, *Consumer Protection and Managed Care: Issues, Reform Proposals, and Trade-Offs*, 32 HOUS. L. REV. 1319-81 (1996).

Take, for example, recent legislation for a "bill of rights" for managed care consumers. n8 These include several items: the right to appeal decisions not to provide services, the ability to sue MCOs for medical malpractice, easy access to specialists, coverage for emergency care, an accessible network of providers, access to out-of-network providers, and prohibitions on MCOs restricting communication between doctor and patient.

n8 Bipartisan Consensus Managed Care Improvement Act Of 1999, H.R. 2723, 106th Congress (1999); Patients' Bill Of Rights Act Of 1999, S. 1344, 106th Congress (1999); JUDITH WAXMAN & GERALDINE DALLEK, FAMILIES USA FOUNDATION, *Hit and Miss: State Managed Care Laws* (1998) <<http://www.familiesusa.org/hitmiss.pdf>>. See generally GERALDINE DALLEK, THE HENRY J. KAISER FAMILY FOUNDATION, CONSUMER PROTECTIONS IN MEDICARE + CHOICE (1998); KAREN POLLITZ ET AL., THE HENRY J. KAISER FAMILY FOUNDATION, EXTERNAL REVIEW OF HEALTH PLAN DECISIONS: AN OVERVIEW OF KEY PROGRAM FEATURES IN THE STATES AND MEDICARE (1998).

Step back from these issues. Underlying all these legislative provisions is one question. Which issues should be left to the market and which should be decided by public policy through some kind of representative process? The spate of current regulation represents political backlash against the policies and practices of MCOs. n9 The public has used the political process to achieve what it could not through the market. This is in sharp contrast to conventional ideas about how consumers affect the behavior of firms: namely that consumer choice in the market will force healthcare providers to cater to their wishes. The fact that there is a political backlash suggests that at least in certain situations the market does not work on its own and that the public relies on an alternative--exercising its voice. n10

n9 Marc A. Rodwin, *Backlash as Prelude to Managing Managed Care*, 24 J. HEALTH POL. POL'Y & L. 1115, 1116-17. Some blame the backlash on the conduct of MCOs; others say providers are merely seeking to protect their own incomes and reassert their own authority. Still others blame the backlash on poor reporting by the press, political leaders pandering for votes, or a misinformed public. See the entire issue of essays entitled *Managed Care Backlash*, 24 J. HEALTH POL. POL'Y & L. (1999).

n10 Marc A. Rodwin, *The Neglected Remedy: Strengthening Consumer Voice in Managed Care*, 34 AM. PROSPECT 45, 50 (1997). For an eloquent argument that justifies regulation of managed care organizations on the basis of market failure, see Russell Korobkin, *The Efficiency Of Managed Care "Patient Protection" Laws: Incomplete Contracts, Bounded Rationality, and Market Failure*, 85 CORNELL L. REV. 1 (1999).

Healthcare represents an unusual case for testing the efficacy of markets, government regulation, and democratic means of exercising public control over firms. n11 U.S. policy has shifted over the years, sometimes intervening in

healthcare markets, other times leaving them alone.

n11 For a contrasting of representative, market and professional models of healthcare accountability, see Ezekiel J. Emanuel and Linda L. Emanuel, *Preserving Community in Health Care*, 22 J. HEALTH POL POLY & L. 147 (1997).

From World War II until the mid-1970s, medical care was viewed as different from most other goods and services. The federal government subsidized the growth of medical schools and in 1965 created Medicare and Medicaid, publicly financed insurance programs for the elderly and the poor. Most people did not believe that the market alone could perform these functions. The government also subsidized health insurance for the middle class through tax subsidies for employer-provided health insurance and health insurance provided by nonprofit insurers and hospitals. n12

n12 However, American suspicion of government prevented this trend from going to its logical conclusion, the creation of a national health insurance program.

Even economists, led by Nobel laureate Kenneth Arrow, believed that markets could not work in healthcare as in other sectors of the economy because of imbalances of information between providers and patients. n13 This skepticism regarding healthcare markets was used to justify professional licensure, regulation of hospital construction using certificate-of-need, and community health planning. It is also supported by an ideal of professionalism, which ceded authority to doctors to regulate themselves and act in the interest of patients, and which provided little external oversight.

n13 Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941, 964-65 (1963).

Health planning in the U.S. was bolstered by the passage of the Comprehensive Health Planning and Public Health Services Amendments of 1966, which required localities to survey and produce health plans. n14 The trend was continued by 1972 legislation creating Professional Standard Review Organizations, which were charged with assessing the appropriateness of hospital care that patients received under Medicare. n15 Hospital expansion was regulated by legislation in 1972. n16 The trend was solidified by enactment in 1974 of the National Health Planning and Resources Development Act, which created Health Systems Agencies with consumer representation to implement health planning. n17

n14 Comprehensive Health Planning and Public Health Services Act, Pub. L. No. 89-749, 80 Stat. 1180 (1966); 42 U.S.C. § 246.

n15 Social Security Amendments of 1972, Pub. L. No. 92-603, § 1151, 86 Stat. 1329, 1429 (1972).

n16 *Id.* § 1122, 86 Stat. at 1412.

n17 National Health Planning and Resources Development Act, Pub. L. No. 93-641, 88 Stat. 2225 (1974).

Yet while healthcare regulation grew in the 1970s, at the same time other trends emerged that promoted a market-oriented approach to healthcare. The tide shifted in the late 1970s and early 1980s, and for the next twenty-five years many restrictions on markets were chipped away. Courts, economists, and critics suggested that regulation of healthcare was fueling healthcare spending and stifling innovation. There was a steady flow of proposals to promote healthcare markets, followed by changes that treated medical care services more like other goods and services. The professional exemptions from antitrust laws were removed by lawsuits in 1975 n18 and 1982. n19 Federal

certificate-of-need regulation of the growth of medical facilities was dismantled in 1980s. n20 Starting in 1978, Alain Enthoven proposed managed competition to control healthcare spending and improve quality. n21 The 1980s and 1990s were also characterized by the rapid growth of the investor-owned for-profit healthcare sector and conversion of not-for-profit providers and insurers to for-profit status. n22 In 1997, 62% of MCOs were for-profit, up from only 12% in 1981. n23

n18 Antitrust lawsuits in the 1970s eliminated the professional exemption. *See Goldfarb v. Virginia State Bar*, 421 U.S. 773 (1975).

n19 *Id.*; *Arizona v. Maricopa County Med. Soc'y*, 457 U.S. 332 (1982); *American Med. Ass'n v. Federal Trade Comm'n*, 638 F.2d 443 (2d Cir. 1980), *aff'd mem.* 455 U.S. 676 (1982).

n20 In the 1980s, the Reagan administration promoted markets and ended federal certificate of need legislation and health planning.

n21 Alain C. Enthoven, *Consumer-Choice Health Plan: A National-Health-Insurance Proposal Based on Regulated Competition in the Private Sector*, 298 NEW ENG. J. MED. 709, 709 (1978). *See* ALAIN C. ENTHOVEN, *HEALTH PLAN: THE ONLY PRACTICAL SOLUTION TO THE SOARING COST OF MEDICAL CARE* (Addison Wesley Publishing Co. 1980); Alain C. Enthoven, *The History and Principles of Managed Competition*, HEALTH AFFAIRS 24, 29 (Supp. 1993).

n22 BRADFORD H. GRAY, *FOR-PROFIT ENTERPRISE IN HEALTH CARE* (National Academy Press 1986); Symposium, *Hospital and Health Plan Conversions*, 16 HEALTH AFFAIRS 1 (1997).

n23 Carolyn Hughes Tuohy, *Dynamics of a Changing Health Sphere: The United States, Britain and Canada*, 18 HEALTH AFFAIRS 114 (1999).

The 1960s skepticism about markets in healthcare gave way to celebration of markets in later years. The language of markets, management and money became integral to discussions of healthcare. n24 Healthcare institutions also changed. The most prominent development was the rise of MCOs, which combined prepaid healthcare insurance with the delivery of healthcare services, frequently with financial and managerial controls over the provision of those services. These organizations had their origins in the 1930s as experiments to deliver healthcare through nonprofit prepaid group practices that increased access to services and lowered costs. Initially viewed as something of a "socialistic" experiment, medical societies fought them. Yet a few such prepaid group practices thrived, including Kaiser Permanente in California, Group Health Cooperative of Puget Sound in Washington state, Group Health Association in Washington, D.C., and Harvard Community Health Plan in Boston. n25 They served as a model for President Nixon's Health Maintenance Organization ("HMO") Act of 1973, and since the 1980s, it has been for-profit variations of such prepaid group practice that have grown most rapidly. As they grew, so did the ways in which insurance and healthcare services could be organized, financed, and marketed. Somewhere around the late 1970s, the term "managed care organization" was coined to describe a wide variety of such organizations that were not organized as the original HMOs were, i.e., as individual organizations integrating both the insurance and delivery of medical services and with physicians as salaried employees.

n24 Rashi Fein, *What is Wrong with the Language of Medicine?*, 306 NEW ENG. J. MED. 863, 863 (1982).

n25 EDWARD D. BERKOWITZ & WENDY WOLF, *GROUP HEALTH ASSOCIATION: A PORTRAIT OF A HEALTH MAINTENANCE ORGANIZATION* (Temple University Press 1988); WALT CROWLEY, *TO SERVE THE GREATEST NUMBER: A HISTORY OF GROUP HEALTH COOPERATIVE OF PUGET SOUND* (University of Washington Press 1996); RICKEY LYNN HENDRICKS, *A MODEL FOR NATIONAL HEALTH CARE: THE HISTORY OF KAISER PERMANENTE* (Rutgers University Press 1993).

During this time, there was also a shift in how the public viewed the users of medical services. Traditionally, they were called patients and usually were treated paternalistically by doctors. But patients' rights, women's health, and disability rights movements helped change the way patients were viewed. Patients' rights advocates argued that doctors should respect the autonomy of patients, obtain their informed consent before providing medical treatment, and allow patients to participate in medical decisionmaking.ⁿ²⁶ Their intent was to foster the autonomy and rights of women, people with disabilities, and patients in general. They engaged in concerted political activity to change our healthcare system.ⁿ²⁷ However, in the process, they encouraged market trends. If people who were ill could make more decisions themselves than doctors had traditionally accorded, then it was easy to conceive of them as medical "consumers" rather than patients.ⁿ²⁸ And indeed, that is what happened. Soon the focus shifted from patients' rights and informed consent to consumer choice and consumer rights.ⁿ²⁹ While these changes eliminated a great deal of physician paternalism, individuals were left to the vagaries of the market with the assumption that they could be better off with unrestricted consumer choice.

ⁿ²⁶ GEORGE J. ANNAS, *JUDGING MEDICINE* (Humana Press 1988).

ⁿ²⁷ Marc A. Rodwin, *Patient Accountability and Quality of Care: Lessons from Medical Consumerism and the Patients' Rights, Women's Health and Disability Rights Movements*, 20 AM. J.L. & MED. 147, 153 (1994) [hereinafter Rodwin, *Patient Accountability*]; Marc A. Rodwin, *Exit and Voice in American Health Care*, 32 MICH. J.L. REFORM 1041, 1042 (1999).

ⁿ²⁸ Analee E. Beisecker & Thomas D. Beisecker, *Using Metaphors to Characterize Doctor-Patient Relationship: Paternalism Versus Consumerism*, 5 HEALTH COMM. 41 (1993).

ⁿ²⁹ Wendy Mariner, *Standards of Care and Standard Form Contracts: Distinguishing Patient Rights and Consumer Rights in Managed Care*, 15 J. CONTEMP. HEALTH L. POL'Y 1 (1998).

B. The Flaw in Current Policy

For the past two decades public policy treated MCOs as if they were providers of most other consumer services, and that with the right market conditions, they would cater to consumer preferences. Major efforts were channeled into providing consumers with information and eliminating other obstacles to healthcare markets functioning well.ⁿ³⁰ Employers and other purchasers also began to use their purchasing power to obtain better value for their money. While admitting that MCOs were not perfect, many people saw increased market competition as the main way to improve managed care.

ⁿ³⁰ For example, Medicare provides an on-line database for beneficiaries to compare health plans. See <http://www.medicare.gov/comparison/search_overview.asp>. For a summary of law and policy promoting disclosure of information to facilitate consumer choice, see William M. Sage & David Anderson, *Health Care Disclosure Requirements*, in HEALTH LAW HANDBOOK (Alice Gosfield ed., Clark Boardman Callaghan Co. 1997); William M. Sage, *Regulating Through Information: Disclosure Laws and American Health Care*, 99 COLUM. L. REV. 1701 (1999). See also Michael S. Klinkman, *The Process of Choice of Health Care Plan and Provider: Development of an Integrated Analytic Framework*, 48 MED. CARE REV. 295 (1991); U.S. Dep't of Health and Human Services, *Consumer Survey Information in a Reforming Health Care System* (1995).

This conception of managed care is flawed. Managed care is not a traditional service, and individual patients and MCO members--whom I will call *consumers* for short--are very different from purchasers or users of most other services. These differences, often ignored by those who advocate consumer choice among alternative MCOs, limit the effectiveness of market approaches as a means to promote accountability of MCOs to the public.

MCOs, unlike providers of most private services, exercise authority over those who receive their services, much the way that governmental institutions exercise authority over citizens who are beneficiaries of their social programs and

policies. There are four key reasons for this.

First, participation in MCOs is often *not voluntary*. For many privately insured individuals, being a managed care subscriber is not a matter of choice. Most employers do not give employees a choice of more than one health plan. In 1999, 35% of covered employees were offered only one plan and only half of employees were offered three or more plans.ⁿ³¹ In 1998, 54% of Medicaid recipients were enrolled in managed care plans.ⁿ³² And, once an individual is enrolled in an MCO, his choice is more restricted than otherwise.

ⁿ³¹ The Kaiser Family Foundation, *Employer Health Benefits: 1999 Annual Survey* (2000) <<http://www.kff.org/content/1999/1538/kff.pdf>>.

ⁿ³² National Summary of Medicaid Managed Care Programs and Enrollment, Health Care Financing Administration (visited Mar. 29, 2001) <<http://www.hcfa.gov/medicaid/trends98.htm>>.

Second, a major distinction between managed care and indemnity insurance is that indemnity insurers do not judge the necessity for medical care or control its use of services, while MCOs do. MCOs mediate what services to provide members and decide what services are medically necessary and how to provide them. MCOs make these choices subject to a limited budget and so effectively *ration* resources.ⁿ³³

ⁿ³³ Courts and public officials have long avoided acknowledging that MCOs ration medical services. However, the Supreme Court recently broke taboos and stated this squarely. *See* *Pegram v. Herdrich*, 120 S. Ct. 2143, 2149 (2000).

Third, MCOs collect approximately equal funds from a large number of individuals and provide differing levels of benefits based on their criteria of need, thereby *redistributing* resources among individuals.

Fourth, the funding for MCO services is *publicly subsidized* and the services they provide are *imbued with a public purpose*. Rather than being merely private purchases, many healthcare services have a public aspect and affect the community as well.

These features make consumer choice in the healthcare market less viable as a way to promote organizational accountability. Traditional government regulation of industry is one way to address this problem, but there is also another: giving the public greater say in the operation of MCOs. Because MCOs exercise authority over their members, individuals subject to MCO authority should receive an accounting for their performance and main policy choices they make. The public should also have some voice in key policies and decisions that MCOs make, just as is the case for governmental agencies. Yet MCOs today perform their work using criteria that are not generally known, let alone subject to public debate, representation, or approval.ⁿ³⁴

ⁿ³⁴ Mark J. Schlesinger, et al., *Medical Professionalism Under Managed Care: The Pros and Cons of Utilization Review*, 16 HEALTH AFFAIRS 106 (1997).

C. Managed Care as a System of Authority

1. Not Voluntary

Most individuals enrolled in MCOs do not choose them from alternatives such as indemnity insurance, nor do most people even have a choice among competing MCOs. Indemnity insurance, once the norm, is now available mainly for the well to do, only approximately 8% of American employees in 2000.ⁿ³⁵ Even choosing among managed care plans is limited. Most employers do not give employees a choice of more than one health plan. In 1999, 35% of employees

were offered only one plan and only half of employees were offered three or more plans. n36 The poor, in particular, have few exit options. n37 Some state Medicaid programs lock beneficiaries into a managed care plan, generally the one with the lowest premium.

n35 William M. Mercer, Inc., *National Survey of Employer-Sponsored Health Plans* (2000). See <<http://www.wmmercer.com/usa/english/resource/index.html>> (Press Release of Dec. 12, 2000 regarding survey results).

n36 William M. Mercer, Inc., *National Survey of Employer-Sponsored Health Benefits* (1999).

n37 Shelly I. White-Means, *Consumer Information, Insurance, and Doctor Shopping: The Elder Consumer's Perspective*, 23 J. CONSUMER AFFAIRS 45, 54-55 (1989).

Moreover, many individuals who would like to be insured by managed care or other health insurance cannot obtain health insurance. Approximately 18% of nonelderly Americans lack health insurance. n38 MCOs and other insurers refuse to enroll many individuals because they are already sick or have a higher than average risk of becoming ill. Still other people lack funds to purchase the most basic insurance. And after Congress passed the Balanced Budget Act of 1997, which created new options for managed care in the Medicare program, most MCOs decided not to participate in the program, effectively denying this as a market option for most seniors. As of January 1999, 10.4 million Medicare beneficiaries had no choice of managed care plan, 4.7 million had only one plan, and 23.8 million had more than one plan to choose from. n39 Moreover, between 1998 and 2000, 198 HMOs dropped out of the Medicare program, forcing 750,000 people to find a new plan. n40 Thus, managed care is imposed on many who would like an alternative, while it is not an option for others who would choose it if they could.

n38 KAISER COMMISSION ON MEDICAID AND THE UNINSURED, UNINSURED IN AMERICA: A CHART BOOK 3 (Henry J. Kaiser Family Foundation 1998).

n39 GENERAL ACCOUNTING OFFICE, MEDICARE MANAGED CARE PLANS: MANY FACTORS CONTRIBUTE TO RECENT WITHDRAWALS, PLAN INTEREST CONTINUES 25 (GAO/HEHS 99-91 1999).

n40 Interview with Diane Archer, Executive Director, Medicare Rights Center, New York, Mar. 13, 2000.

2. Rationing and Redistribution

MCOs not only provide services but also ration medical care for their members. MCOs receive fixed premiums and are responsible for providing all necessary medical services for their subscribers (subject to exclusions specified in their policies). To stay solvent MCOs must manage their costs and spending and develop ways to deliver their services efficiently. However, there is also a trade-off between the money spent on patient care and the profit or surplus the MCO receives. n41 In short, the main way MCOs control spending is by limiting the volume and cost of services they provide to subscribers.

n41 Similar trade-offs exist for expenditure on administration and MCO profit. However, there is much more spent on medical care than on administration of MCOs. Typically MCOs spend between 10% and 20% of their premiums on administrative costs and profits.

To limit their costs, most MCOs create procedures and rules to control access to specialists, hospital care, pharmaceutical products, and other services. n42 They set guidelines for treating different medical conditions and the length of hospitalization. MCOs also typically review the necessity of medical services that doctors recommend and can veto or modify choices that doctors make. In so doing, MCOs limit the discretion of the individual clinician as an agent

for patients. In making such decisions, MCOs assess the value of reducing different categories of medical risk, in effect balancing claims to services from competing groups. Such choices are not merely technical or reducible to medical knowledge, science, or an economic calculus. They require judgments about values that are essentially political. In effect, health policy is delegated to MCOs and their agents.

n42 Alan L. Hillman, *Managing the Physician: Rules Versus Incentives*, 10 HEALTH AFFAIRS 138, 139 (1991).

Of course, MCOs tend not to override or ignore most physician decisions about what care is medically necessary. So MCOs enlist the aid of doctors in rationing medical care. MCOs attempt to change the standard of care and the individual decisions of doctors. They harness physician self-interest as a tool to control resource use. They pay doctors in ways that give them financial incentives to be frugal in using or recommending services or referring patients to specialists or hospitals. Doctors in most MCOs bear part of the cost for the resources the MCO uses, a powerful incentive to make clinical choices in ways that reduce resource use. The fewer costs incurred for patient care, the greater the income physicians will receive. Doctors are now partners with MCOs in controlling costs through rationing. n43

n43 MARC A. RODWIN, *MEDICINE, MONEY AND MORALS: PHYSICIANS' CONFLICTS OF INTEREST* 139 (Oxford University Press 1993).

Health insurance by its nature redistributes resources from the healthy to the sick. People pay for health insurance because they want to be able to tap medical benefits should they need them, but do not know when or whether they will. They pay premiums regardless of their health, but do not reap the benefits unless they need medical services. This redistributive function makes enrolling in an MCO or other health insurance more like funding a governmental program than purchasing an individual product. The insurance plan, like a government social program, provides economic security for all those who are eligible to receive benefits, and the individuals who do not need the service in effect subsidize the program for those who do. Willingly (or reluctantly), we pay taxes to fund a government program because we feel obligated to help those the program supports and because the program might help us. Yet in the case of governmental programs, the public can use the political process to determine how the program works. There is little public input into the operations of managed care.

3. Public Subsidy

Our private health insurance system and infrastructure are publicly subsidized. In 1998 approximately 46% of U.S. healthcare spending was paid for directly with public funds through programs such as Medicare, Medicaid, and the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS"). n44

n44 Katharine Levit et al., *Health Spending in 1998: Signals of Change*, 19 HEALTH AFFAIRS 124 (2000).

Even private payments are subsidized by tax expenditures. Employers' payments for health insurance premiums are tax-deductible business expenses. Employees, too, often pay their share of premiums with pre-tax earnings through workplace tax benefit plans, which have the same effect as a tax deduction. Individuals who purchase health insurance on their own also can deduct their premiums. The loss of tax revenue from such subsidies, the so-called "tax expenditure," was \$ 111 billion in 1998. n45 Our medical infrastructure is subsidized as well. Government funds have contributed to construction of nearly all U.S. hospitals through the Hill-Burton Act. Graduate medical education and biomedical research are heavily subsidized by the National Institutes of Health. MCOs share in this subsidy.

n45 John Sheils & Paul Hogan, *Cost of Tax-Exempt Health Benefits in 1998*, 18 HEALTH AFFAIRS 176 (1999).

In sum, MCOs make public policy on medical matters, have significant control over the lives of their members, and use public funds to perform their work. This itself is reason for giving the public voice into MCO policies and requiring MCOs to account for their decisions to the public. Yet many people shy away from public solutions. They prefer to let individual choice in the market be the means to make private firms responsive to consumers. They say that individuals can leave one MCO for another. However, such an approach is sorely inadequate for managed care.

D. Why Market Choice Alone Cannot Make MCO Respond to Consumers

Typically, private firms have good reasons to cater to consumer wishes. If they provide poor services, they risk losing consumers to competing firms. Providing good service is in the firm's interest, especially when a business relies on repeat customers and long term relationships for its reputation. This need to attract and keep customers helps restrain the interest of a firm in maximizing its short-run profit by skimping on quality. In principle, MCOs should behave in the same way as other firms and thus resist temptations to provide too few or poor quality services. These general incentives, however, do not work as well for MCOs for several reasons.

MCOs have no financial incentives to cater to the needs of members who can use medical care the most, those with chronic, high-cost illnesses. Such individuals represent a loss to MCOs because they cost much more to treat than the premiums they pay. MCOs are better off deterring such individuals from joining rather than attracting them. The threat of leaving is not an effective means for such individuals to make their MCO respond to their needs.

Moreover, it is typically employers, not employees, that decide which MCOs or other health insurance plan to offer to employees. This reduces the responsiveness of MCOs to individual members because employers are imperfect agents for their employees. While employers and employees have common concerns, their interests are not always the same, a fact evident from management-labor disputes. Certainly, employers need to treat employees well enough to retain a ready supply of labor and therefore will try to maintain a minimum level of satisfaction. However, a firm's loyalty and obligations are primarily to shareholders or other owners, not employees.

Ownership of MCOs is also becoming concentrated, and this limits available choice. Some analysts believe that a few oligopolies will soon dominate the market. If this occurs, these MCOs may become complacent about the risk of losing market share and thus less responsive to consumer switching. n46 Albert Hirschman calls attention to lazy monopoly or collusive behavior. n47 In a restricted market, a firm may choose to be rid of its difficult customers rather than change its behavior to please them. If a problem is endemic among all rival plans, dissatisfied customers will only be able to switch to an equally unresponsive competitor.

n46 PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 429-30 (Basic Books 1982); Richard Kronick et al., *The Marketplace in Health Care Reform: The Demographic Limitation of Managed Competition*, 328 *NEW ENG. J. MED.* 145-48 (1993).

n47 ALBERT O. HIRSCHMAN, *EXIT, VOICE, AND LOYALTY* 57-60 (Harvard University Press, 1970).

However, choice within an MCO or physician network might render unnecessary choice among competing MCOs. Is this so? Will MCOs respond to consumers if they can choose among several physician groups, or go outside the preferred provider network? Such choice would not produce options for consumers that make the most significant difference. MCOs restrict the clinical decisions of all physicians through organizational rules and influence physician discretion through financial incentives. n48 Thus, when consumers switch doctors, they are subject to the same organizational constraints that significantly affect the care they receive. Moreover, many consumers in preferred provider organizations cannot afford to pay the extra fees required to seek care outside the list of preferred providers.

n48 Hillman, *supra* note 42, at 139.

Unlike many other services, there are high costs for most people to switch MCOs. For one, patients are often loyal to their doctors. Switching doctors may also mean severing an established patient-physician relationship. Exit is especially difficult for patients with chronic or complex conditions that require coordination among medical personnel or particular knowledge of the case. And especially for the sick and the frail, shopping for medical care may be physically and emotionally difficult. n49 If the MCO's performance is mediocre but not terrible, patients may simply suffer poor quality and the market will not do its work.

n49 See Judith H. Hibbard & Edward C. Weeks, *Consumerism in Health Care: Prevalence and Predictors*, 25 MED. CARE 1019, 1020-21 (1987); Judith H. Hibbard & Edward C. Weeks, *Does the Dissemination of Comparative Data on Physician Fees Affect Consumer Use of Services?*, 27 MED. CARE 1167-74 (1989); Judith H. Hibbard & Edward C. Weeks, *Consumers in a Competition-Based Cost Containment Environment*, 9 J. PUB. HEALTH POL'Y 233, 245 (1988).

The fact that managed care provides a bundle of varied medical services, medical providers, and health insurance also makes exit a crude tool. Consider a family of three, each with different medical problems: the father with a cardiac problem, the mother with breast cancer, and the child with asthma. Suppose that the family can choose among three managed care organizations, each of which is strong in only one area of medical care that the family needs. n50 Which should the family choose?

n50 Rudolf Klein, *Models of Man and Models of Policy: Reflections on Exit, Voice, and Loyalty Ten Years Later*, 58 MILBANK MEMORIAL FUND Q./HEALTH AND SOC'Y 416, 422-23 (1980).

E. Rational Consumer Choice and Report Cards

Individuals are also not in a good position to evaluate MCOs. For most purchases consumers make--food, clothing, home products, restaurants, and rental housing--the stakes are low and the variables that differentiate the product or service relatively few. People make these purchases frequently and when they make a bad choice they learn quickly, without much cost, and are better informed the next time.

Choosing an MCO is a different matter. The consequences can be great; the number of factors that differentiate MCOs are many and often not apparent to the layperson. People make such choices infrequently. Experience is also an inadequate guide. Because most people are healthy, they will not encounter the effect of their MCO policies or learn how well it performs until they are ill--which is when they will need it most. Even then, their experience probably will not be a good guide for the future. Unless consumers have a chronic condition, they probably will not need the care of the same doctors and other providers again. Other medical personnel may perform very differently, and so might the MCO for different kinds of medical problems.

The lack of knowledge that most people have about medicine has always been an obstacle to making choices. n51 However, it is much harder to compare two MCOs than two physicians practicing the same specialty because the number of variables is much greater and there is much less reliable information. n52 In choosing among MCOs, consumers compare two networks of physicians, hospitals, and other medical personnel. In addition, one must compare systems of quality assurance and methods of administration, including systems for resolving complaints, handling appeals, and organizing personnel and services. Each is difficult to assess. Consumers would like to know whether the MCO would provide good care for them when they need it. But because most people do not know what illness they will have and thus what medical personnel will provide the service, it is hard to compare two different MCOs. Moreover, most MCOs can contract with different providers yearly; thus, even a careful assessment of which MCO has the best provider network is constantly in flux.

n51 Arrow, *supra* note 13.

n52 A. R. Jadad & A. Gagliardi, *Rating Health Information on the Internet: Navigating to Knowledge or to Babel?*, 279 JAMA 611 (1998); see M. Gottlieb, *Picking a Health Plan: A Shot in the Dark*, N.Y. TIMES, Jan. 14, 1996, at 1.

There is now a movement to create report cards that rank MCO performance along several dimensions to help consumers choose among them. n53 Still in their infancy, most report cards have focused on consumer satisfaction and medical outcomes for a few medical conditions. They measure quality based on proxies such as the rate of childhood immunizations or the success rate in coronary artery bypass surgery.

n53 This movement has been endorsed by law for Medicare in the Balanced Budget Act. Balanced Budget Act of 1997, Medicare, Medicaid and Children's Health Provisions, tit. 18, §§ 1851, 1853. See, e.g., the report cards and performance measures of the National Committee for Quality Assurance, available at <<http://www.ncqa.org/Pages/Main/index.htm>>; Joseph W. Thompson et al., *The NCQA's Quality Compass: Evaluating Managed Care in the United States*, 17 HEALTH AFFAIRS 152 (1998); see also GENERAL ACCOUNTING OFFICE, MEDICARE: HCFA SHOULD RELEASE DATA TO AID CONSUMERS, PROMPT BETTER HMO PERFORMANCE (GAO/HEHS-97-23 1996). Some consumer groups also prepare report cards that are for the general public. See CONSUMER REPORTS MAGAZINE, HOW GOOD IS YOUR HEALTH PLAN? (PART I AND II) (1996). For discussion of the issues surrounding the crafting of these report cards, see Judith H. Hibbard & Jacquelyn J. Jewett, *What Type of Quality Information do Consumers Want in a Health Care Report Card?*, 53 MED. CARE RES. & REV. 28 (1996). Yet these report cards have limitations. See GENERAL ACCOUNTING OFFICE, HEALTH CARE REFORM: "REPORT CARDS" ARE USEFUL BUT SIGNIFICANT ISSUES NEED TO BE ADDRESSED (GAO/HEHS-94-219 1994). This movement for report cards goes beyond healthcare. See WILLIAM T. GORMLEY JR. & DAVID L. WEIMER, *ORGANIZATIONAL REPORT CARDS* (Harvard University Press 1997).

Typically designed to be understandable by the layperson, report cards focus on a few key measures and in doing so simplify and screen out a great deal of pertinent information. For example, there is very little public information on the internal operations of MCOs, their management practices, the criteria they use for utilization review and the process used to conduct it, and the incentives paid to physicians for cost containment. There is also little data available on the performance of physician groups, which are now assuming functions that were traditionally the province of MCOs, including bearing financial risk, overseeing quality assurance and utilization review, and monitoring consumer complaints. Furthermore, much of the data is not collected using uniform standards and is not subject to audit.

Also, report cards infrequently provide data related to MCO performance in addressing particular medical conditions, which would help people who are most apt to make comparisons: those with chronic illnesses. And most report card measures of outcome are based on averages of all physicians in the MCO, rather than the much smaller physician groups that will serve a particular member. The measures of outcome therefore do not accurately reflect the experience of the doctors consumers will use.

Report cards aimed at individual consumers greatly simplify and therefore lack detail that would allow a robust and sophisticated assessment of MCOs. Information about MCOs that are not included in report cards could reveal a great deal about an MCO's values, particularly on how and where to ration and what groups gain and lose by the way the MCO manages costs. However, providing a great deal of detailed and complex information about MCOs probably would overwhelm most lay-people. n54 This problem could be overcome if instead a great deal of information was made available to expert intermediaries. They could use such information to make informed judgments and advise consumers on which MCOs to avoid or to seek out. n55 That is the model and lesson of information disclosure in the securities markets. n56

n54 J.H. Hibbard & J.J. Jewett, *Comprehension of Quality Care Indicators: Differences Among Privately Insured, the Publicly Insured, and the Uninsured*, 18 HEALTH CARE FINANCING REV. 75 (1996); J.H. Hibbard et al., *Informing Consumer Decisions in Health Care: Implications from Decision-Making Research*, 75 MILBANK Q. 395, 396 (1997); S. T. Mennemeyer et al., *Death and Reputation: How Consumers Acted upon HCFA Mortality Information*, 34 INQUIRY 117 (1997).

n55 RODWIN, *supra* note 43, at 239-41; W. M. Sage, *Mandatory Public Disclosure in Managed Care: Lessons from the Securities Industry*, in ACHIEVING QUALITY IN MANAGED CARE: THE ROLE OF LAW 99-121 (ABA Health Law Section Monograph 5, 1997); L. Etheredge, *Promarket Regulation: An SEC-FASB Model*, 16 HEALTH AFFAIRS 22-25 (1997).

n56 Louis Lowenstein, *Financial Transparency and Corporate Governance: You Manage What you Measure*, 96 COLUM. L. REV. 1335, 1335 (1996); see E.F. Fama, *Efficient Capital Markets: A Review of Theory and Empirical Work*, 25 J. FIN. 383, 413-14 (1970).

Nevertheless, it will be hard for anyone to perform this expert-intermediary role because much of the kind of data that would allow a thoughtful assessment of the performance of MCOs and providers is not publicly available. MCOs have or could produce most of this information but are unlikely to do so voluntarily. They consider this information their private property, and making it public is costly and offers MCOs few benefits. Rather, it raises potential dangers--for example, that outsiders will raise questions about their performance or that other firms will use the information to compete with them. Most HMOs also are worried that releasing information could yield increased regulatory oversight or could help lawyers bring lawsuits against them.

As we have seen, consumers' relations to MCOs are very different from their relations to providers of other services; they are more like that of citizens to a governmental program providing benefits. Moreover, choice of MCOs is less effective as a tool to make MCOs responsive to consumers than is the case for many other services. Small wonder then, that as managed care became the predominant means by which the public received healthcare and problems with managed care came to light, there was a public backlash.

F. Why Current Proposals for a Patients' Bill of Rights Are an Important but Insufficient Remedy

Current public debate over how to reform managed care ignores key issues. Some proposals would provide consumers with more information so that the market may work better. Thus, bills introduced in numerous state legislatures required that MCOs disclose to their subscribers the financial incentives that doctors receive to be frugal in providing services and a good deal of other information about how MCOs work. n57 The assumption behind such disclosure is that informed consumers can make better choices among competing MCOs and thereby force MCOs to cater to their preferences or lose business.

n57 *E.g.*, H.B. 4525, 182d General Court, 2000 Regular Session (Mass. 2000).

Other groups champion "patient bills of rights" that allow lawsuits against MCOs, as well as appeals from their decisions not to provide a service, and the establishment of various minimum standards. These reform proposals seek legislative fixes to particular problems and provide important new remedies. Once in place, such standards, appeals, and the right to sue can improve performance, deter negligence, and provide important feedback to MCOs, advocacy groups, and oversight agencies. However, legislation creating due process rights neither changes what causes problems that give rise to grievances nor creates a mechanism to incorporate citizen voice into future policies or decisions of MCOs short of another round of legislation. Such legislation, although an important reform, leaves control over the policies and rationing priorities in the hands of MCO managers, not in those of the people who may use the services and ultimately pay for them.

The notion that consumers should have a right to appeal decisions denying services to a neutral party is based on ideas about fair judicial process that every American takes for granted. The Constitution requires that government agencies provide due process when important individual rights or benefits are at stake. Government agencies may not deprive citizens of property or important interests unless they do so using fair procedures and allow the individual to challenge the state action before a neutral party. n58

n58 *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976); *Goldberg v. Kelly*, 397 U.S. 254, 260-61 (1970).

Constitutional requirements for due process, however, apply only when there is state action and so do not pertain to the actions of firms acting in private capacity. n59 Currently, Medicaid patients are entitled to constitutional due process and fair hearing requirements and Medicaid MCOs are legally obliged to provide such hearings. n60 Medicare patients

are entitled to appeals by federal regulation. n61 It is therefore significant that legislation has previously been passed by both houses of Congress to create due process rights for all enrollees in MCOs. n62 This type of legislation, if again passed and signed into law, would be an important step in **protecting** consumers and making their grievances heard.

n59 A few courts, however, have imposed fair hearing requirements for physicians who are deselected from MCOs in the private sector. *Potvin v. Metropolitan Life Ins. Co.*, 63 Cal. Rptr. 2d 202, 210 (Ct. App. 1997).

n60 *Goldberg*, 397 U.S. at 254 (1970); *Daniels v. Wadley*, 926 F. Supp. 1305 (M.D. Tenn 1996), *vacated in part*, *Daniels v. Menke*, 145 F.3d 1330 (6th Cir. 1998); *J.K. v. Dillenberg*, 836 F. Supp. 694 (D. Ariz. 1993). These rights have been codified into Medicaid Law (42 U.S.C. § 1396a(a)(3); 42 C.F.R. §§ 431.200-.250).

n61 The Medicare program reviews all claims for services or reimbursement that are denied. It contracts with an independent group, the Center for Health Care Dispute Resolution, to review denied claims. In 1998, a federal court of appeals ruled that Medicare beneficiaries are entitled to constitutional due process hearings whenever a managed care organization that contracts with Medicare denies the Medicare beneficiary services. *Grijalva v. Shalala*, 946 F. Supp. 747, 755 (D. Ariz. 1996), *aff'd*, 152 F.3d 1115 (9th Cir. 1998), *vacated*, 119 S. Ct. 1573, *remanded* to 185 F.3d 1075 (9th Cir. 1999). However, the Supreme Court, when it vacated and remanded the case, cited *American Mfrs. Mut. Ins. Co. v. Sullivan*, 119 S. Ct. 977, 980 (1999), which held that the actions of a contractor with a government program often do not constitute state action. As a result, it is likely that there is no state action when MCOs that contract with Medicare deny services to beneficiaries.

n62 Bipartisan Consensus Managed Care Improvement Act of 1999, H.R. 2723, as amended and voted on 7 October, 1999; Patients' Bill of Rights Act of 1999, S. 1334, as amended and voted on 15 July, 1999.

Appeals of MCO decisions not to provide a service give consumers the opportunity to be heard by a neutral party who can require the MCO to provide the service. However, this kind of consumer voice does not address many problems. Such appeals can only change what services are provided in individual cases. They do not create precedents that bind the MCO (or other MCOs) to provide the same services to other individuals in similar circumstances. They cannot change the MCO's general policies or the criteria it uses to decide what services are medically necessary. Nor do independent reviewers have authority to change rules and incentives that give rise to inappropriate denials. Typically, the substance of decisions of independent reviewers and the reason for their decisions are not published. There is, therefore, little opportunity for the public to learn what problems they have in common and to seek changes in organization policy.

Relying on individuals to file appeals is also inadequate as a remedy for mistakes. The evidence from studies of consumer complaints show that the overwhelming majority of individuals with problems do not bother to make complaints. n63 Doing so is time-consuming and costly. Most individuals also lack confidence that speaking out will help them or they lack the ability to do so. The evidence of this is striking for medical malpractice. A study that independently measured the rates of injury to patients due to negligent conduct in hospitals showed few people brought claims. There were seven times as many negligent injuries as claims. Because some claims occurred when there was no negligence, the number of people who suffer malpractice that bring claims is even less, between fifteen and thirty cases of malpractice injury for every claim made. n64

n63 Arthur Best & Alan R. Andreasen, *Consumer Response to Unsatisfactory Purchases: A Survey of Perceiving Defects, Voicing Complaints, and Obtaining Redress*, 11 L. & SOC'Y REV. 701 (1977); Jane Kolodinsky, *Complaints, Redress, and Subsequent Purchases of Medical Service by Dissatisfied Consumers*, 16 J. CONSUMER POL'Y 193, 196 (1993).

n64 PAUL WEILER ET AL., *A MEASURE OF MALPRACTICE: MEDICAL INJURY, MALPRACTICE LITIGATION, AND PATIENT COMPENSATION* (Harvard University Press 1993).

G. What Consumer Voice Can Contribute

Today, the priorities, standards, and processes MCOs use to limit services are not transparent, subject to public scrutiny, or dependent upon public approval. This should not be the case. Consumers can insist that managers publicly account for their rationing and management strategies and should have means to ensure that MCO policies meet their approval. The use of consumer voice can help in four ways: (1) it can set standards and priorities for benefit coverage decisions; (2) it can open to public scrutiny the process by which MCOs make key decisions about rationing healthcare; (3) it can provide feedback about local problems; and (4) it can spur organizational change.

HMOs necessarily make many health policy choices for their members. Market exit is often a crude tool for gauging consumer satisfaction on such matters because the choice of whether or not to leave reflects the consumer views on a bundle of issues. Yet with a voice in MCO policy, consumers could steer the organization in the direction they wanted. The affected public could help re-orient priorities and values when MCOs veered away from the sentiments of its members. Consumers could exercise choices about the scope of benefits as well as the direction, priorities, and standards of MCOs.

Of course, affected members are unlikely to become involved in the details of organizational policy choices. It is not practical to involve MCOs' members on most detailed issues. But consumers could have a say in the major decisions the organization makes and their approval could be required for strategic plans. There are likely to be periods when only a few members are interested in becoming involved. But if MCOs lose touch with their members, consumers are likely to become dissatisfied and more members will assert their views.

Consumer involvement opens up decisionmaking to public scrutiny. When key choices are presented to MCO members, the public can analyze them and subject MCO choices to criticism. Such a process can generate ideas that would not have been considered if a few managers made decisions privately, without a thorough discussion of the issues. The process of having to present and defend organizational choices to the public forces managers to think through options carefully, thereby promoting better decisionmaking. Potential problems will become known and managers can plan accordingly.

Consumer criticism can be a valuable source of information for MCOs. Often, however, the criticism is ignored by organizations. Yet, when complaints are publicly available, they cannot be buried in files and managers are more likely to respond to them. Complaints may include the potential for embarrassing disclosures that could cause some members to leave, other potential members not to join, regulators to conduct an investigation, or the press to highlight the MCO in an unfavorable way. Consumer complaints, either through public forms or private correspondence, provide feedback to an organization. The disclosure of complaints may prompt the further monitoring of the MCO by consumer groups and public and private officials.

Consumer involvement in MCOs may decrease organizational efficiency because it can slow decisionmaking or call into question standard practices. Yet, that is also its virtue. By shifting some authority from other groups with power, consumer voice can be an engine of change. Organizational and professional routines are often conservative. If unquestioned, the status quo may continue even when new circumstances make change preferable.

II. Challenges to Effective Consumer Representation

A. A History of Consumer Involvement in American Healthcare

Consumer representation and citizen participation blossomed in the Johnson administration's War on Poverty. n65 Several statutes imposed citizen participation requirements on Community Health Centers, Community Action Programs, and other recipients of federal funds. This trend continued until the 1980s. n66

n65 Donald Brieland, *Community Advisor Boards and Maximum Feasible Participation*, 61 AM. J. PUB. HEALTH 292 (1971).

n66 By 1982, over 155 federal grant programs imposed citizen participation requirements on the recipients. See Mark Goldberg, *Evaluation and Procedural Reform*, in *CITIZEN PARTICIPATION: MODELS AND METHODS OF EVALUATION* (Nelson Rosenbaum ed., Center for Responsive Government 1982).

The Community Action Programs, created by the Office of Economic Opportunity ("OEO"), received a legislative mandate for "maximum feasible participation" of the poor. n67 It was a prominent experiment. The key idea was that institutions governed by community representatives could set priorities, manage a budget, and produce better programs than a governmental agency without roots in the community. n68

n67 The Economic Opportunity Act of 1964 calls for the development of Community Action Programs ("CAPs") and requires that these programs be "developed, conducted, and administered with the maximum feasible participation of residents of areas and members of groups served." Pub. L. No. 88-452, § 202(a)(3), 78 Stat. 308, 516. See DANIEL P. MOYNIHAN, *MAXIMUM FEASIBLE MISUNDERSTANDING: COMMUNITY ACTION IN WAR ON POVERTY* (1969); S. M. Miller & Martin Rein, *Participation, Poverty, and Administration*, 29 PUB. ADMIN. REV. 15 (1969); Herbert Notkin & Marilyn S. Notkin, *Community Participation in Health Services: A Review Article* 27 MED. CARE REV. 1178 (1970); Lillian B. Rubin, *Maximum Feasible Participation: The Origins, Implications, and Present Status*, 385 ANNALS AM. ACAD. POL. & SOC. SCI. 14 (1969). See also JAMES A. MORONE, *THE DEMOCRATIC WISH* 218-52 (1990).

n68 Steven Jonas, *Limitations of Community Control of Health Facilities and Services*, 68 AM. J. PUB. HEALTH 541 (1978); Steven Jonas, *A Theoretical Approach to the Question of 'Community Control' of Health Services Facilities*, 61 AM. J. PUB. HEALTH 916 (1971).

There was little direction and a constant struggle over how to implement the participation requirements. Those speaking for the poor wanted both employment in the programs and a role in policy making. There was controversy, too, about how many poor people should serve on a community board, n69 whether citizens should give advice or make policy, and the jurisdiction of the board. n70

n69 Also, representatives to be selected democratically should be residents of the particular poverty area that they represent, and special emphasis is given to the participation of those who are themselves poor. The 1967 amendments further specified the composition of the Community Action Agency Board. Economic Opportunity Amendments of 1967, Pub. L. No. 90-222, § 104, 81 Stat. 672, 690-96. See Rubin, *supra* note 67.

n70 Donald Brieland, *supra* note 65.

The Office of Economic Opportunity Neighborhood Health Centers encouraged consumer participation and the formation of citizen advisory councils for several purposes: to shape health center policy, to implement the program, and to evaluate the center's service. n71 Neighborhood Health Centers had a majority of consumers on their boards, as did City Poverty Councils. n72 The ambulatory services advisory committee of the Ghetto Medicine Program of New York also required citizen participation. n73 Medicare was required to have consumer representation on the Health Insurance Benefits Advisory Committee, while Medicaid law mandated consumer representatives on state Medical Care Advisory Committees. n74

n71 Jonathan M. Metsch & James E. Veney, *Consumer Participation and Social Accountability*, 14 MED. CARE 283, 284 (1976).

n72 Paul E. Peterson, *Forms of Representation: Participation of the Poor in the Community Action Program*, 64 AM. POL. SCI. REV. 491 (1970).

n73 Lowell Eliezer Bellin et al., *Phase One of Consumer Participation in Policies of 22 Voluntary Hospitals in New York City*, 62 AM. J. PUB. HEALTH. 1370 (1972).

n74 Social Security Act, 42 U.S.C. § 1396a (a)(4), 22(D) (2000); 42 C.F.R. § 432.31 (2001). For the most comprehensive discussion of consumer participation and voice in Medicaid managed care, see JANE PERKINS ET AL., *MAKING THE CONSUMERS' VOICE HEARD IN MEDICAID MANAGED CARE: INCREASING PARTICIPATION, PROTECTION AND SATISFACTION* (1996) (finding nine main mechanisms for consumer involvement in Medicaid: advisory boards, hotlines, grievance processes, ombud programs, member advocates, focus groups, consumer surveys, Medicaid recipient employees, public hearings and forms). See also KRISTI OLSON & JANE PERKINS, *RECOMMENDATIONS FOR MAKING THE CONSUMERS' VOICE HEARD IN MEDICAID MANAGED CARE: A GUIDE TO EFFECTIVE CONSUMER INVOLVEMENT* (1999) (making recommendations).

The idea of citizen participation was later applied to local health planning agencies. n75 These local agencies were created to plan the use of regional resources and to control healthcare spending. Federal legislation mandated consumer representation on health system agencies as part of an implicit program of representing interest groups. n76 The health planning process proved only partially effective in restraining health spending for several reasons. n77 Local health planning boards did not control funds. Hospitals or groups wanting to build facilities mobilized opposition that often overrode the health planning agencies. Individuals chosen to represent consumers typically lacked the clout, resources, and institutional support that providers had. Consumer groups were not as easily or effectively organized as providers. n78

n75 The National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, 88 Stat. 2225 (1975); The Emergency Medical Services Systems Act of 1973, Pub. L. No. 93-154, 87 Stat. 594; BARRY CHECKOWAY, *CITIZENS AND HEALTH CARE: PARTICIPATION AND PLANNING FOR SOCIAL CHANGE* (1981). Participation requirements were also included in other federal programs, including Urban Renewal and Model Cities. Unlike earlier legislation in the 1960s, legislation of the 1970s has been assessed as vague and nonspecific with respect to the role and responsibilities for consumer participants.

n76 Bruce C. Vladeck, *Interest-Group Representation and the HSAs: Health Planning and Political Theory*, 67 AM. J. PUB. HEALTH 23 (1977).

n77 Lawrence D. Brown, *Some Structural Issues in the Health Planning Program*, in 2 HEALTH PLANNING IN THE UNITED STATES: SELECTED POLICY ISSUES 1-53 (Institute of Medicine ed., 1981).

n78 James A. Morone, *Models of Representation: Consumers and the HSAs*, in 2 HEALTH PLANNING IN THE UNITED STATES: SELECTED POLICY ISSUES, 225-56 (Institute of Medicine ed., 1981).

Similar interest in consumer participation led to the requirements in the HMO Act of 1973 for consumer representation. Under the statute, federally qualified HMOs had to have at least one-third of their policymaking bodies drawn from their members. The representatives had to include medically underserved populations. This requirement was often ignored, and there is little evidence of significant consumer participation in federally qualified HMOs. The requirement was eliminated from the statute in 1988. n79

n79 The Health Maintenance Organization Act of 1973, Pub. L. No. 93-222, § 1301(c), 87 Stat. 914:

Each health maintenance organization shall . . . (6) be organized in such a manner that assures that (A) at least one-third of the membership of the policymaking body of the health maintenance organization will be members of the organization, and (B) there will be equitable representation on such body of members from medically underserved populations served by the organization.

In 1978, the statute was amended. The revised and more extensive consumer representation provision, listed below, was deleted when the statute was amended again, in 1988.

in the case of a private health maintenance organization, be organized in such a manner that assures that (i) at least one-third of the membership of the policymaking body of the health maintenance organization will be members of the organization, and (ii) there will be equitable representation of such body of members from medically under served populations served by the organization, and (B) in the case of a public health maintenance organization, have an advisory board to the policymaking body of the public entity operating the organization which board meets the requirements of

clause (A) of this paragraph and to which may be delegated policymaking authority for the organization.

Pub. L. No. 95-626, § 2744, 92 Stat. 3551 (1978). See Lawrence K. Koseki, *Consumer Participation in Health Maintenance Organizations*, 2 HEALTH & SOC. WORK 51, 53 (1997).

There were important exceptions, however. A few HMOs, most of which started as cooperatives in the 1940s, had a long tradition of consumer governance prior to the HMO Act. The most notable examples were Group Health Cooperative of Puget Sound and Group Health Association in Washington, D.C. In these HMOs, consumers elected the board of trustees and there was a culture of consumer participation. n80

n80 Group Health Cooperative of Puget Sound has thrived. In 1997 it formed an alliance with Kaiser Permanente Northwest under which a new entity, Kaiser Group Health ("KGH") is delegated responsibility for strategic planning and major financial decisions. Six members of the KGH board are appointed by Kaiser and five members are appointed by Group Health Cooperative of Puget Sound. On the other hand, Group Health Association of Washington D.C. had financial problems and voted to become part of Humana, Inc., in 1993. It was purchased by Kaiser Permanente in 1997. For histories of both HMOs, see EDWARD D. BERKOWITZ & WENDY WOLFF, *GROUP HEALTH ASSOCIATION: A PORTRAIT OF A HEALTH MAINTENANCE ORGANIZATION* (1988). See also WALT CROWLEY, *TO SERVE THE GREATEST NUMBER: A HISTORY OF GROUP HEALTH COOPERATIVE OF PUGET SOUND* (1996).

By the end of the 1970s, the effectiveness of health planning agencies and the idea that consumer voice would be a force for positive change in health policy was questioned by many, although never adequately assessed. n81 The Reagan administration defunded federal health planning agencies in 1986 and instead encouraged the use of markets to reduce healthcare spending.

n81 Judy B. Rosener, *Citizen Participation: Can We Measure its Effectiveness?*, 38 PUB. ADMIN. REV. 457, 457 (1978).

James Morone, who has written the leading book on the history of participation in American politics, argues that citizen consumer voice in health planning made enduring contributions. n82 He contends that it changed the political agenda, wrested authority from medical professionals, and shifted authority from the medical profession to public and private healthcare organizations. Such changes are ironic, for they spurred the growth of managed care and for-profit medical institutions.

n82 MORONE *supra* note 67.

There are few empirical studies evaluating the costs and benefits of consumer participation or the pros and cons of different approaches. Yet analysts have noted failures and successes. n83 Some note the trade-offs in program efficiency and democratic participation. n84 Others doubt whether such programs produce increased accountability. n85 Still others think that the goals of participation should be made clear in designing the programs. n86 James Morone suggests that such programs are based on a "democratic wish": the idea that "direct participation of a united people pursuing a shared communal interest" will overcome conflicts between diverse interests and groups and solve problems of government. n87

n83 Nelson Rosenbaum, *Citizen Participation: Models and Methods of Evaluation*, in *CITIZEN PARTICIPATION: MODELS AND METHODS OF EVALUATION* (Nelson Rosenbaum ed., Center for Responsive Government 1982).

n84 Edmund M. Burke, *Citizen Participation Strategies*, 34 J. AM. INST. PLANNERS 287 (1968).

n85 Metsch & Veney, *supra* note 71.

n86 Cathy Charles & Suzanne DeMaio, *Lay Participation in Health Care Decision Making: A Conceptual Framework*, 18 J. HEALTH POL., POL'Y & L. 881 (1993).

n87 MORONE, *supra* note 67.

This idea waxes and wanes, but does not disappear. n88 Witness the state of Oregon's recent process combining public deliberation and representation to set healthcare priorities for healthcare coverage for Medicaid and uninsured groups. n89 Morone suggests that the democratic wish often does not work as proponents of popular participation expect that it will. Yet it has, he argues, been a central instrument to bring about political and social change. Consumer voice might then help transform managed care in ways that will improve it. Nevertheless, there are many challenges to making consumer voice an effective instrument of change.

n88 ADVISORY COMMISSION OF INTERGOVERNMENTAL RELATIONS, *CITIZEN PARTICIPATION IN THE AMERICAN FEDERAL SYSTEM* (G.P.O. 1980).

n89 Jack H. Nagel, *Combining Deliberation and Fair Representation in Community Health Decisions*, 140 U. PA. L. REV. 1965, 1965 (1992). These issues arise in other countries as well. For a review of the literature, see Richard B. Saltman, *Patient Choice and Patient Empowerment in Northern European Health Systems: A Conceptual Framework*, 24 INT'L J. HEALTH SERVICES 201 (1994); *see also* Michel O'Neill, *Community Participation in Quebec's Health System: A Strategy to Curtail Community Empowerment?*, 22 INT'L J. HEALTH SERVICES 287 (1992).

B. How to Represent Healthcare Consumers

1. Organized Constituencies

The idea of representing healthcare consumers is appealingly simple but how can it be done? Who should speak for consumers? There are many ways to select consumer representatives and different institutional means to channel consumer voice. The nature of American politics, however, probably makes it necessary to have organized constituencies to effectively represent them. n90

n90 Marc A. Rodwin, *Consumer Protection and Managed Care: The Need for Organized Consumers*, 15 HEALTH AFFAIRS 110 (1996).

This poses a fundamental problem because currently there are few organized consumer health constituencies. Everyone is a potential medical consumer, but most people do not need extensive medical care. When individuals do, it is frequently for an acute injury or illness so they will not remain a medical consumer for long. As a result, few people have strong or lasting identities as medical consumers, and this inhibits forming healthcare consumer constituencies or long term consumer involvement. n91 The result: although there are many consumer advocacy groups, there are few organized consumer health constituencies.

n91 Rodwin, *Patient Accountability*, *supra* note 27, at 153-54.

There are some important exceptions. People with chronic illnesses (e.g., AIDS, breast cancer, renal failure, diabetes, or polio) have special concerns and long term interests. They have often organized groups around their health concerns to promote greater funding and better treatment. There is also an active women's health movement and a disabilities rights movement, which have organized groups to advance their interests on medical and other matters. The elderly have also organized on health issues, particularly regarding the Medicare program. Such groups can effectively represent their constituencies. n92 They provide a model for organizing other constituencies around specific diseases,

status (gender, age cohort, ethnic group), or through one's place of employment. Although these groups are not organized to represent consumers on managed care issues or within managed care organizations, they are familiar with health issues and consumers. In many situations, disease specific groups may advocate for changes in MCOs that will affect quality of care and patients' rights generally. Such groups are likely to make MCOs more responsive to patients and to improve the quality of care for all consumers. Disease specific and other interest groups may therefore be a vehicle for improving quality for all healthcare consumers.

n92 *Id.* at 150.

However, there are limits to representation through interest groups. Interest groups excel at representing their own constituency by focusing on their narrow concerns. The problem is that not all consumer interests are easy to organize. As is true for American politics generally, those interests that are not organized will be neglected. n93 Furthermore, most healthcare constituencies currently organized do not have managed care as their focus. Nevertheless, for practical purposes, drawing on organized constituencies is probably the most effective way to represent healthcare consumers. Such groups will promote consumer welfare better when they are broad-based coalitions of discrete interest groups. Consumer advocates can and should organize such consumer groups. n94

n93 Robert A. Dahl, *Epilogue*, in *POLITICAL OPPOSITIONS IN WESTERN DEMOCRACIES* 396-97 (Robert A. Dahl ed., 1969).

n94 Community Catalyst 2000, *Health Care Justice: Linking Grass Roots Leadership and Legal Advocacy* (Washington, D.C., Public Welfare Foundation).

2. Institutional Consumer Advocates

An alternative or complement to organized constituencies representing consumers is to have institutions that are designated to advocate for consumers. These could include a government agency for health consumer affairs, a division of consumer affairs in an Attorney General's Office, or a consumer representative in state healthcare insurance commissions or departments. It could also include Ombud in MCOs and other healthcare organizations.

Representatives in Attorneys General Offices. Many states have established divisions to advocate for consumers in utility hearings. n95 Often situated in the state Attorney General's office, these units take part in rate setting. Such offices have been very effective in analyzing finance and equity issues and in convincing rate setting bureaus to heed their advice. A consumer affairs unit following the utility model could be established in state offices that regulate insurance or healthcare. They could evaluate information that managed care firms disclose and recommend policy changes or oversight if needed. Such representatives could develop expertise and be in a position to influence the decisions of the regulatory agency. n96

n95 William A. Spatley, *State Utility Consumer Advocates*, in *ENCYCLOPEDIA OF CONSUMERISM* (Stephen Brobeck, ed., 1997)

n96 William T. Gormley, Jr., *The Representation Revolution: Reforming State Regulation Through Public Representation*, 18 *ADMIN. & SOC.* 179 (1986); William T. Gormley, Jr., *Policy, Politics, and Public Utility Regulation*, 27 *AM. J. POL. SCI.* 86, 87-89 (1982).

Ombud. n97 MCOs and state or federal agencies could create ombud programs for healthcare consumers. Some MCOs have already done so. n98 They serve several functions. They provide information and assistance to individuals in resolving problems they have with an organization. Ombuds also inform the organization of problems it has and, where appropriate, suggest changes in organizational policy or procedures. They also advocate for consumers, both to resolve individual problems and to change policy. There are several examples of ombud or independent assistance

programs for healthcare. The National Health Law Program is coordinating ombuds in six sites. n99 The Center for Consumer Rights in California has also created an independent assistance program.

n97 The traditional Swedish term is *ombudsman*. There are two gender neutral variants: *ombud* and *ombudsperson*. I have chosen to use the shorter.

n98 Health Insurance Plan of New York, for example, has an Ombud.

n99 For a thoughtful report on Ombud programs, see JANE PERKINS ET AL., OMBUDSPROGRAMS AND MEMBER ADVOCATES: CONSUMER-ORIENTED APPROACHES TO PROBLEM-SOLVING IN MEDICAID MANAGED CARE (1998).

There are two main models: (1) those independent of the organization they investigate, and (2) those that work within the organization they investigate. Ombuds independent of the organization have much more freedom, but not necessarily much clout with the organization. Those working within the organization are likely to have access to officials and information, as well as better relations with the MCO, but also face divided loyalties and less discretion. To be effective, ombuds need security of tenure, independence, resources, clout, and political savvy. The role requires a combination of skills: cajoling insiders informally, making use of the press, building allies with outside groups or public agencies to put pressure on an organization, and writing reports that command respect.

Legal Services Organizations. Through grants to state legal aid organizations, the federal government provides legal aid for the poor. Legal service organizations provide assistance to individuals, often on issues involving Medicaid, Medicare, and other healthcare programs. Legal aid organizations have expertise on the common legal problems the poor and elderly encounter. They are an important institutional base for representing the poor on healthcare problems involving managed care. n100

n100 See Joel D. Ferber, *Medicaid Advocacy and Managed Care: The Missouri Experience*, 31 CLEARINGHOUSE REV. 601 (1998).

C. Potential Healthcare Constituencies

Disease specific groups. Many advocates for people with specific chronic illnesses have designated constituencies (e.g., for AIDS, Gay Men's Health Crisis). Having a focused concern gives such groups a defined mission and facilitates advocacy. Depending on their political clout these groups can be very effective. Can individuals with other diseases or medical conditions also form constituencies to promote their interests? Yes, for certain illnesses, but not for many others. For purposes of organizing it helps to have a chronic medical condition. It also facilitates organizing if the individuals likely to be affected share a common status or background (being a woman, or gay). People with episodic or acute illnesses are less likely to identify themselves as a group or to organize. Thus people who have a wide variety of nonchronic diseases are unlikely to organize as constituencies.

The Elderly and Other Age Cohorts. Since the creation of the Medicare program in 1966, the elderly have become a potent political force on healthcare issues. Medicare entitled them to healthcare benefits, which concentrated their interests in program benefits and policies. The elderly mobilized easily because their interests were clear: they are more likely to use healthcare than younger people and program benefits affect them directly. As a group they also have more income and leisure than the average American. Groups such as the American Association of Retired Persons have represented the healthcare interests of the elderly. Other groups, such as the Medicare Rights Center (New York), have formed to advocate for Medicare beneficiaries.

Today there are attempts to expand health insurance to cover the young. Groups such as the Children's Defense Fund have made such an effort one of their priorities. However, there are certain obstacles to youth becoming an

organized healthcare constituency. Individuals under eighteen cannot vote, typically do not have serious illnesses, and are economically dependent on parents or guardians. They also will outgrow their group membership as they age. These factors make it harder to organize the young than the elderly as a constituency for healthcare.

Gender. Starting in the late 1960s, women organized to advocate for their rights in employment, education, health, and other areas of social life. They opposed stereotypes that portrayed them as less capable than men and discrimination that blocked opportunities. Although they did not conceive of themselves as healthcare consumers, as women they encountered common problems with the way doctors and the healthcare system treated them. The fact that there was already a women's movement and women's groups facilitated mobilization around healthcare issues.

The issues raised by the women's health movement started with reproductive rights, birthing, and gynecological issues. It soon expanded to include a much wider range of issues. It now even includes advocacy for using women as research subjects so that differences in physiology will be considered in developing medicines and medical procedures. It also includes advocacy for better treatment of women with cardio-vascular and other diseases that are often neglected because doctors do not perceive them as affecting women to the degree that they affect men. What is notable about the women's health movement is its resiliency. The issues and strategies have evolved, but the ability to mobilize women around common issues has not diminished even among women who do not view themselves as feminists or politically active.

Ethnic Groups. Ethnic groups are a potent force in American politics. They have electoral influence and a net of related community and national organizations to represent them. Could they be a vehicle for representing healthcare consumers? In part, they could. The question is whether healthcare issues are a prominent enough issue to be the focus of their concerns. It is likely to be so when particular illnesses or healthcare issues affect them disproportionately and are not being adequately addressed in other ways. However, illness or healthcare issues are not the basis for their being a constituency or, in the American experience thus far, for their forming interest groups.

Employees. Most people receive their health insurance through their employer, which makes groups representing employees, such as labor unions, a natural forum to represent healthcare consumers. However, less than 14% of the American work force is unionized, so this approach would not work for the majority of Americans. n101 For unionized employees, this could be an effective means to represent worker interests. Unions already have an organizational means to express their views to employers, resources to address employee concerns, and a system of electing leadership to represent the views of members. Most unions bargain over the extent of health benefit coverage and costs of insurance for employees. Some unions have sponsored Taft-Hartley health plans, which purchase healthcare for employees. Still, unions have not typically joined employers in representing employee views in purchasing cooperatives that buy health insurance for large employers or made representing employee healthcare interests a significant part of their mission. Yet unions could become a significant vehicle to represent consumer/employee voice if they chose to do so, as could other employee organizations that might be formed for this purpose. n102

n101 Department of Labor, Bureau of Labor Statistics, <<http://www.bls.gov/news.release/union2.nr0.htm>>.

n102 Unions representing nurses and other healthcare workers would like to position themselves as patient or quality of care advocates, however their primary interest is in maintaining employment and enhancing the working conditions of healthcare workers.

Independent Consumer Advocacy Groups. Several consumer groups (including the National Health Law Program, Families U.S.A., the Public Citizen Health Research Group, Consumers Union, and the Center for Health Care Rights) advocate for consumers on health issues without having a precise or narrowly defined constituency that they must answer to. n103 These self-appointed consumer advocates are often very effective at lobbying for legislation or changes in regulation, initiating strategic litigation, analyzing consumer healthcare issues, assessing choices available to consumers, and speaking truth to power. They represent consumers before state and federal legislatures, monitor the actions of private firms and governmental institutions, and disseminate information to consumers. They have performed

important functions by championing a patients' bill of rights for MCOs, and assessing federal and state laws regulating managed care (Families U.S.A.); by advocating for the poor and elderly and assisting in coalition building (the National Health Law Program); by criticizing the abuses of MCOs and advocating for health system reform beyond incremental change (Public Citizen Health Research Group); by evaluating MCOs (Consumer's Union); and by creating ombud programs and analyzing consumers rights (Center for Health Care Rights). They are likely to continue to be key sources for representing health consumers in national forums. However, they are unlikely to be vehicles to represent consumers at the local level or within individual MCOs.

n103 Among the leading groups are Center for Health Care Rights, Consumers Union, Families U.S.A., the National Health Law Program, Public Citizen Health Research Group, and the Medicare Rights Center.

D. Choosing Consumer Representatives

Often MCOs or other organizations will need a consumer representative. Such representatives can either be appointed or elected. n104 If appointed, the representatives can be chosen by consumer groups, governmental agencies, MCOs, or by a neutral party. Alternatively, a board of two or more such groups can choose the representative. n105

n104 The pros and cons of electing versus having citizen groups select representatives in Community Action Programs is discussed in ALAN A. ALTSCHULER, *COMMUNITY CONTROL: THE BLACK DEMAND FOR PARTICIPATION IN LARGE AMERICAN CITIES* (1970).

n105 The National Association of Insurance Commissioners uses this model.

1. Appointments

There are advantages in having established consumer organizations appoint consumer representatives. There is a greater chance that they will represent a constituency and the organizational representative will have greater credibility than most unaffiliated individuals. The organization also will be able to provide resources, expertise, and experience to assist the representative and they will have some formal or informal means to ensure that the representative is accountable to the group. On the other hand, critics can always ask whether the organization in fact represents consumers beyond its members.

But which consumer health organization should represent consumers? Usually there is more than one that would like to assume the role. Choosing the organizational representative is more difficult than choosing who should represent workers in labor-management negotiations. There, the National Labor Relations Act establishes procedures for employees to vote for union representatives and for designating a union as the exclusive agent of employees for bargaining with management over employment contracts. One way to address this issue is to have the leading consumer health groups form a coalition or consortium for purposes of choosing representatives. n106

n106 Governmental agencies or MCOs may not want to cede authority to consumer groups to choose consumer representatives. They might ask consumer groups to nominate a list of individuals from which the agency or MCO can choose consumer representatives. Or, the agency (or MCO) could propose names of representatives and ask for consumer groups to rate the individuals in priority.

If organizations that represent constituencies are not used to represent healthcare consumers then one needs to seek out appropriate individuals through other means. How might healthcare consumer representatives be chosen? What individuals might perform such roles? Many people now believe that representatives should reflect the social, ethnic, or other characteristics of the population they represent. By virtue of their similar characteristics, such individuals are assumed to have the viewpoint and opinions of the group and to be able to represent its interests. Being poor was one of

the main qualifications for selection of a substantial portion of the members of Neighborhood Health Centers established under the War on Poverty programs in the 1960s. Similarly, a program targeting youth would try to involve young persons as representatives. Often racial or other ethnic background is considered sufficient to represent a particular racial or ethnic group. For healthcare issues, individuals might be chosen because of their medical characteristics. For example, people with different diseases or disabilities could be chosen to represent the point of view of persons with their specific conditions. Choosing representatives because they reflect the social or medical characteristics of the group they represent, however, assumes that most individuals in such a class or ethnic group will have similar views and interests. That's not necessarily so. Choosing representatives to look like the represented group with nothing more in common is likely to offer only symbolic representation.

Many people believe that if an individual is chosen to represent the members of a particular MCO, the representative should be a member of the MCO. Membership will ensure some familiarity with the organization, but it will not necessarily ensure that the representative has knowledge of healthcare issues or expertise, or that he or she is an effective advocate, qualities which are more important than organizational membership.

2. Elections

There are some advantages in electing rather than appointing representatives. Elected representatives can be removed if they do not reflect the voters' views or otherwise perform poorly. There are fewer issues concerning the representative's legitimacy. The most practical way to elect consumer representatives is through existing organizations representing defined constituencies, because we lack a tradition or other institutional means to elect consumer representatives from the public at large or to represent a region.

Consumer representatives could be elected by members of each MCO. Such representation is the exception rather than the rule, the main example being Group Health Cooperative of Puget Sound ("GHCPs"), whose members elect its governing board. Although GHCPs has had an effective board, consumer governance is not feasible for for-profit MCOs, which must be responsive primarily to stockholders. But consumer representatives who did not have ultimate responsibility for governing the MCO could be elected in most MCOs. It is not clear, however, that there will be much participation in such elections. Even at GHCPs, which has a long tradition of being consumer governed, voter turnout for election of trustees has been low, around 5% for most of the last decade and only up to 15% for the last few years when there were controversial issues. n107

n107 In 1996, GHCPs formed an alliance with Kaiser Permanente Northwest. Under that alliance governance of the GHCPs facilities is directed by a joint board jointly appointed by management at Kaiser and the consumer elected board at GHCPs.

Although the idea of electing consumer representatives for MCOs may seem daunting, there are some models of such organizational democracy. Most schools have Parent Teacher Associations ("PTAs") that are elected and in some school districts the associations can even control funds they raise for hiring additional teachers. Even when they do not control funds, PTAs can exert voice and can command respect from school administrations for a range of issues. Some cities have active "block associations" of neighborhood residents. Tenants have formed renters' associations. If individuals can become involved and elect representatives in such local associations, they might do so for consumer associations in MCOs if such associations had real power or influence.

E. Will Representatives Have Influence?

A formal means to choose consumer representatives is necessary for effective representation; however, it is not sufficient. A seat on a board or committee has value based on what the representative can do. In some instances the representative's influence may be minimal because the board or committee on which the representative serves lacks power or influence. This fundamental point is often ignored. Considerable effort is spent in creating representative mechanisms without considering the influence representatives would have. Often consumer representatives serve on

boards that have only symbolic value or token influence.

Even if a consumer representative sits on a board that has power, the consumer voice may be drowned out by others. A single consumer representative serving on a board of twelve individuals will have little impact on the outcome of votes. Of course, the consumer representative can try to persuade the majority of the board. However, reason is enhanced when backed by power. The persuasiveness of a consumer representative is strengthened if the representative is backed by consumer groups that must be taken into account because they can influence consumer enrollment in MCOs or use their clout to get legislation enacted.

Sometimes consumer representatives may lack influence because they are unfamiliar with the issues or untrained in disciplines that would help them work with healthcare and management professionals. Some observers have advocated training for representatives to improve the effectiveness of consumer participation. The Citizen Advocacy Center has worked for several years providing such training. n108 However, good training cannot make up for deficiencies in the resources, organizational support, or networks the representative can command. n109

n108 CITIZEN ADVOCACY CENTER, PUBLIC REPRESENTATION ON HEALTH CARE REGULATORY, GOVERNING, AND OVERSIGHT BODIES. STRATEGIES FOR SUCCESS (Citizen Advocacy Center 1996); Alberta W. Parker, *The Consumer as Policy-Maker: Issues of Training*, 60 AM. J. PUB. HEALTH 2139 (1970).

n109 Brieland, *supra* note 65; Warren R. Paap, *Consumer-Based Boards of Health Centers: Structural Problems in Achieving Effective Control*, 68 AM. J. PUB. HEALTH 578 (1978).

Representatives may lack the time, funds, and other support to evaluate claims that management and other groups make, conduct research, assess how consumer interests are affected by different proposals or policies, write reports, mobilize support, and perform similar activities. Such resources for consumer representatives can be provided either by the organization in which the consumer serves or a consumer group.

An MCO or state agency can put its own professional staff in the service of consumers. This might be administratively simpler than other approaches. Staff drawn from the MCO is likely to be familiar with managed care issues and perhaps have greater access to information from the organization. Moreover, advocacy staff drawn from the MCO can also promote consumer-oriented values in the organization, which probably would facilitate consumer proposals being accepted by operating personnel. The experience with the consumer advisory board suggests that proposals are more likely to be implemented if the organization's staff as well as top management supports them.

MCO staff members, however, will have divided loyalties and might not provide consumer representatives with the kind of neutral analysis or effective consumer advocacy they desire. Consumers would also be limited by whatever information the MCO staff provides. An alternative would be for organizations or consumer representatives to hire their own professional staff. An advantage of using consumer organization staff is that they are likely to have expertise in areas of consumer concerns and share consumer perspectives. There may also be economies of scale because the same staff could provide information and analysis for representatives serving in several different forums. Drawing on staff of consumer organizations would also encourage communication between the organization and consumer representatives. It would promote accountability of the representatives to the organization.

It will be easier for MCOs to raise funds for professional staff than it will be for consumer groups because MCOs can assess the fee as part of the premium for all their members. This is an efficient mechanism to raise funds and the means to collect them are already in place. The argument for such premium-based funding is simple. The services will benefit all members, and so the cost of services should be shared by all. Moreover, if all MCOs fund consumer representatives this way, no MCO will be at a competitive disadvantage. Such a consumer representation fee could be tried as an experiment by states, perhaps through their regulation of health insurance, and continued or eliminated, depending on the experience.

III. The Range of Different Ways Through Which Consumer Voice Can Influence Managed Care

A. Consumer Influence from Within MCOs

Avenues for consumer voice, participation, and representation within MCOs are relatively unexplored. n110 In at least one other industry, there has been some experimentation with representing consumer views. A study of the auto supply industry by the economist Susan Helper showed that firms with combined systems for soliciting both employee suggestions and consumer voice achieved greater cost savings and improvements in quality than firms that did not use both employee and consumer voice. n111 Helper concluded that representing consumer voice within firms is particularly valuable when there is a long term relationship between producers and consumers, conditions that appear to hold for managed care. n112

n110 For a review of current attempts to represent consumers in managed care, see Rebecca A. Cohen & David A. Swankin, *Consumer and Enrollee Participation, in* MANAGED CARE PLAN GOVERNANCE, POLICY MAKING AND OPERATIONS: A SURVEY OF HEALTH PLANS AND LEGAL REQUIREMENTS (Citizen Advocacy Center 1998).

n111 Susan Helper, *Exit, Voice and Cost Reduction: Evidence from the Auto Supply Industry*. Paper prepared for presentation to the Societa Italiana degli Economisti (1996).

n112 These have been explored particularly where consumers are continuing relations between purchasers and suppliers and virtual integration or longterm relations through contracts. There are strong analogies to consumers in managed care. Most consumers have contractual relationships with MCOs for a year and so are locked in. Rather than purchasing discrete items, they are buying a bundle of services and an open-ended commitment by MCOs to provide necessary services. And the objectives of managed care are best achieved through long-term relationships which would increase the incentive for investment in preventive care that is costly up front.

Voice, participation, and representation within MCOs would offer additional benefits not available through consumer involvement in outside groups that can influence MCOs. Such representatives would be close to the consumers served, aware of local problems, and positioned to focus on them. There might also be greater willingness for consumers to become involved in institutions that would directly affect the healthcare they received.

The systematic representation of consumer views could be part of the process by which MCOs learn, adapt, and improve. The views of consumers could be represented in oversight, governance, and advisory boards, as well as in the management of operations. Data on complaints and grievances, as well as opinion surveys, reveal consumer views. There are several examples of how this might work.

Oversight Boards. Many organizations provide for oversight by quasi-independent officials. Banks and other financial institutions have auditors. Government agencies have inspectors general, and both private and public organizations have experimented with ombud. These officials typically have authority to conduct investigations and obtain information that is confidential.

MCOs could create oversight boards modeled on inspectors general or auditors that report to a consumer board or a board with consumer representatives as well as to top management. Such a board would play a role *only* when there were significant problems, scandals, or the appearance of impropriety. However, their existence would bolster public confidence and consumer trust.

Governance. Consumer representation on a governing board would allow voice and participation in the direction of managed care organizations through consumer representatives. The power and operation of these boards varies widely, yet all may provide some opportunity for consumer representation.

For-profit MCOs are usually monitored by a board of directors, which oversees management and has power to dismiss the Chief Executive Officer. Elected by shareholders, directors are supposed to act in shareholders'

interests--not those of consumers. However, a few corporations have appointed a trustee to represent environmental interests (for example, Exxon after the Valdez oil spill). And in recent years, organized labor has purchased stock and been represented on the board of directors of some firms, for example, United Airlines. Consumer representatives might also be granted a seat on the MCO boards. However, without a constituency that owned stock, they would have less clout.

A board of trustees directs nonprofit MCOs. They are supposed to act in the interest of the public, which includes but is not limited to consumers. However, typically, there is no election or other mechanism to ensure that trustees represent the interests or views of consumers and it is usually management who nominates or chooses trustees. Nonetheless, nonprofit MCOs could place consumer representatives on their boards.

A cooperative is the easiest means to represent consumers in governance because it is the consumer members who vote for trustees. Group Health Cooperative of Puget Sound has health plan members vote for trustees. Even with consumers electing trustees, there are difficulties in fostering consumer participation and voice. And in the current healthcare market, starting a new cooperative would be difficult since a new nonprofit organization would have difficulty gaining access to capital or a significant membership.

Operations. Trustees and top management set the direction of a firm. Others control daily operations--which are crucial to organizational success. With increasing frequency, MCOs have physicians and other providers serve on committees or participate in groups that set medical protocols and organizational policies. Consumer views could also be represented on various MCO boards and committees that deal with operations. These might include boards reviewing grievances and appeals, committees that set policies for benefits covered, and committees that address particular issues of operations. n113 Voice in day-to-day operations could well have the greatest impact on how consumers experience managed care.

n113 Meredith M. Higgins, *Member Appeals for Payment of Non-Plan Care: Consumer Involvement in Review*, in PROCEEDINGS OF THE 1982 GROUP HEALTH INSTITUTE 337-43 (Group Health Association of America 1982).

Complaints and Grievances. Many states require MCOs to have an internal grievance process. The National Committee for Quality Assurance ("NCQA") also requires an internal grievance process for its accreditation; however, NCQA accreditation is not necessary for MCOs to operate in all states. Federally qualified HMOs must also meet provisions of the HMO Act of 1973. These provide an opportunity for consumers to voice their complaints or to appeal an MCO's denial of service. Complaints can be a source of information for management to supplement opinion surveys. Such mechanisms are a useful--yet limited--vehicle for individual consumer voice. Most consumers with problems do not bother to file complaints or appeal organization decisions, and many individuals do not have the resources to adequately represent themselves in the appeals process.

Many, if not most, MCOs review appeals internally according to their own organization's criteria. Such processes can weed out errors made by individuals in applying organizational standards and may help alert MCOs to problems of which they are not aware. However, they cannot help correct other problems resulting from MCO standards that consumers or others believe are inappropriate. To resolve such problems, there needs to be review by independent parties not chosen by the MCO.

Two approaches in particular could foster the role of participation and voice. First, MCOs might place members or consumer representatives on the committee that reviews complaints and appeals, perhaps as a majority. Second, MCOs could be required to publish information about the complaints received and their resolution. The first approach allows consumers a role in administering standards. The second would help ensure that problems receive the attention of top management, because the MCO would seek to avoid the negative publicity of unfavorable reports.

Advisory Boards. Advisory boards can be used in multiple areas of an MCO, including oversight, governance, and

operations. Advisory boards can range from those created with specific mandates and limited time spans to standing boards or committees of general jurisdiction that can offer continuing feedback and address numerous issues as they arise. Some of the most effective advisory boards are those convened to address specific issues. They have a focus and bring together people chosen for a distinct task. For example, several electric, gas, and telephone **companies** have convened advisory groups for advice on creating billing statements that are easier for consumers to read and understand. Kaiser Permanente has recently convened a blue ribbon advisory panel to advise it on improving its system for arbitrating malpractice claims. Advisory boards are frequently used to represent the views of consumers or other groups. They allow firms to obtain advice, satisfy demands for change, and yet still leave management discretion in decisionmaking if they do not wish to follow the advice.

Public Opinion Surveys and Focus Groups. MCOs typically survey consumer opinion using focus groups, satisfaction surveys, exit polls, and other approaches. Such information helps management obtain information to gauge consumer wants and correct problems. It can be used for marketing purposes as well. If conducted properly, surveys can more accurately and precisely measure the opinion of MCO members, or of particular groups within MCOs than can voice expressed through representative institutions or advisory boards. Surveys also allow opinion gathering on detailed issues, something that representative institutions are not designed to do. Another advantage of such information to the firm is that it is usually confidential and there is little risk that the process of obtaining information will cause embarrassment, stir up consumer dissatisfaction, or lead to new consumer demands.

From the consumer perspective, most surveys of consumer opinion are limited because they are not instigated, directed, interpreted, or routinely accessible to consumers.ⁿ¹¹⁴ They remain a management tool and can be used for management's purposes. If consumers directed what would be surveyed and controlled the dissemination, such information could become a powerful tool for consumers.

ⁿ¹¹⁴ Some consumer surveys are publicly available, notably consumer satisfaction surveys conducted by the National Committee for Quality Assurance as part of their HEDIS (Health Plan Employer Data and Information Set) measures. Most MCOs, however, carry out many more surveys than this for internal use and these are usually not subject to outside scrutiny.

Consumer groups could design surveys and decide what questions are asked and how the answers are disseminated. Neutral outside groups, too, could design and carry out surveys. In any event, if groups outside of MCOs carry out a survey of several MCOs, this would facilitate comparison among organizations. If made public, such information could affect the choice of health plans by employers and consumers, which in turn could prompt MCOs to respond to consumer concerns.

B. Consumer Influence from Outside MCOs

Today there are more opportunities for representing consumers in institutions outside of MCOs than from within. The policies and actions of both private groups and public agencies influence MCOs.

1. Consumer Influence in the Public Sector

The public sector influences MCOs mainly through public purchasers, legislatures, administrative agencies, boards or commissions, ombud, grievance and appeal mechanisms, and courts.

Through legislatures, administrative agencies, the executive branch, and independent commissions, government has authority to act on behalf of the public, including consumers. Such public authority can provide a variety of ways to oversee MCOs for consumers. The most important are noted below.

a. State and Federal Legislatures. Elected by the public at large, legislatures are the classic democratic means to represent the public's views. Our system of interest group pluralism, however, assures that the best organized groups will be better able to influence legislators and are therefore most effectively represented.ⁿ¹¹⁵ It is typically producer or

provider groups--rather than consumers--that have concentrated interests and are most influential.

n115 Consumers tend to be underrepresented in groups that draft model legislation on insurance and other issues. See Norman I. Silber, *Consumer Participation in the Law-Drafting Process: Past, Present, and Future*, 9 ADVANCING THE CONSUMER INTEREST 27, 27 (1997).

However, on some issues consumer groups are able to marshal effective public support and form strategic alliances to enact legislation they favor. The recent outpouring of legislation restricting drive-through deliveries, gag rules, and other regulation of managed care show that consumer voice can result in legislation that changes how MCOs operate. The advantage of legislation is that it creates binding legal authority. Nevertheless, it is only one of several avenues for consumer voice, and it has limitations. It is easier to pass than implement legislation. Legislation is also time consuming and cumbersome. Moreover, it is usually more appropriate when used to address general problems, set broad standards, or create regulatory authority than to resolve detailed problems in the organization of managed care.

One potential use of legislation would be to create new institutions--both within and outside of MCOs--in which to represent consumers' views. Proposals promoting such organizational democracy will be viewed as radical and are unlikely to be enacted anytime soon. Ironically, experiments in organizational democracy might come about voluntarily as MCOs decide they would prefer to have consumers play a greater role within their own organizations rather than have them exercise their voice through legislation. Recent voluntary consumer protection standards proposed by the industry are an example of the managed care industry's response to consumer protection legislation and the prospect of greater governmental supervision. n116

n116 In the summer of 1997, Kaiser Permanente and Group Health Cooperative of Puget Sound combined with Families U.S.A. and the American Association of Retired Persons in calling for federal legislation to enforce new standards for managed care and a consumer bill of rights. However, the American Association of Health Plans promoted a program called "Putting Patients First" and suggested that a good deal of proposed legislation is not necessary or even helpful. In the spring of 1998, the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry proposed voluntary compliance with its proposed bill of rights. In the meantime legislation has been introduced in Congress and state legislatures that would implement some of the Advisory Commission's recommendations and/or further regulate managed care.

b. State and Federal Agencies. MCOs are now subject to divided oversight by multiple state agencies with diverse missions. These state agencies include those that regulate insurance, healthcare, private and charitable corporations, and Medicaid programs, as well as Attorney General Offices, which in most states have general jurisdiction to protect consumers. These agencies were not established for the purpose of overseeing managed care in a comprehensive way. The requirements of the agencies also vary. Some oblige MCOs to report information, while other state agencies approve an MCO benefit package and other terms of the contract with consumers. Still other agencies can investigate or sanction MCOs.

Consolidating some of these functions in a new agency would have advantages. n117 The new agency could oversee healthcare or managed care, acquire expertise, and develop a focus. Activities that now take place in different agencies could be coordinated more easily. If established with appropriate powers, the new agency would have tools to represent consumers that do not exist currently.

n117 The California Managed Health Care Improvement Task Force called for a new state agency to oversee MCOs to provide such coordinated oversight. On May 1, 2000, Governor Wilson recommended to a Little Hoover Commission that such a department be created. The proposed reorganization became law on July 1, 2000.

There are, however, limitations to a new agency. It may lack the political independence and strong mission for consumer protection that the Attorney General and other directly elected state officials now have. It might also lack the

powers, resources, or expertise of other state agencies. Also, if a single agency oversees all of healthcare or managed care, representing consumers may not take as high a priority given its multiple missions.

Today, several states have an office to advocate for consumers in utility rate-setting hearings or health insurance. It may conduct research, analyze evidence, and make recommendations in hearings. Such consumer bureaus serve as a model for representing consumers in managed care or healthcare more generally. Although such intervenors have focused on financial issues for consumers (cost savings from lower premiums/rates), intervenors in managed care could also focus on broader issues, including quality of care.

The Office of the Attorney General is a particularly appropriate site for a managed care consumer advocacy bureau. Attorneys General have an independent source of authority in that they are directly elected. They perform multiple functions, including enforcement of consumer protection laws, lobbying for new consumer legislation, resolution of consumer disputes through alternative dispute resolution, and public education on consumer issues. These features make the Office of the Attorney General institutionally flexible and competent to address new consumer issues. Other bureaus in various state agencies could also advocate for healthcare consumers if they were granted appropriate authority.

Federal agencies also oversee MCOs through various federal programs. These include the Health Care Financing Administration ("HCFA") (which is responsible for Medicare), the Department of Labor (which the Employee Retirement Income Security Act authorizes to supervise employee benefits, including health benefits of self-insured firms), the Veteran's Administration, and the CHAMPUS program. Consumers could be given more voice in policies that these agencies adopt.

HCFA has a list of 150 consumer advocacy groups, which it consults on various initiatives. All groups are invited to a monthly meeting; usually about forty-five attend. HCFA also consults with advocacy groups when issues arise. Recently it consulted consumer groups on marketing guidelines for HMOs and a booklet on consumer rights in HMOs. Several states also have consumer representatives on Medicaid advisory boards, and states have Medical Care Advisory Committees for Medicaid. The latter have not focused on managed care and have not generally had significant influence. n118 Several states have also held hearings in developing their Medicaid managed care programs.

n118 PERKINS ET AL., *supra* note 74.

c. State and Federal Boards or Commissions. State and federal governments frequently establish commissions, task forces, or boards to oversee a program or to investigate a problem; these groups can include consumer representatives. n119 Some are ad-hoc or short term, such as the Clinton Presidential Commission on Consumer Protection and Health Care Quality and the California Managed Health Care Improvement Task Force. Each of these has members who were appointed to represent the interests of consumers. Other long-standing commissions that influence policy include the Medical Payment Assessment Commission ("MedPAC"), the former Physician Payment Review Commission ("PPRC"), and the Prospective Payment Assessment Commission ("ProPAC"). These commissions do not have representatives appointed specifically to represent the interests of consumers; however, it may be appropriate to have consumer representatives in the future.

n119 Mary Kathryn Palladino, *Ensuring Coverage, Balance, Openness and Ethical Conduct for Advisory Committee Members under the Federal Advisory Committee Act*, 5 ADMIN. L.J. 231, 231 (1991).

d. State and Federal Ombud Program. State and federal governments could establish ombud programs for managed care plans that they oversee in Medicare and Medicaid. n120 Several states have established such programs. n121 Given appropriate new legislation they might also create similar state or federal programs for firms in the private sector as well. A useful model for such a program is the **nursing home** ombud created by the Older Americans' Act.

n120 For a comparison of ombud programs in several countries and its potential applications to U.S. governmental agencies, see WALTER GELLHORN, OMBUDSMEN AND OTHERS: CITIZENS' PROTECTORS IN NINE COUNTRIES (1966).

n121 OLSON AND PERKINS, *supra* note 74.

Nursing home ombuds have two main functions: (1) to advocate for individuals in **nursing homes** and other institutions for long term care; and (2) to advocate for policy changes and to promote the development of citizen organizations and resident and family councils. The Institute of Medicine evaluation of the long term Ombud program suggests that it is more difficult to successfully advocate for policy changes and integrate state policy than to perform individual advocacy services. Policy advocacy might be easier to perform if the program were not so decentralized.

The federal government funds the **nursing home** Ombud program and specifies the functions to be performed, but administration is carried out by states. State Units on Aging direct most programs and either report to the Governor or to larger agencies of which they are a part. The State Units on Aging often contract with public or private nonprofit agencies to carry out their responsibilities, but some hire staff and supervise volunteers directly.

State programs vary, of course, but all investigate and resolve complaints, monitor **nursing home** compliance with law, and disseminate information. Ombuds are directed to advocate for residents of long term care facilities rather than serve as neutral parties. **Nursing home** residents are guaranteed direct access to ombud services. States, too, generally are required to guarantee ombud access to **nursing homes** and patient records.

e. Medicare Appeals/Center for Health Care Dispute Resolution. HCFA hires an independent group--the Center for Health Care Dispute Resolution ("CHDR")--to review Medicare beneficiaries' appeals from denial of claims or services. The independent review that CHDR performs allows consumer voice to be heard by evaluators outside MCOs, and the information CHDR receives is available to HCFA administrators. Although the information is public, it is not publicized. Publishing and disseminating this information might make MCOs with problems more attentive and spur corrective actions.

f. State and Federal Courts. Consumers can use courts to voice their complaints and represent their interests on private and public disputes. Courts can order parties who cause consumers harm to pay compensation, or require private organizations to change their practices to conform to the law. The use of litigation to resolve individual disputes is very costly and often not economically viable except in class action lawsuits. Nevertheless, strategic lawsuits can change policy. For example, class action law suits were instrumental in getting HCFA to develop stronger due process rights in managed care. n122 Although other ways of representing consumer interests are often preferable, most parties do bargain with a sense of what they might win or lose if the disputes are resolved in court.

n122 See *Grijalva v. Shalala*, 946 F. Supp. 747 (D. Ariz. 1996), *aff'd*, 152 F.3d 1115 (9th Cir. 1998), *vacated*, 119 S. Ct. 1573, *remanded to* 185 F.3d 1075 (9th Cir. 1999).

Consumers have used courts to bring suits against private firms that do not respect their rights and against governmental agencies that do not perform their oversight roles. Recently, a federal court, although overturned on appeal, found that the Medicare system of grievance and appeals did not provide due process of law and ordered changes in the program. n123 And the California Supreme Court allowed a suit to proceed a suit which charged that an MCO had unfairly administered its binding arbitration system for resolving malpractice disputes. n124

n123 *Id.*

n124 *Engalla v. Permanente Medical Group*, 938 P.2d 903 (Cal. 1997); see EUGENE F. LYNCH ET AL., BLUE RIBBON ADVISORY PANEL ON KAISER PERMANENTE ARBITRATION, THE KAISER PERMANENTE ARBITRATION SYSTEM: A

REVIEW AND RECOMMENDATIONS FOR IMPROVEMENT (1998).

2. Consumer Influence in the Private or Nonprofit Sector

The main private and nonprofit sector influences on MCO policies come in four ways: from purchasers, private accrediting or standard setting agencies, Ombud programs run by private nonprofit groups, and public opinion surveys.

a. Purchasers of Healthcare and Third-Party Payors. Third-party payors and purchasers of healthcare negotiate with MCOs over benefits, premiums, quality, and the terms under which services are provided. Employers have used their purchasing power to negotiate arrangements they prefer for their employees. In some cases they have imposed more stringent demands on MCOs than most governmental rules. Employers have represented their interests as individual firms and sometimes collectively through purchasing cooperatives which pool the purchasing power of several firms or governmental agencies. These include the Pacific Business Group on Health and the Washington State Health Care Authority. ⁿ¹²⁵ Purchasing cooperatives can coordinate the views of disparate purchasers and bargain with MCOs. Because they control the flow of funds to MCOs, they can have extraordinary clout.

ⁿ¹²⁵ There are also public sector group purchasers of healthcare, such as the California Public Employees Retirement System ("CalPERS").

While purchasing cooperatives buy health insurance on behalf of their employee-consumers, it is employers who control what is purchased, and their interests are not always the same as employees. What is now lacking in purchasing cooperatives are mechanisms for directly representing consumers. Consumers neither control the funds nor have sufficient clout to have a significant role. In the future, employee-consumers might seek representatives on boards of purchasing cooperatives. Representatives might be appointed by unions, elected by employees, or jointly chosen by management and employees.

There are also some opportunities to represent consumers for firms that self-insure. Union or other employee representatives could participate in the oversight or management of the managed care plan. Representatives could provide advice or participate in the management or operation of health plans. Even with third-party payors, such as Blue Cross-Blue Shield or private insurers, there are opportunities for representing consumers.

b. Private Accrediting or Standard Setting Organizations. Several private organizations set industry standards or draft model laws for MCOs. These include the NCQA, the Foundation for Accountability ("FACT"), the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO"), and the National Association of Insurance Commissioners ("NAIC"). Most, if not all, now designate consumer representatives either to advise them or to serve on committees that develop standards. Representation of these groups is a constructive way to affect the practices and policies of the managed care industry.

Standard setting organizations use a variety of ways to select consumer representatives. For example, the NAIC, which drafts model state laws on insurance, budgets \$ 60,000 a year to pay the out-of-pocket expenses of the twelve consumer representatives who participate in quarterly meetings and work groups. Approximately 1500 individuals, primarily from the insurance industry and state insurance agencies, attend the quarterly meetings. Consumer representatives take part in meetings and offer advice and comments on draft model laws. But only insurance commissioners or their staffs are on the committees that draft the model laws.

The funding for the twelve NAIC consumer representatives is awarded by the ten-person board, which includes five insurance commissioners and five consumer representatives serving staggered terms. The five insurance commissioners and those consumer representatives continuing on the board select the new consumer board members. ⁿ¹²⁶ The board reviews applications from individuals or groups and decides which individuals would be most appropriate to fund, considering both the group represented and the financial needs of the organization.

n126 Three of the insurance commissioners on the board are officers of NAIC elected by insurance commissioners. They choose the other two insurance commissioners on the board.

The NAIC and other standard setting organizations have chosen individuals with credible qualifications to represent consumers. Having consumer representatives ensures that some consumer concerns are heard. However, these representatives usually lack time and resources--and sometimes expertise as well. Currently, representatives are not accountable to consumers in general, although members of consumer organizations are likely to represent at least the views of those organizations. n127 The small number of consumer representatives in these standard-setting organizations also reduces their influence.

n127 Silber, *supra* note 115.

Standard setting organizations such as NCQA and JCAHO also evaluate MCOs as part of the process of granting accreditation. HCFA also inspects HMOs that participate in Medicare. Typically, consumer representatives do not participate in these inspections and lack access to the detailed findings.

Standard setting organizations affect the practices of the managed care industry across the board. Involving consumers at this level can have a national impact and may eliminate problems by ensuring that all MCOs conform to minimum standards. However, consumers may also seek opportunities to address the problems of individual MCOs and for this they will need to become involved within MCOs.

c. Privately Run Ombud or Independent Assistance Programs. Such programs can help consumers when they have difficulties in dealings with MCOs. Ombuds assist consumers with grievances, identify systematic organizational or industry problems, and make recommendations for addressing them. In brief, they represent consumer interests and voice their concerns.

The classic tension in Ombud programs is between independence and control. Ombud programs lodged within a MCO or governmental agency may lack independence, either in action or funding, but they are likely to have greater authority and the ability to contact directly and influence key individuals who can resolve the problem. Free-standing programs are more likely to be independent but are also more likely to be perceived as outsiders; they have less influence and often lack knowledge of the most effective means to address the organizational problem. In general, the program's effectiveness depends on the skills of the individuals who run it and the way it is organized and financed.

One way to set up an Ombud or independent assistance program is for the state to contract with independent organizations to perform these functions for an area. For example, the Center for Health Care Rights in Los Angeles, with funding from private foundations, runs an independent assistance program for members of managed care organizations in four counties in the Sacramento area. n128 It operates a hot line, makes referrals, offers advice, and collects complaint information for analysis, intervention, and public dissemination. It also assists individuals in filing appeals within MCOs.

n128 There are other notable programs run by nonprofit agencies, such as the *Medicare Rights Center*, and plans run by for-profit groups, such as *Patients First* and *Care Counsel*.

One important feature of independent assistance/Ombud programs is often overlooked: the link between individual assistance and advocacy and efforts to address systemic problems. With appropriate resources, programs that provide services for individuals are able to identify patterns that reveal problems best addressed through general organizational or policy changes. If these problems are then addressed, the Ombud/independent assistance program will have helped all consumers, not only those who voiced their complaints and sought assistance. The broader the base of consumers served by the ombud, the more easily such systemic change is facilitated. However, certain populations, such as

Medicare beneficiaries, may have special concerns. These concerns might be better addressed by Ombud programs designed to serve them exclusively. The Medicare Rights Center performs such a role now, and future assistance programs could be created to serve other groups.

d. Public Opinion Surveys. Surveys reveal the views of consumers who do not normally voice their opinions or actively participate in organizations. They also enable complex analysis of how the opinions or experience of consumers vary depending on several variables, including different social characteristics, diverse organizations or medical practices, and how these change over time. They can be a powerful tool to discern consumer views and perceptions. MCO management, consumer advocates, representatives, and public officials often use surveys to inform their choices.

There are advantages in having independent groups poll consumers using surveys and focus groups, rather than rely on the survey information provided by MCOs. The results may be less biased. An independent group can also obtain information across MCOs using the same survey instrument, thereby facilitating comparison. In addition, independent groups can design surveys to obtain the information that consumer advocates and representatives need rather than rely on information obtained for purposes of marketing or other uses by MCOs.

The information that independent groups obtain from surveys is not a substitute for consumer participation. Information alone does not produce change. Nevertheless, the information can be reported to and used by consumer groups and representatives (as well as MCOs and public officials).

IV. Voice and Representation in Perspective

Today, MCOs benefit from public subsidies, exercise authority over individuals, and redistribute and ration resources. MCOs thus have enormous influence over the kinds of services that individuals receive and the quality of their lives. In effect, private institutions are assuming public functions. Yet, most individuals have little choice over whether or not they receive healthcare through such organizations. By and large, public policy treats MCOs as if they were merely private organizations that only incidentally affect the public. Yet the enormous influence that such institutions play in making policy suggests that the public should have a greater voice in the policies and processes of MCOs. Moreover, the usual approach to making organizations respond--letting individuals choose among competing providers--is not sufficient to make MCOs accountable to the public.

Relegated to the periphery of our healthcare system for most of the last thirty-five years, consumer voice and representation currently play only a minor role. There are, however, several models for representing consumer interests. This Article explores the pros and cons of options to represent consumers. These include a variety of ways to exercise voice within MCOs and additional ways to represent consumers within public and private institutions that affect the policies of MCOs. We may also need to create new ways in which the consuming public can exercise its voice in MCOs.

There are also, of course, limitations of consumer voice. Unchecked, consumer voice could lead to as much imbalance as when the healthcare system is dominated by providers. Consumers might demand too many services. Consumer groups may become divided and polarize issues, leading to increased conflict.ⁿ¹²⁹ The idea of participation might become a goal in itself rather than a means to improve services for MCO members.ⁿ¹³⁰ Consumer voice can make decisionmaking slower and less efficient and organizational planning more complex.ⁿ¹³¹

ⁿ¹²⁹ Frank Reissman and Alan Gartener, *Community Control and Radical Social Change*, 1 SOC. POL'Y 52, 54 (1970); see MOYNIHAN, *supra* note 67.

ⁿ¹³⁰ Daniel M. Fox & Jean W. Wofford, *Citizen Participation: A Substitute for Action*, 32 HEALTH EDUC. MONOGRAPHS 37 (1972).

n131 Robert A. Aleshire, *Power to the People: An Assessment of the Community Action and Model Cities Experience*, 32 PUB. ADMIN. REV. 428 (1972); Sidney Verba, *Democratic Participation*, 373 ANNALS AM. ACAD. POL. & SOC. SCI. 53-78 (1967).

However, these are not the problems of our healthcare system today, and they can best be addressed when consumer representation develops a more significant role. We currently lack a reasonable balance between consumer voice and management. The overriding problem of MCOs today are the absence of effective consumer voice or institutions to represent consumer interests. n132 Rather than too much consumer involvement, it is far more likely that MCOs and other organizations might create institutions to represent consumers that are symbolic rather than real. n133 Symbolic representation might then be used to contain consumer involvement to minor choices, or to co-opt consumers into supporting the decisions and plans set by management rather than promoting accountability. n134 There is also the risk of providers masquerading as consumers.

n132 Rodwin, *supra* note 10, at 48.

n133 For a summary of strategies used to thwart effective participation and also the problems in achieving effective citizen or community control, see James Riedel, *Citizen Participation: Myths and Realities*, 32 PUB. ADMIN. REV. 211 (1972).

n134 Metsch & Veney, *supra* note 71.

Today, the public needs a greater consumer role in the governance, operations, and oversight of MCOs. To be effective, representatives must have real authority and influence, rather than merely the ability to offer advice, or participate in decisionmaking in a tangential way. The experience of public representation in other areas suggests that constituencies need to be organized to effectively represent consumers and that representatives need to be answerable to these constituencies. Training, funding, and support by constituency organizations are also important if representatives are to play an effective role.

Our future challenge is to foster balanced and effective use of consumer voice. Under the right circumstances, consumer involvement can put managers in touch with the experience and desires of customers and be a countervailing power to providers, insurers, and payors. n135 It can set priorities for benefit coverage, make public the means and criteria by which MCOs make decisions about rationing, and require managers to account for their decisions. It can set organizational standards. Enhancing consumer voice should not be merely another way to implement policy; rather, it can be a vehicle to transform it. Consumer voice can be an engine for change when other means do not work.

n135 Increased political participation is a feature of modern political systems. See Samuel P. Huntington, *Political Development and Political Decay*, 17 WORLD POL. 386, 388-89 (1965).

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LENGTH: 20328 words**TITLE:** Schiavo's Lessons For Health Attorneys When Good Law Is All You Have: Reflections Of The Special Guardian Ad Litem To Theresa Marie Schiavo**AUTHOR:** Jay Wolfson *

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TEXT:

ABSTRACT: Rarely have all the branches of federal and state government converged upon a single issue, a single person as they did in the tragic and acrimonious case of Theresa Maria Schiavo. In late 2003, the Florida Legislature passed what become known as "Terri's Law" and in Spring of 2005, Congress and the President of the United States sought to directly intervene in the care of the severely brain damaged woman. During that period, the state and federal court systems, through the highest courts in both venues, ruled on Ms. Schiavo's life, resulting in the removal of an artificial feeding tube and her death during Easter week. The legal and medical issues in this complex, politically and emotionally charged case continue to raise important questions for health attorneys. In this Article, Professor Wolfson, who served as the legislatively mandated, court appointed special guardian ad litem for Theresa Schiavo in late 2003, provides a distinctive first-person overview of the *Schiavo* case.

In October of 2003, the Florida Legislature passed Florida H.B. 35 E, which became known as "Terri's Law." n1 It afforded Florida Governor Jeb Bush the prerogative of intervening in the nearly ten year court battle over the guardianship and control of Theresa Marie Schiavo, a severely brain damaged woman. Ms. Schiavo's artificial feeding and hydration tube was disconnected subsequent to a court order following years of litigation between her guardian husband and her parents. Within days, the Florida Legislature convened in an extraordinary session to create a constitutionally distinct statutory vehicle by which the Governor could re-insert the tube pending a study performed by a specially appointed guardian ad litem.

n1 H.B. 35-E, 2003 Leg., Spec. Sess. E (Fla. 2003).

I was appointed to this special guardianship and given thirty days to conduct a comprehensive legal and medical review of the previous fourteen years of records. The purpose of the appointment was to provide the Governor and courts with guidance in determining whether additional tests should be performed. During that thirty day period, I reviewed and analyzed more than 30,000 medical and legal documents.

I spent twenty of those thirty days with Ms. Schiavo for up to four hours a day, sometimes more than once each day. I held her hand, stroked her hair, played music for her, cajoled, indeed, begged her to display responsive (rather

than reflexive) behaviors. In addition to the medical and legal evidence in the file, and the reports of family, hospice staff, and attorneys, I sought some independent understanding of her condition and state. I met and worked with family members and attorneys on both sides of the dispute.

Healthcare attorneys often have to delve deeply into technical areas of medicine or policy. For many of us, translating aspects of science, technology, and clinical practice is an important part of our work. As a research professor of health law at a university and law school, I often work closely with clinicians, scientists, and practitioners to communicate information effectively and accurately to policymakers, the press, and lay groups. My responsibilities include the design and conduct of scientific studies. Additionally, my principally defense practice involves a variety of issues including fraud and abuse and representation of healthcare professionals before state licensure boards. This requires me to translate state and federal policy into and out of practice settings and negotiate disputes among parties. I had never served as a guardian ad litem and had not followed the details of what had already become a nationally prominent case.

I. The Legal Context

Florida H.B. 35 E was a curious and distinctive piece of legislation, passed in a special session of a tumultuous legislative cycle. There were five special sessions of the Florida Legislature in 2003, the final one coming less than one week after Ms. Schiavo's feeding and hydration tube was surgically removed. The Florida Legislature convened, then quickly crafted a law that afforded the Governor of Florida

the authority to issue a one-time stay to prevent the withholding of nutrition and hydration from a patient if, as of October 15, 2003: (a) That patient has no written advance directive; (b) The court has found that patient to be in a persistent vegetative state; (c) That patient has had nutrition and hydration withheld; and (d) A member of that patient's family has challenged the withholding of nutrition and hydration. n2

n2 *Id.*

The language was crafted in such a way that, although it never specifically mentions her, it could only apply to one person, Theresa Schiavo.

Upon the issuance of the stay, a guardian ad litem (GAL) was to be appointed by the Chief Judge of the circuit court to make recommendations to the Governor and the court.

On October 31, 2003, following the directives of the law, the Chief Judge of the Sixth Florida Judicial Circuit appointed me as the GAL with the following charge:

[M]ake a report and recommendations to the Governor as to whether the Governor should lift the stay that he previously entered. The report will specifically address the feasibility and value of swallow tests for this ward and the feasibility and value of swallow therapy. Additionally, the report will include a thorough summary of everything that has taken place in the trial court and the appellate court concerning this case. n3

n3 Jay Wolfson, A Report to Governor Jeb Bush and the 6th Judicial Circuit in the Matter of Theresa Marie Schiavo, abstractappeal.com/schiavo/WolfsonReport.pdf (Dec. 1, 2003) (last visited Sept. 21, 2005) ("GAL Report"). The GAL Report also is attached as *Appendix A* to this Article.

Florida law affords considerable scope and flexibility in the duties and powers of a GAL, as set forth in section 61.403 of the Florida Statutes. n4 The statute makes it clear that the responsibility of the GAL is to act in the best interests of his or her charge and not as an attorney or advocate. In furtherance of this duty the statute grants broad powers to the GAL "to the extent necessary to advance the best interest of the child," including but not limited to: investigating the allegations of the pleadings by interviewing the parties; obtaining orders allowing the GAL to inspect and copy records; obtaining examinations of the parties by doctors or psychiatrists; making recommendations to the court; and filing pleadings, motions, or petitions for relief. n5

n4 FLA. STAT. § 61.403 (2005).

A guardian ad litem when appointed shall act as next friend of the child, investigator or evaluator, not as attorney or advocate but shall act in the child's best interest. A guardian ad litem shall have the powers, privileges, and responsibilities to the extent necessary to advance the best interest of the child, including, but not limited to, the following:

- (1) The guardian ad litem may investigate the allegations of the pleadings affecting the child, and, after proper notice to interested parties to the litigation and subject to conditions set by the court, may interview the child, witnesses, or any other person having information concerning the welfare of the child.
- (2) The guardian ad litem, through counsel, may petition the court for an order directed to a specified person, agency, or organization, including, but not limited to, hospitals, medical doctors, dentists, psychologists, and psychiatrists, which order directs that the guardian ad litem be allowed to inspect and copy any records and documents which relate to the minor child or to the child's parents or other custodial persons or household members with whom the child resides. Such order shall be obtained only after notice to all parties and hearing thereon.
- (3) The guardian ad litem, through counsel, may request the court to order expert examinations of the child, the child's parents, or other interested parties in the action, by medical doctors, dentists, and other providers of health care including psychiatrists, psychologists, or other mental health professionals.
- (4) The guardian ad litem may assist the court in obtaining impartial expert examinations.
- (5) The guardian ad litem may address the court and make written or oral recommendations to the court. The guardian ad litem shall file a written report which may include recommendations and a statement of the wishes of the child. The report must be filed and served on all parties at least 20 days prior to the hearing at which it will be presented unless the court waives such time limit. The guardian ad litem must be provided with copies of all pleadings, notices, and other documents filed in the action and is entitled to reasonable notice before any action affecting the child is taken by either of the parties, their counsel, or the court.
- (6) A guardian ad litem, acting through counsel, may file such pleadings, motions, or petitions for relief as the guardian ad litem deems appropriate or necessary in furtherance of the guardian's function. The guardian ad litem, through counsel, is entitled to be present and to participate in all depositions, hearings, and other proceedings in the action, and, through counsel, may compel the attendance of witnesses.
- (7) The duties and rights of nonattorney guardians do not include the right to practice law.
- (8) The guardian ad litem shall submit his or her recommendations to the court regarding any stipulation or agreement, whether incidental, temporary, or permanent, which affects the interest or welfare of the minor child, within 10 days after the date such stipulation or agreement is served upon the guardian ad litem.

n5 *Id.*

In this case, however, the court ordered charge was more of a "special guardian ad litem" appointment, specific and narrowly constructed, especially with respect to which questions were to be addressed. Some might argue the task assigned reflected duties similar to a Special Master as opposed to somebody representing the interests of the ward. The language of the general statute makes it clear that a GAL serves in the "best interests" of the ward--not as an advocate or attorney. Acting in somebody's best interests is not the same as advocating for them. This may be because the entire principle of "best interests" carries with it what have emerged post-Schiavo as profound ambiguities and possible

difficulties. There is little doubt these ambiguities and difficulties are likely to be addressed by state legislatures as they revisit the way decisions are made in lieu of express, written advance directives.

II. My Appointment and its Challenges

Following the passage of the special session law, the judicial system sought to comply with the directive to appoint the GAL. I was nominated by several sources upon inquiry from the courts and Governor's office, and received a phone call asking if I would be interested in serving on the case. The court system could pay me \$ 50 per hour, and I would have thirty days to perform the totality of tasks. These were the only directions provided, and I could not receive any further instruction. Once I accepted, I worked closely with the court administrator for the Sixth Florida Judicial Circuit in accessing all documents; and sought to establish close, working relationships with the family and with attorneys for all of the parties, including the Governor's office.

The role of Special Guardian in *Schiavo* presented several challenges:

- . zealously representing the interests of my ward, Ms. Schiavo, within the framework of the Florida Guardianship Law n6 and the Florida Advance Directive Statutes; n7

- . responding to the distinctive and express charges of the state law that appointed me--requiring that I carefully and completely apply the best knowledge regarding medical standards to her case within the construct of Florida Rules of Evidence, Florida Rules of Civil Procedure, the Florida Guardianship and Advance Directives Statutes, and Florida case law; and

- . functioning within an exceptionally charged political and media environment without losing sight of the professional responsibility and the importance of applying good law and good medicine.

n6 *Id.* §§ 744.101-.715.

n7 *Id.* §§ 765.101-.113.

The technical and evidentiary issues I confronted were daunting. The court documents consisted of boxes of files containing medical records, test results, memoranda of law, depositions, hearing transcripts, correspondence, details of trust expenditures, hundreds of motions, judgments, dozens of appellate filings, cartons of evidence, sealed files, and miscellaneous folders, personal artifacts, and photographs.

Where to start? I began with a manually constructed chronology and document map--sorting out the history of the case, legally and medically, and attempting to discern the nature and scope of the tens of thousands of pages contained in the court records. Within days of my appointment, I met with the two lead attorneys in the case, Pat Anderson for Ms. Schiavo's parents, the Shindlers, and George Felos for her husband, Michael Schiavo. They were helpful in providing chronologies and focus on the hot button evidentiary issues that had characterized the case. In addition, some of the appellate documents contained cogent case chronologies. The combination of these resources provided me with a map of where the case had traveled over a ten year period, what had been addressed, and how the courts had responded to the myriad issues.

With this overview in place, I was able to focus on my charge of addressing the issue of Ms. Schiavo's ability to swallow, which had been the principal concern of the Governor. Swallowing was important because if Ms. Schiavo had the capacity to swallow, she would not require artificial feeding and hydration. Therefore, the evidentiary foundations relating to the swallowing issue served as my guideposts. In terms of medicine and science this meant quite a bit, given the physiology of swallowing and the nature of the underlying condition(s) afflicting Ms. Schiavo. The research

demanded a considerable reference to the neuro-sciences.

I was fortunate to have some clinical knowledge and experience, and access to clinicians and researchers at my own medical school and colleagues around the nation. I also knew that I would have to do what many trial attorneys do--dig a deep and narrow path into the technical aspects of the case by reading the scientific literature and familiarizing myself with how other jurisdictions have dealt with similar matters. My modest background in physiology and anatomy was refreshed, and I engaged the literature on neuro-anatomy, neuro-physiology, swallowing disorders and tests, persistent vegetative states, minimally conscious states, and locked-in syndrome.

Throughout the effort I had to keep legal measures in mind, specifically, the Florida Rules of Evidence and the Florida Rules of Civil Procedure, and the requirement that evidence regarding the core decisions in the case meet a clear and convincing test.

There was no single template. I elected to allow the law to guide my assessment of the process, and good science and medicine to guide my assessment of the substance. Keeping personal biases separate remained a constant issue.

I worked from early morning till late in the afternoon in the courthouse, ravenously perusing documents out of numbered folders in boxes brought to me non-stop. I kept notes of the categories and substance of documents I was reviewing. I arranged for copies of thousands of documents to be made so that I could continue my review at home. I would alternate mornings, afternoons, and evenings meeting with Ms. Schiavo, her family members, the attorneys, or with medical or legal colleagues. Several of my colleagues made themselves available to me for consultation, and I am sure I imposed on others. One, in particular, Professor Rebecca Morgan, Chair of Elder Law at Stetson University College of Law, was literally available twenty-four hours a day and served as my personal counsel. Other attorneys and physicians were invaluable sources of technical information.

Tracking the case, keeping the facts straight, focusing on the points of law, legal process, and legal reasoning are things we are taught to do in law school. This was a marathon experience. Maintaining a physical log of what I was doing and creating what amounted to a war room in my house made it possible to construct some order and trajectory in the face of the masses of documents.

I refused to interact with the press and had the advantage of knowing many of the producers and editors. I made it clear that this was a private, family matter, that I had been appointed to serve in a special capacity, and that I would not speak about the case at all. My requests were honored, and I gave no thought to the press machinations. I began receiving thousands, probably tens of thousands, of emails from all over the world. Only a few were negative--most were offers of support, best wishes, documents, and articles. Most were in support of keeping Ms. Schiavo alive. Many were deeply emotional. Some were from family members of severely disabled persons, offering to share their experiences with me.

My family, friends, and colleagues were supportive. I often functioned on adrenaline, sleeping only a few hours a day, and sometimes working without sleep for two days. It was very similar to intense litigation preparation; however, I had no staff, though my wife, who is also an attorney, helped me to organize my notes and thinking as the deadline approached. I read all of the documents myself, took notes, pasted maps and chronologies throughout work areas in my home and office, and sought to maintain order and focus on the court's charge. My legal training and experience, combined with my extensive research and writing experience served me well.

Given the above prelude, I will now discuss the specifics of the case. The law of death is not usually polite conversation in health law, except among bioethicists, pathologists, and risk managers, or during estate planning. We tend to focus on fraud and abuse, intellectual property, contracts, transactional matters, government regulation, and reimbursement. For most health lawyers, *Schiavo* may have played out in the margins of their practice--unless they represented Catholic healthcare facilities following Pope John Paul II's non-encyclical, personal admonition against terminating artificial nutrition. n8 In the midst of the *Schiavo* dispute, the Pope stated that nutrition and hydration were

not artificial medical interventions, and that they should not be removed to hasten death. n9 This statement rocked Catholic healthcare organizations, particularly in the face of years of existing accepted practice, underwritten by the U.S. Congress of Bishops, accepting the termination of artificial nutrition in specific circumstances. n10

n8 Pope John Paul II, *Life-Sustaining Treatments and Vegetative State: Scientific Advances and Ethical Dilemmas*, Address to the Participants in the International Congress (Mar. 20, 2004), at www.vatican.va/holy_father/john_paul_ii/speeches/2004/march/documents/hf_jp-ii_spe_20040320_congress-fiamc_en.html (last visited Sept. 10, 2005).

n9 *Id.*

n10 SECRETARIAT FOR PRO-LIFE ACTIVITIES, U. S. CONG. OF CATH. BISHOPS, NUTRITION AND HYDRATION: MORAL AND PASTORAL REFLECTIONS, at Conclusion (1992), at www.usccb.org/prolife/issues/euthanas/nutindex.htm (last visited Sept. 10, 2005); see John F. Kavanaugh, *Artificial Feeding: The Pope's Argument Rests on Human Rights. Why Can't We See That?*, AM.: NAT'L CATH. WKLY., June 21, 2004, at 7, available at <http://tinyurl.com/8n9fe> (last visited Nov. 20, 2005).

The law in the matter of Theresa Marie Schiavo raised issues of death and dying to a level that involved a state governor and legislature, the U.S. Congress, the President of the United States, and the courts at all levels, both state and federal.

The world watched as Theresa Schiavo's partially naked, obviously disabled person was displayed on TV and in the tabloids. The legal battles between her parents and her husband, which had raged in the Florida courts for a decade, catapulted into the federal system as family members, persons genuinely concerned about clarifying the rights of disabled persons, and some political opportunists all dove into the waiting pools of media attention and law-making frenzy. In the process, the underlying science, medicine, and law directly affecting the case were subjected to legal and religious challenges, interpretations, and even gross misrepresentations. Ms. Schiavo's personal circumstance occurred just at the right time to help create a perfect storm for a passionate political, legal, religious, and media hurricane.

III. The *Schiavo* Case Story

Theresa and Michael Schiavo had been married for six years, and were living in St. Petersburg, Florida, not far from Theresa's parents and siblings. As a child in Philadelphia, Ms. Schiavo had weighed 250 pounds, but at age eighteen, she decided to lose weight, and had dropped to 150 pounds. It was at this point that she met Michael. They wed and she continued to lose weight, until she suffered a cardiac arrest, in the early morning hours of February 25, 1990, when she weighed only 110 pounds. That night, Ms. Schiavo collapsed at home, her husband called 911, and about 11-12 minutes later the Emergency Medical Technicians arrived. They performed CPR, intubated her, and brought her to a hospital about an hour later, where she was trached and placed on a respirator. She remained in a coma for a month, and when she emerged was diagnosed as being nonresponsive and vegetative. She received physical and occupational therapy for more than three years and was brought to California to have electrodes implanted in an effort to stimulate her brain. Mr. Schiavo and his mother-in-law, Mary Schindler, worked as a tireless team, providing care and nearly full time personal attention to the woman they both loved. Extensive neurological testing determined over and over that she had lapsed into a persistent vegetative state, with no hope of recovery. The brain damage caused by the lack of oxygen following her cardiac arrest was profound.

For about eighteen months prior to her collapse, the Schiavos had sought fertility counseling in an effort to have a child. Subsequent to the accident, Mr. Schiavo initiated a malpractice lawsuit against the treating obstetrician, alleging that a complete and proper history and physical examination had never been performed--and that if they had, Ms. Schiavo's possible eating disorder might have been diagnosed. Many attorneys refused the case, and a reading of the complaint does not offer much promise of success. Nonetheless, three years later, a sympathetic jury awarded Mr. Schiavo \$ 300,000 for loss of consortium, and Ms. Schiavo more than \$ 700,000, placed in a court supervised trust,

intended for her maintenance.

The autopsy performed by the medical examiner in 2005 did not rule out bulimia as a factor causing her cardiac arrest, but no cause of her initial collapse was determined. The final autopsy revealed brain damage even more extensive than had earlier been diagnosed, and the medical examiner emphatically stated that Ms. Schiavo could never have experienced a recovery, though she could have remained alive for some time with artificial nutrition and hydration. Her formal cause of death was dehydration, commonly associated with a "natural" death when food and water are no longer administered. There has never been any basis for substantiating any claims of abuse or mistreatment, despite post-mortem sensationalists proffering unfounded theories about how Ms. Schiavo may have collapsed in the first place.

Within a year of the malpractice settlement, Mr. Schiavo, having been told consistently that there was no hope of recovery, began the process of making the decision to withdraw artificial life supportⁿ¹¹ because his wife was in a persistent vegetative state (one of the "end of life" conditions for which artificial feeding could, by law, be removed).ⁿ¹² At this juncture, there occurred a rift between Mr. Schiavo and his in-laws, the Schindlers. What had been a closely knit family devolved rapidly into a media-fueled feud. Mr. Schiavo had been appointed to serve as his wife's guardian shortly after her accident, without any objection from the family. His decision to remove the feeding/nutrition tube caused her parents to challenge his guardianship powers.

ⁿ¹¹ Florida law defines a "life prolonging procedure," or artificial life support, as including "artificially provided sustenance and hydration." FLA. STAT. § 765.101(10) (2005).

ⁿ¹² *See id.* § 765.305.

Ms. Schiavo did not have a written advance directive--no healthcare surrogate and no living will. In these circumstances, Florida law provides for the application of a substituted judgment test by the guardian, in the best interests of the ward.ⁿ¹³ It also provides for the introduction of parol evidence in support of what the incapacitated ward's intentions might have been.ⁿ¹⁴ Mr. Schiavo introduced what amounted to hearsay evidence, statements made by Ms. Schiavo in the presence of others, on at least two occasions (funerals of relatives) where she allegedly stated that she would never want to be kept alive by artificial means. This evidence was challenged by the parents who also sought to introduce clinical evidence that Ms. Schiavo was not in a persistent vegetative state and that she did have a reasonable medical hope of recovery. Toward this latter end, the Schindlers relied upon the testimony of physicians who were not able to produce any published studies, written by them or anybody else, to substantiate their clinical findings and prognoses given the documented facts in her case history and the contrary testimony of other medical experts.

ⁿ¹³ *See id.* § 765.401(2).

ⁿ¹⁴ *See id.*

The bottom line with respect to the clinical evidence was that a panel of medical experts was assembled by the courts. Two were selected by Mr. Schiavo, two by the Schindlers, and one by the court. They each examined Ms. Schiavo and her medical record, and reported to the court. Their reports and their testimony were subjected to the clear and convincing test, per the Florida Rules of Evidence. By this standard, the clinical evidence substantiating the diagnosis of persistent vegetative state was met, and the Schindler's experts failed sorely to counter the medical and scientific evidence presented by Mr. Schiavo.

It was in these matters that principles of health law, as they relate to standards for expert testimony, such as the *Daubert* and *Frye* tests,ⁿ¹⁵ came into play, and my acquired knowledge of the health and medical care system were useful in interpreting the masses of data. Additionally, I had access to neuroscientists and other clinical specialists

across the nation who were willing to review aspects of Ms. Schiavo's case and provide clinical guidance regarding the validity and merit of the data in her file.

n15 *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579 (1993); *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923).

With respect to Ms. Schiavo's intentions, Florida's Rules of Evidence and Civil Procedure again played a vital role, along with the Florida Guardianship Law, n16 and previous Florida case law. n17 The evidence presented by Mr. Schiavo in support of his contention that his wife would not wish to be kept alive met the clear and convincing standard test as well. The Shindlers reduced the credibility of their objection by testifying that even if their daughter had executed a living will, they would have fought to nullify it; and by further stating that keeping her alive brought *them* "joy." Allowing these views to be entered into the record damaged the Schindler's case. When I spoke with them about this, they said that they did not really mean the things that had been elicited during testimony--but had been backed into making those statements by a very effective attorney.

n16 FLA. STAT. § 744.401(3) ("[A] proxy's decision to withhold or withdraw life-prolonging procedures must be supported by clear and convincing evidence that the decision would have been the one the patient would have chosen had the patient been competent.").

n17 *In re Guardianship of Browning v. Herbert*, 568 So. 2d 4 (Fla. 1990).

Throughout my tenure as Ms. Schiavo's special guardian ad litem, I was deeply moved by the love and care that both her parents and her husband had for my ward. I was struck by the impossible position of parents faced with a child predeceasing them and with the prospect of standing by and watching their child die. The Shindlers are decent, caring people, who found themselves in a horrible and painful circumstance. Mr. Schiavo sought to fulfill what he believed to be his wife's intentions and did so at the expense of vilification. There was no life insurance policy and no money left in the trust fund from which he would benefit.

In my report to the Governor and the court, I concluded that sometimes good science, good medicine, and good law are not sufficient. In this matter, the person of Theresa Schiavo became lost in the media and political process, particularly during the last two years of her life, when third-party interests attached themselves to her case. Yet in the midst of the fury and controversy, there was one venue that exercised ultimate control over the circumstances: the courts.

The local courts in this case held innumerable hearings, often on the same topic, often responding to nearly identical motions. A review of the lower court decisions indicates remarkably meticulous and sensitive analyses and dispositions. Judge George Greer, who had local responsibility for the case, provided carefully crafted, thoughtful orders and decisions throughout the pendency of the protracted litigation. His decisions were consistently reviewed favorably by the state appellate and state supreme courts--and ultimately, by the federal courts. In the face of remarkable legislative activism and executive branch outcry, the judicial branch maintained a consistency, not only in the conclusions of law, but in the scope and sensitivity of the analyses that each court brought to the written opinions. At the federal court level, Judge James Whittemore responded to a hastily crafted new federal law with a detailed, legally sound analysis that withstood the tests of appellate and U.S. Supreme Court review. n18

n18 *Schiavo ex rel. Schindler v. Schiavo*, 358 F. Supp. 2d 1161 (M.D. Fla.), *aff'd*, 403 F. 3d. 1289 (11th Cir.), *denying stay*, 125 S. Ct. 1722 (2005).

While the Schiavo matter evolved far beyond the issues affecting Theresa Marie, the courts maintained a focus on the application of Florida law. It is noteworthy that Florida law regarding guardianship procedures and end of life

decisions had been carefully crafted. This was no hasty exercise by the Florida courts to sculpt a response to a politically sensitive event. Rather, more than fifteen years of bipartisan legislative and executive branch task forces, work groups, and hearings had resulted in the statutory provisions that were subject to judicial reference in this case.

During the intense research and discussions with attorneys and family members, an opportunity emerged as I came to "know" Ms. Schiavo and her character. Throughout the years of litigation, there had not been an objective third party outside of the court system capable of engendering trust among the parties. My insistence on good medicine, good science, and good law, and my effort to maintain a positive and trusting relationship with the Shindlers, Mr. Schiavo, and the Governor's office, led to a discussion about a possible resolution.

Surprisingly, all of the parties were attracted to the idea of an objective, trusted process that could yield an acceptable result. This led to what became a "Platform of Understanding" that spelled out an agreement among the parties to allow for an entirely independent, third-party-selected panel of experts to conduct a thorough swallowing and neurological assessment of Ms. Schiavo. Trusting in the objectivity of the third party, if the results of the assessment determined that there was capacity to swallow and/or neurological competence, then Mr. Schiavo would give up the guardianship claims over his wife--something he had long said he would be willing to do. If, however, there was no objectively determined capacity, then the Schindlers would give up their fight to control the destiny of their daughter. The attorneys for all of the parties, including the Governor's office, participated in the drafting. This occurred during the last forty-eight hours prior to the deadline for the submission of the final report to the Governor and the Court.

At ten minutes before midnight, on the eve of the report deadline, Mr. Felos, the attorney for Michael Schiavo, called to cancel progress. He stated that since he was objecting to the constitutionality of the law that had appointed me, he could not lend any credence to a substantive recommendation I had made, because it would dilute his constitutional argument. He was correct, legally. But an opportunity was lost--one that would have allowed for closure, both personal and scientific, insulated from the pressures of the press and the public.

My final report answered the formal questions with a set of hypotheses about Ms. Schiavo's condition. These hypotheses guided my recommendations and served as the framework for the report. The hypothetical scenarios ranged from a determination that she could swallow, to the horrific nightmare of her having no awareness except that of hopelessness and darkness. n19 As I examined these scenarios within the context of the medical and scientific data in the case and about Ms. Schiavo's condition, I was further drawn to fundamental questions of consciousness, awareness, and hope. For these matters, I drew substantial intellectual and some spiritual direction from Dante and Descartes. "Lasciate ogni speranza, voi ch'intrate" the immortal words inscribed over the gates of hell, admonish the traveler to "abandon all hope, you who enter here." n20 Without hope, what would Ms. Schiavo's loving parent's have? And without the cognition and awareness ascribed by Descartes' "Cogito ergo sum," what hope would Ms. Schiavo have? n21

n19 GAL Report, *supra* note 3, at 4-5; *Appendix A*, 38 J. HEALTH L. at p. 552.

n20 DANTE ALIGHIERI, *INFERNO OF DANTE*, at Canto III 24-25 (Robert Pinsky trans., Farrar, Straus & Giroux 1994) (1310).

n21 RENE DESCARTES, *Principles of Philosophy*, in *A DISCOURSE ON METHOD* 167 (John Veitch trans., J.M. Dent & Sons 1975) (1642).

The dynamic tension created by the admonitions of Dante and Descartes helped to shape the final report and its recommendations:

Summary of Guardian Ad Litem Recommendations

Restatement of the Questions Posed and the GAL's Recommendations

1. Should the Governor lift the stay that he previously entered relative to Theresa Schiavo's feeding tube?

a. Yes. The Governor should lift the stay, if valid, independent scientific medical evidence clearly indicates that Theresa has no reasonable medical hope of regaining any swallowing function and/or if there is no evidence of cognitive function and no hope of improvement.

b. No. The Governor should not lift the stay if valid, independent scientific medical evidence clearly indicates that Theresa has a reasonable medical hope of regaining any swallowing function and/or if there is evidence of cognitive function with or without hope of improvement.

2. Is there feasibility and value in swallowing tests and swallowing therapy given the totality of circumstances?

a. Yes. There is feasibility and value in swallowing tests and swallowing therapy being administered if the parties agree in advance as to how the results of these tests will be used with respect to the decision about Theresa's future. If the parties do not agree in advance as to how the tests will be used, then the court must be prepared to once again make a final judgment on the matter. Given the history of the case, this would not, in and of itself, assure a resolution, and is not, therefore, deemed either feasible or of value to Theresa Schiavo without prior agreement.

The GAL concludes from the medical records and consultations with medical experts that the scope and weight of the medical information within the file concerning Theresa Schiavo consists of competent, well documented information that she is in a persistent vegetative state with no likelihood of improvement, and that the neurological and speech pathology evidence in the file support the contention that she cannot take oral nutrition or hydration and cannot consciously interact with her environment.

The GAL concludes that the trier of fact and the evidence that served as the basis for the decisions regarding Theresa Schiavo were firmly grounded within Florida statutory and case law, which clearly and unequivocally provide for the removal of artificial nutrition in cases of persistent vegetative states, where there is no advance directive, through substituted/proxy judgment of the guardian and/or the court as guardian, and with the use of evidence regarding the medical condition and the intent of the parties that was deemed, by the trier of fact to be clear and convincing. n22

n22 GAL Report, *supra* note 3, at 32-34; *Appendix A*, 38 J. HEALTH L. at p. 552.

Living wills, healthcare surrogates, and decisions to withhold treatment at the end of life are not new. The states vary in terms of the specific conditions and arrangements legally permitted for termination of medical treatment decisions to be made in end of life decision cases. Following the experiences in *Cruzan* n23 most legal scholars believed there would be little room for question about how right to die matters would be managed within the construct of state law--where the Supreme Court stated it clearly and distinctively belonged.

n23 *Cruzan v. Mo. Dep't of Health*, 497 U.S. 261 (1990).

In the shadow of Ms. Schiavo's tragic case, there are important health law lessons. These include fundamental

questions about how healthcare resource allocation decisions shall be made for a rapidly aging population. These questions raise complex issues regarding the appropriate and timely use of technology in diagnosing, treating, or maintaining the status of individuals. These options in turn are affected by policy decisions of public and private entities about what will be reimbursed. State Medicaid programs, already choking in shortfalls and cutbacks, and soon to be reeling from clawback payments under Medicare Part D, n24 must face the growing number of aging eligibles who will clamor for expensive services--including many provided during end of life periods.

n24 Clawback refers to the mechanism by which states will help finance Medicare Part D through a monthly payment that roughly reflects the expenditures the state Medicaid program would have made for prescription drugs on behalf of low-income elderly who are enrolled in both Medicare and Medicaid. *See generally* ANDY SCHNEIDER, THE HENRY J. KAISER FAMILY FOUND, THE "CLAWBACK:" STATE FINANCING OF MEDICARE DRUG COVERAGE (2004).

The fallout from *Schiavo* is very much a health law issue at the federal and state policy levels, at institutional practice levels where care and technology use decisions will be made, and within healthcare risk management venues where we advise clients about liability avoidance.

As a tribute to the memory of Ms. Schiavo, rather than continue to wring hands over winners and losers, we should capitalize upon the opportunity to learn from the experience and address the very substantial health law and policy challenges that are beyond our doorstep and already entering our living rooms. If five years from now, we should face another *Schiavo* case, it would be a tragedy of public policy.

Appendix A

A REPORT TO GOVERNOR JEB BUSH AND THE 6<TH> JUDICIAL CIRCUIT IN THE MATTER OF THERESA MARIE SCHIAVO

Pursuant to the requirements of H.B. 35-E (Chapter 2003-418, Laws of Florida) and the Order of the Hon. David Demers, Chief Judge, Florida 6<th> Judicial Circuit regarding the appointment and duties of a Guardian Ad Litem in the matter of Theresa Marie Schiavo, Incapacitated.

Respectfully Submitted Jay Wolfson, DrPH, JD, Guardian Ad Litem for Theresa Marie Schiavo

1 December 2003

Introduction

Sometimes good law is not enough, good medicine is not enough, and all too often, good intentions do not suffice. Sometimes, the answer is in the process, not the presumed outcome. We must be left with hope that the right thing will be done well.

We are, each of us, standing in Theresa Marie Schiavo's shoes. Each of us is profoundly affected by the decisions that have and will be made in this case. Advocates of privacy rights and death with dignity, and advocates of right to life and rights of the disabled provide the compelling definitional parameters of this matter.

On 31 October 2003, pursuant to the requirements of Florida H.B. 35-E (Chapter 2003-418, Laws of Florida) and the order of the Hon. David Demers, Chief Judge, Florida 6<th> Judicial Circuit, a Guardian Ad Litem was appointed for a period of thirty days with the following charge:

". . . make a report and recommendations to the Governor as to whether the Governor should lift the stay that he previously entered. The report will specifically address the feasibility and value of swallow tests for this ward and the feasibility and value of swallow therapy. Additionally, the report will include a thorough summary of everything that has taken place in the trial court and the appellate court concerning

this case."

The legislature instructed the court to appoint a Guardian Ad Litem to report to the court and the Governor. Florida law regarding the duties and powers of the Guardian Ad Litem afford considerable scope and flexibility. The specific court ordered charge is narrowly constructed, particularly with respect to the questions to be addressed.

The recommendations proffered herein are intended for both the Governor and the court, on behalf of Theresa Marie Schiavo.

The Guardian Ad Litem's efforts have been to deduce and represent the best wishes and best interests of Theresa Schiavo. In that no express, written advance directive existed, determining what Theresa's wishes might be require a combination of substituted judgment, reasonable person considerations, and an aggressive, objective assessment of the massive legal and clinical record that has been compiled over thirteen years.

The entire court file of thirteen years, including items of evidence, has been reviewed and studied, with particular attention given to decision points in the case history that are reflected in motions to and orders by the Court. The case review has included clinical and medical records, discussions with members of the family, caregivers, and with medical, legal, bioethical and religious practitioners and scholars and the conduct of independent research into the substantive issues in this case. The GAL has met regularly with Ms. Schiavo, his ward.

Below, the questions posed to the GAL are addressed with recommendations, followed by an introduction to the case, a summary of the case, a summary of legal and medical issues in this case, and an expanded analysis of the recommendations at the conclusion of the report.

Questions and Recommendations

The two questions which the GAL is directed to address, and respective recommendations are:

1. Should the Governor lift the stay that he previously entered relative to Theresa Schiavo's feeding tube?
 - a. Yes. The Governor should lift the stay, if valid, independent scientific medical evidence clearly indicates that Theresa has no reasonable medical hope of regaining any swallowing function and/or if there is no evidence of cognitive function and no hope of improvement.
 - b. No. The Governor should not lift the stay if valid, independent scientific medical evidence clearly indicates that Theresa has a reasonable medical hope of regaining any swallowing function and/or if there is evidence of cognitive function with or without hope of improvement.
2. Is there feasibility and value in swallowing tests and swallowing therapy given the totality of circumstances?
 - a. Yes. There is feasibility and value in swallowing tests and swallowing therapy being administered if the parties agree in advance as to how the results of these tests will be used with respect to the decision about Theresa's future. If the parties do not agree in advance as to how the tests will be used, then the court must be prepared to once again make a final judgment on the matter. Given the history of the case, this would not, in and of itself, assure a resolution, and is not, therefore, deemed either feasible or of value to Theresa Schiavo without prior agreement.

A detailed discussion of these recommendations within the context of the GAL's findings and analyses concludes this report.

Within the construct of the GAL's role, an additional recommendation is proffered to the court and to the Governor. During the more than nine years of adversarial relationships involving Theresa, no permanent Guardian Ad Litem has been appointed to stand exclusively in her shoes. It is the additional recommendation of the GAL that as long as controversy and an adversarial legal relationship exist in Theresa's case, a Guardian Ad Litem should be appointed to represent her exclusive interests. This is in no way intended to detract from or impugn the role of Theresa's existing Guardian, Michael Schiavo.

A central, statutory and moral role of the GAL is to seek to stand in Theresa Schiavo's shoes and speak for her with respect to her circumstance. The intentions of Theresa are central and vital to this case, because by law, they serve as a basis upon which reasoned decisions may be made regarding the removal of artificial life support.

To frame the issue for the reader, the GAL posits four, alternative, hypotheses that reasonably reflect the scope of circumstances affecting Theresa. These are intentionally graphic and specific. Responses that Theresa might proffer to these circumstances are then suggested.

Hypothesis I

Theresa, though profoundly disabled, with massive loss of cognitive function, maintains some cognitive capacity that has not been fully recognized. She is aware of aspects of her environment, though she requires great effort and energy to respond in the smallest way. She is capable of some interactive capacity, and can be brought, through therapy, to receive oral nutrition and hydration and possibly to enjoy other interactive competencies.

If she could speak to us, assume that Theresa would ask to be maintained and cared for under these circumstances.

Hypothesis II

Same as above, except Theresa's cognitive functions cannot improve, she will not be able to take oral nutrition and hydration, and she will not display any interactive or cognitive functions beyond what she has over the past 13 years. She can be maintained and cared for through an indefinite period of time.

If she could speak to us, assume that Theresa would ask to be maintained and cared for under these circumstances, or in the alternative, assume that Theresa would ask not to be maintained under these circumstances.

Hypothesis III

Theresa's exclusive awareness for 13 years, to the extent she may be aware of anything, is the equivalent of fear and perpetual horror. She is unable to hear, see, speak or interact, and unable to die, but she is not "locked in".

If she could speak to us Theresa would ask to be released from this condition and allowed to die.

Hypothesis IV

Same as I and/or II above, except the litigation surrounding Theresa continues,

resulting in years of more of the same process that has been experienced to date, including orders and actions to remove her feeding tube and orders and actions to replace her feeding tube, multiple additional times.

If Theresa could speak to us, she would claim to be the victim of cruel and unusual punishment, protected by the U.S. Constitution.

Justice O'Connor's concurring opinion in *Cruzan* helps to establish the foundations for Hypotheses III and IV:

A seriously ill or dying patient whose wishes are not honored may feel a captive of the machinery required for life-sustaining measures or other medical interventions. Such forced treatment may burden that individual's liberty interests as much as any state coercion. *Cruzan v. Director, MDH*, 497, U.S. 261 (1990)

Feasible and valuable recommendations on Theresa's behalf cannot be made without framing her circumstance in clear and express terms.

Theresa has survived in a diagnosed persistent vegetative state for more than thirteen years since her tragic accident and through nearly ten years of litigation; one clamping and one removal of her gastric feeding tube with subsequent replacement ordered by Governor Bush pursuant to a statutory intervention; the exhaustion of monies in a trust fund derived from a medical malpractice economic damages award; and the extensive, extraordinary, exquisite, nearly acrobatic legal efforts of attorneys and circuit court and appellate judges. Yet the matter of Theresa Schiavo remains unresolved.

Following nearly a decade of hostile and expensive litigation between parties having an interest in Theresa Schiavo, the Florida Legislature and the Governor of Florida have intervened in the case. That intervention, by way of a H.B. 35-E, passed during a special session of the Legislature, authorized the Governor to stay a court ordered removal of a gastric feeding tube and required the appointment of a Guardian Ad Litem (hereinafter, "GAL") to proffer recommendations to the Governor.

The charge to this GAL is to review the entire Theresa Schiavo court file, summarize it, and report recommendations to the Governor regarding his stay on removing artificial nutrition, and with particularity on the "feasibility and value" of swallowing tests and swallowing therapy for Theresa Schiavo. These tests go the heart of the issues that have driven the contentions in this case for nearly a decade.

Merriam-Webster defines feasible as reasonable do-ability:

- 1: capable of being done or carried out <a feasible plan>
- 2: capable of being used or dealt with successfully: SUITABLE
- 3: REASONABLE, LIKELY

If therefore, something is not feasible, it is not capable of being done or likely to be done without success.

Value is defined as relative worth:

- 1: a fair return or equivalent in goods, services, or money for something exchanged
- 2: the monetary worth of something: marketable price
- 3: relative worth, utility, or importance <a good value at the price><the value of base stealing in baseball> <had nothing of value to say>

4a: a numerical quantity that is assigned or is determined by calculation or measurement <let x take on positive values> <a value for the age of the earth> b : precise signification <value of a word>

7: something (as a principle or quality) intrinsically valuable or desirable <sought material values instead of human values

(Merriam-Webster, 2001)

The relativity of "value" is clear, particularly as it may apply to a principle or quality, rather than empirical measurement.

If the Guardian Ad Litem's recommendations are neither feasible nor valuable--to and on behalf of Theresa Schiavo, then they fail in their purpose. For them to be feasible and valuable, they must be capable of being done in a manner that affords relative and intrinsic worth for Theresa; not for her husband; not for her parents and siblings; not for the Governor or the Legislature.

The history and key legal/medical events that have occurred since Theresa's tragic accident informed the charge to the Guardian Ad Litem.

Historical Facts in Theresa Marie Schiavo's Case

Theresa Marie Schiavo was born in the Philadelphia, Pennsylvania area on 3 December 1963 to Robert and Mary Schindler. She has two, younger siblings, Robert Jr., and Susan. Through the age of 18, Theresa was, according to her parents, very overweight, until she chose to lose weight with the guidance of a physician. She dropped from 250 pounds to around 150 pounds, at which time she met Michael Schiavo. They dated for many months and married in November of 1984. The Schiavo and Schindler families were close and friendly.

Theresa and Michael moved to Florida in 1986 and were followed shortly thereafter by Theresa's parents and siblings. Theresa worked for the Prudential Life Insurance **Company** and Michael was a restaurant manager.

About three years later, without the apparent knowledge of her parents, Theresa and Michael sought assistance in becoming pregnant through an obstetrician who specialized in fertility services. For over a year, Theresa and Michael received fertility services and counseling in order to enhance their strongly held desire to have a child. By this time, Theresa's weight had dropped even further, to 110 pounds. She was very proud of her fabulous figure and her stunning appearance, wearing bikini bathing suits for the first time and taking great pride in her improved good looks. Testimony and photographs bare witness to these facts.

On the tragic early morning of 25 February 1990, Theresa collapsed in the hallway of her apartment, waking Michael, who called Theresa's family and 911. The lives of Theresa, Michael and the Schindlers were to change forever.

Theresa suffered a cardiac arrest. During the several minutes it took for paramedics to arrive, Theresa experienced loss of oxygen to the brain, or anoxia, for a period sufficiently long to cause permanent loss of brain function. Despite heroic efforts to resuscitate, Theresa remained unconscious and slipped into a coma. She was intubated, ventilated and trached, meaning that she was given life saving medical technological interventions, without which she surely would have died that day.

The cause of the cardiac arrest was adduced to a dramatically reduced potassium level in Theresa's body. Sodium and potassium maintain a vital, chemical balance in the human body that helps define the electrolyte levels. The cause of the imbalance was not clearly identified, but may be linked, in theory, to her drinking 10-15 glasses of iced tea each day. While no formal proof emerged, the medical records note that the combination of aggressive weight loss, diet control and excessive hydration raised questions about Theresa suffering from Bulimia, an eating disorder, more common among women than men, in which purging through vomiting, laxatives and other methods of diet control

becomes obsessive.

Theresa spent two and a half months as an inpatient at Humana Northside Hospital, eventually emerging from her coma state, but not recovering consciousness. On 12 May 1990, following extensive testing, therapy and observation, she was discharged to the College Park skilled care and rehabilitation facility. Forty-nine days later, she was transferred again to Bayfront Hospital for additional, aggressive rehabilitation efforts. In September of 1990, she was brought home, but following only three weeks, she was returned to the College Park facility because the "family was overwhelmed by Terry's care needs."

On 18 June 1990, Michael was formally appointed by the court to serve as Theresa's legal guardian, because she was adjudicated to be incompetent by law. Michael's appointment was undisputed by the parties.

The clinical records within the massive case file indicate that Theresa was not responsive to neurological and swallowing tests. She received regular and intense physical, occupational and speech therapies.

Theresa's husband, Michael Schiavo and her mother, Mary Schindler, were virtual partners in their care of and dedication to Theresa. There is no question but that complete trust, mutual caring, explicit love and a common goal of caring for and rehabilitating Theresa, were the shared intentions of Michael Schiavo and the Schindlers.

In late Autumn of 1990, following months of therapy and testing, formal diagnoses of persistent vegetative state with no evidence of improvement, Michael took Theresa to California, where she received an experimental thalamic stimulator implant in her brain. Michael remained in California caring for Theresa during a period of several months and returned to Florida with her in January of 1991. Theresa was transferred to the Mediplex Rehabilitation Center in Brandon, where she received 24 hour skilled care, physical, occupational, speech and recreational therapies.

Despite aggressive therapies, physician and other clinical assessments consistently revealed no functional abilities, only reflexive, rather than cognitive movements, random eye opening, no communication system and little change cognitively or functionally.

On 19 July 1991 Theresa was transferred to the Sable Palms skilled care facility. Periodic neurological exams, regular and aggressive physical, occupational and speech therapy continued through 1994.

Michael Schiavo, on Theresa's and his own behalf, initiated a medical malpractice lawsuit against the obstetrician who had been overseeing Theresa's fertility therapy. In 1993, the malpractice action concluded in Theresa and Michael's favor, resulting in a two element award: More than \$ 750,000 in economic damages for Theresa, and a loss of consortium award (non economic damages) of \$ 300,000 to Michael. The court established a trust fund for Theresa's financial award, with SouthTrust Bank as the Guardian and an independent trustee. This fund was meticulously managed and accounted for and Michael Schiavo had no control over its use. There is no evidence in the record of the trust administration documents of any mismanagement of Theresa's estate, and the records on this matter are excellently maintained.

After the malpractice case judgment, evidence of disaffection between the Schindlers and Michael Schiavo openly emerged for the first time. The Schindlers petitioned the court to remove Michael as Guardian. They made allegations that he was not caring for Theresa, and that his behavior was disruptive to Theresa's treatment and condition.

Proceedings concluded that there was no basis for the removal of Michael as Guardian. Further, it was determined that he had been very aggressive and attentive in his care of Theresa. His demanding concern for her well being and meticulous care by the **nursing home** earned him the characterization by the administrator as "a **nursing home** administrator's nightmare". It is notable that through more than thirteen years after Theresa's collapse, she has never had a bedsore.

By 1994, Michael's attitude and perspective about Theresa's condition changed. During the previous four years, he

had insistently held to the premise that Theresa could recover and the evidence is incontrovertible that he gave his heart and soul to her treatment and care. This was in the face of consistent medical reports indicating that there was little or no likelihood for her improvement.

In early 1994 Theresa contracted a urinary tract infection and Michael, in consultation with Theresa's treating physician, elected not to treat the infection and simultaneously imposed a "do not resuscitate" order should Theresa experience cardiac arrest. When the nursing facility initiated an intervention to challenge this decision, Michael cancelled the orders. Following the incident involving the infection, Theresa was transferred to another skilled nursing facility.

Michael's decision not to treat was based upon discussions and consultation with Theresa's doctor, and was predicated on his reasoned belief that there was no longer any hope for Theresa's recovery. It had taken Michael more than three years to accommodate this reality and he was beginning to accept the idea of allowing Theresa to die naturally rather than remain in the non-cognitive, vegetative state. It took Michael a long time to consider the prospect of getting on with his life -- something he was actively encouraged to do by the Schindlers, long before enmity tore them apart. He was even encouraged by the Schindlers to date, and introduced his in-law family to women he was dating. But this was just prior to the malpractice case ending.

As part of the first challenge to Michael's Guardianship, the court appointed John H. Pecarek as Guardian Ad Litem to determine if there had been any abuse by Michael Schiavo. His report, issued 1 March 1994, found no inappropriate actions and indicated that Michael had been very attentive to Theresa. After two more years of legal contention, the Schindlers action against Michael was dismissed with prejudice. Efforts to remove Michael as Guardian were attempted in subsequent years, without success.

Hostilities increased and the Schindlers and Michael Schiavo did not communicate directly. By June of 1996, the court had to order that copies of medical reports be shared with the Schindlers and that all health care providers be permitted to discuss Theresa's condition with the Schindlers--something Michael had temporarily precluded.

In 1997, six years after Theresa's tragic collapse, Michael elected to initiate an action to withdraw artificial life support from Theresa. More than a year later, in May of 1998, the first petition to discontinue life support was entered. The court appointed Richard Pearse, Esq., to serve as Guardian Ad Litem to review the request for withdrawal, a standard procedure.

Mr. Pearse's report, submitted to the court on 20 December 1998 contains what appear to be objective and challenging findings. His review of the clinical record confirmed that Theresa's condition was that of a diagnosed persistent vegetative state with no chance of improvement. Mr. Pearse's investigation concluded that the statements of Mrs. Schindler, Theresa's mother, indicated that Theresa displayed special responses, mostly to her, but that these were not observed or documented.

Mr. Pearse documents the evolving disaffections between the Schindlers and Michael Schiavo. He concludes that Michael Schiavo's testimony regarding the basis for his decision to withdraw life support -- a conversation he had with his wife, Theresa, was not clear and convincing, and that potential conflicts of interest regarding the disposition of residual funds in Theresa's trust account following her death affected Michael and the Schindlers -- but he placed greater emphasis on the impact it might have had on Michael's decision to discontinue artificial life support. At the time of Mr. Pearse's report, more than \$ 700,000 remained in the guardianship estate.

Mr. Pearse concludes that Michael's hearsay testimony about Theresa's intent is "necessarily adversely affected by the obvious financial benefit to him of being the sole heir at law . . ." and ". . . by the chronology of this case . . .", specifically referencing Michael's change in position relative to maintaining Theresa following the malpractice award.

Mr. Pearse recommended that the petition for removal of the feeding tube be denied, or in the alternative, if the court found the evidence to be clear and convincing, the feeding tube should be withdrawn.

Mr. Pearse also recommended that a Guardian Ad Litem continue to serve in all subsequent proceedings.

In response to Mr. Pearse's report, Michael Schiavo filed a Suggestion of Bias against Mr. Pearse. This document notes that Mr. Pearse failed to mention in his report that Michael Schiavo had earlier, formally offered to divest himself entirely of his financial interest in the guardianship estate. The criticism continues to note that Mr. Pearse's concern about abuse of inheritance potential was directed solely at Michael, not at the Schindlers in the event they might become the heirs and also choose to terminate artificial life support. Further, significant chronological deficits and factual errors are noted, detracting from and prejudicing the objective credibility of Mr. Pearse's report.

The Suggestion of Bias challenges premises and findings of Mr. Pearse, establishing a well pleaded case for bias.

In February of 1999, Mr. Pearse tendered his petition for additional authority or discharge. He was discharged in June of 1999 and no new Guardian Ad Litem was named.

Actions by the Schindlers to remove Michael as Guardian and to block the petition to remove artificial life support took on a frenetic quality at this juncture. More external parties on both sides made appearances as potential interveners.

On 11 February 2000, consequent to hearings and the presentation of competent evidence, Judge Greer ordered the removal of Theresa's artificial life support.

The Schindlers aggressively sought means by which to stop the removal of Theresa's feeding tube. Most of the motions in these efforts were denied, but not without apparent careful and detailed review by the court, often involving hearings at which considerable latitude was afforded the Schindlers in their efforts to proffer testimony and admit evidence.

The motion and hearing process continued through 2000. Then the Schindler's sought to introduce new evidence that was believed to be of a sufficiently substantial nature as to change the court's decision regarding the removal of the feeding tube.

The hearings and testimony before the trial court leading to the decision to discontinue artificial life support included admitted hearsay from Theresa's brother-in-law (Michael Schiavo's brother) and his wife (Michael's Schiavo's sister-in-law) along with testimony from Michael.

The testimony of these parties referenced specific conversations in which Theresa commented about her desire never to be placed on artificial life support. The testimony reflected conversations at or proximate to funerals of close family members who had been on artificial life support. The context and content of the testimony, while hearsay, was deemed credible and consistent and was used by the court as a supporting bases for its decision to discontinue artificial life support.

The Schindler's new evidence ostensibly reflected adversely on Michael Schiavo's role as Guardian. It related to his personal romantic life, the fact that he had relationships with other women, that he had allegedly failed to provide appropriate care and treatment for Theresa, that he was wasting the assets within the guardianship account, and that he was no longer competent to represent Theresa's best interests.

Testimony provided by members of the Schindler family included very personal statements about their desire and intention to ensure that Theresa remain alive. Throughout the course of the litigation, deposition and trial testimony by members of the Schindler family voiced the disturbing belief that they would keep Theresa alive at any and all costs. Nearly gruesome examples were given, eliciting agreement by family members that in the event Theresa should contract diabetes and subsequent gangrene in each of her limbs, they would agree to amputate each limb, and would then, were she to be diagnosed with heart disease, perform open heart surgery. There was additional, difficult testimony that appeared to establish that despite the sad and undesirable condition of Theresa, the parents still derived joy from having her alive, even if Theresa might not be at all aware of her environment given the persistent vegetative state. Within the

testimony, as part of the hypotheticals presented, Schindler family members stated that even if Theresa had told them of her intention to have artificial nutrition withdrawn, they would not do it. Throughout this painful and difficult trial, the family acknowledged that Theresa was in a diagnosed persistent vegetative state.

The court denied the Schindler's motions to remove the guardian, allowing that the evidence was not sufficient and in some instances, not relevant. It set a date for the artificial life support to be discontinued, as of 24 April 2001.

The decision was appealed to the Florida 2<nd> District Court of Appeals (DCA), and was affirmed in January 2001. The requested appeal to the Florida Supreme Court was denied on 23 April 2001, one day before the scheduled removal of Theresa's feeding tube.

On 24 April 2001, Theresa Schiavo's artificial feeding tube was clamped, and she ceased receiving nutrition and hydration. Under normal circumstances, Theresa would die naturally within a week to ten days.

Two days after the clamping of Theresa's feeding tube, the Schindlers filed a civil action in their capacity as "natural guardians" for Theresa. The trial court, in emergency review, granted a temporary injunction and the tube was unclamped. Michael Schiavo filed an emergency motion to vacate the injunction. This led to the second review and appeal to the 2<nd> DCA.

The 2<nd> DCA found that the intention of Florida Statutes 765 with respect to matters such as Theresa's, is to help expedite proceedings of the court when decisions have been made by the bona fide guardian. The 2<nd> DCA also noted that the Court had acted independently as proxy decision maker regarding the removal of artificial life support.

In October 2001, the 2<nd> DCA concluded that the Schindlers "have presented no credible evidence suggesting new treatment can restore Mrs. Schiavo." The injunction was lifted and plans moved forward to discontinue artificial nutrition.

Fresh and exhaustive motions regarding new evidence were again crafted and proffered to the trial court by the Schindlers resulting in a lengthy hearing. Affidavits from medical doctors and others alleged that Theresa's condition could be improved.

In particular, the sworn statement of a single, osteopathic physician, Dr. Webber, claimed that he could improve Theresa's condition and had done so in like and similar cases.

The quality of evidence in this affidavit was marginal, but the court allowed it to create a colorable entitlement to additional medical review. The case was remanded to the trial court with the charge that each side would select two expert physicians (a neurologist or a neurosurgeon, according to the court) and agree between them regarding a fifth, and if they could not agree on the fifth, the court would select it.

By May of 2002, the physicians were selected by both sides, but no agreement could be reached about a fifth, so the court selected one. Curiously and surprisingly, Dr. Webber, who had served as the basis for this entire process at the 2<nd> DCA, did not participate in the exams or the procedure.

Each of the physicians was afforded access to Theresa for the purpose of conducting a thorough examination. Video tape recordings were made of some of the examinations along with segments in which family members interacted with Theresa. The physicians were deposed and proffered testimony regarding their findings.

Written reports of the examinations were prepared by all five physicians, and a very detailed hearing was held in October of 2002.

The clinical evidence presented by the five physicians reflected their examinations and reviews of the medical records. Four of the physicians were board certified in neurology, as suggested by the court, and one physician was

board certified in radiology and hyperbaric medicine. All of the physicians had excellent pedigrees of medical training.

The scientific quality, value and relevance of the testimony varied. The two neurologists testifying for Michael Schiavo provided strong, academically based, and scientifically supported evidence that was reasonably deemed clear and convincing by the court. Of the two physicians testifying for the Schindlers, only one was a neurologist, the other was a radiologist/hyperbaric physician. The testimony of the Schindler's physicians was substantially anecdotal, and was reasonably deemed to be not clear and convincing.

The fifth physician, chosen by the court because the two parties could not agree, presented scientifically grounded, academically based evidence that was reasonably deemed to be clear and convincing by the court.

Following exhaustive testimony and the viewing of video tapes, the trial court concluded that no substantial evidence had been presented to indicate any promising treatment that might improve Theresa's cognition. The court sought to glean scientific, case, research-based foundations for the contentions of the Schindler's physician experts, but received principally anecdotal information.

Evidence presented by Michael Schiavo's two physicians and the fifth physician selected by the court was reasonably deemed clear and convincing in support of Theresa being in a persistent vegetative state with no hope for improvement.

Simultaneous appeals of this decision and renewed actions to remove Michael Schiavo as Guardian were initiated based upon new evidence.

The June 2003 appeal to the 2nd DCA was Schiavo IV. The 2nd DCA panel of judges engaged in what approximated a de novo review of all of the facts, testimony and video tapes presented at trial. The appellate court affirmed the trial court's ruling and its conclusions, and in addition, ordered the trial court to set a hearing date for removal of the artificial life support.

The trial court set 15 October 2003 as the date for the removal of Theresa's artificial nutrition tube.

The Schindler's renewed efforts to remove Michael Schiavo as Guardian, and to disqualify judges, were not successful. Multiple amicus briefs and affidavits from parties supporting the Schindler's were submitted through the Schindler's actions and in some instances, independently to the court.

By mid 2003, the landscape and texture of Theresa Schiavo's case underwent profound changes. National media coverage, active involvement by groups advocating right to life, and the attention of the Governor's office and the Florida Legislature, catapulted Theresa's case into a different dimension.

The Schindlers, acting on behalf of Theresa, filed a motion in federal district court seeking a preliminary injunction to stay the removal of the artificial life support from Theresa, scheduled to occur on 15 October 2003. On 6 October 2003, Florida Governor Jeb Bush filed an Amicus brief in support of the motion for a preliminary injunction. The brief argues that removal of artificial nutrition, resulting in death, should be avoided if that person can take oral nutrition and hydration. The Governor predicates his memorandum on the pivotal question as to whether Theresa could ingest food and water on her own. That Theresa is in a diagnosed, persistent vegetative state is explicitly recognized.

On 15 October 2003, Theresa Maria Schiavo's artificial feeding tube was disconnected, for the second time.

The Florida legislature, in special session, passed HB 35 E on 21 October 2003, authorizing the Governor to stay the disconnection of the artificial feeding tube and required, among other things, the appointment of a Guardian Ad Litem to produce this report.

On that same day, 21 October 2003, the artificial feeding tube was re-inserted per the stay ordered by Governor

Bush. Other suits and actions were initiated immediately. The governor became a named party in the matters involving Theresa Schiavo.

This Guardian Ad Litem is not addressing any of the Constitutional causes of action arising subsequent to the passage of HB 35 E and the Governor's action.

In addition to the historical facts in the case, a summary of the nature of Florida's legal and policy treatment of decisions involving death and dying, artificial life support, and artificial nutrition, are essential to the charge of the Guardian Ad Litem.

Guardian Ad Litem's Findings

The Information Acquisition Process

Upon appointment, this Guardian Ad Litem met with the Schindler family and their attorneys, Michael Schiavo and his attorney, and with the Ward, Theresa Marie Schiavo. The establishment of a trusting relationship with all of the parties was a priority in order to ensure that any recommendations would be feasible and valuable. Only thirty days were afforded to the process.

All court records were accessed and reviewed, including all items of evidence in the case. Extensive discussions were held with family members and caregivers along with the acquisition and review of background data and information from the case file to assist the Guardian Ad Litem in becoming as personally acquainted with his ward, Theresa Schiavo as possible, in the short time available. The Guardian Ad Litem has made numerous and frequent visits to Theresa at the hospice where she resides, including an arranged visit with her parents to observe interactions. The Guardian ad Litem has met with and discussed aspects of Theresa's case with hospice staff, physician cardiologists, gastroenterologists, internists, neurologists, neurosurgeons, trauma specialists, anesthesiologists, swallowing disorder specialists; speech pathologists specializing in rehabilitation, swallowing tests and swallowing therapy; and with clergy, elder law specialists, bioethicists, and health policy specialists. In addition to reading the nearly 30,000 pages of court records, the Guardian Ad Litem has conducted a review of the medical literature and has received thousands of unsolicited documents, sources of referral, claims regarding successful interventions, and wishes of good luck. Governor Bush, to whom this report is directed, requested a meeting with the Guardian Ad Litem to discuss the charge. The Guardian Ad Litem met with the Governor, his General Counsel and private external counsel to review the Guardian Ad Litem's plan and direction. The meeting was valuable in establishing the expanded trust among the parties that the Guardian Ad Litem has sought to cultivate from the inception of his appointment.

The Evolution of the Law about Dying and Nutrition in Florida Our society is at a legal, political, biotechnological, bioethical and spiritual crossroad. Theresa Schiavo is alternately depicted as a living, loving person, capable of interacting at a level of cognition with her family and deserving of the right to continue to live--and as a tragically and profoundly brain damaged person, who earlier expressed a desire never to find herself in a circumstance analogous to waking up in a coffin--and being there forever. But she cannot speak to us now. So we must rely upon the auspices of good law and good medicine and the good intentions of those who marshal these arts in order to do our best to do the right thing well for Theresa Schiavo.

During the early 1970s the States began to revise their Probate Codes. There were many reasons for this, including a rapidly aging population, larger numbers of aged persons in the population, people living longer, new and advancing medical technologies that enhanced, extended and affected life, and changing values and orientations about death, dying and the medical-decision processes. These matters have been seriously addressed through a combination of inquiries and actions by church leaders, legislators, medical scientists, and the courts, as all have sought to respond to emerging issues such as those in the Quinlan, Cruzan, Browning, and now the Schiavo cases.

States cooperated with the federal Administration on Aging to address legislative and policy challenges surfacing around these matters. A particularly important topic related to medical technology and its use in the care, treatment and

maintenance of patients, is when, who and by what means "artificial" life support and other medical interventions should or could be removed or never withheld in the first place.

Today, most states would afford an adult person the right to deny most health care treatments. But if the patient is a minor, unconscious, in a coma, in a vegetative state, or unable to communicate personal wishes and intentions, there are serious moral, ethical and legal questions that demanded attention. There had been inconsistencies, even within states, as to how decisions regarding termination or removal or withholding a procedure were made. There was also a long standing, well accepted recognition that the relationship between the patient and the physician--the sacred trust--served as the foundation for how and where and when many of these decisions would be made. Often, physicians, in consultation with family members and the patient have done what was deemed to be in best interests of the patient, given the physician's medical opinion and the express, known or believed intentions of the patient.

To reduce ambiguities, many states began to encourage and accept written advance directives as the basis for decisions regarding end of life treatment. Living wills, durable powers of attorney for health care and health care surrogate documents, stating a person's explicit intentions regarding end of life care, became increasingly accepted and even formalized into the statutory framework of most states. A written expression was deemed to be an important element in this process to avoid the possibility of confusion or uncertainty with respect to a person's intention regarding their health and medical care.

Throughout the 1980s and 1990s, Florida lawmakers struggled with how they would provide individuals with the prerogatives for establishing their wishes regarding end of life decisions, while at the same time, **protecting** against perceived and actual abuses and assisted suicides. Among the most sensitive of issues in this regard has been the withdrawal of artificial life support in the form of nutrition and hydration. The idea of withholding or withdrawing these has created significant debates within and across religious, philosophical and political groups and interests. But the topic has been addressed at great lengths by each of these groups, and there is surprising consensus in principle and even in practice.

The current, generally accepted applications to terminal illness or persistent vegetative state define artificial feeding as artificial life support that may be withheld or withdrawn. In 1989, the Florida Legislature permitted the withdrawal of artificial nutrition and hydration under very specific circumstances. In 1999, following extensive bipartisan efforts, life-prolonging procedures were redefined as "any medical procedure, treatment, or intervention, including artificially provided sustenance and hydration, which sustains, restores, or supplants a spontaneous vital function." It is noteworthy that the general principle of artificial nutrition as artificial life support that may be removed in terminal and even vegetative state conditions is reflected in nearly all state's laws and within the guidelines of end of life care enunciated by the American Conference of Catholic Bishops and other religious denominations.

These general principles are in no way intended to encourage or condone suicide or assisted suicide. But they reflect the acceptance of artificial nutrition as artificial life support that may be withdrawn or withheld as a matter of public policy, when these decisions capture the intentions of the person and with the premise that people should not be required to remain "artificially alive", or to have their natural peaceful deaths postponed and prolonged if they would otherwise choose not to, and that they should be allowed to die with dignity, and return, if their beliefs so accommodate, to God.

When written advance directives are not available, and the affected person is incompetent and unable to communicate, a decision to discontinue nutrition and hydration is especially challenging. But Florida law, as reflected in F.S. 765, and as interpreted through *In re Guardianship of Browning*, 568 So. 2d 4 (Fla. 1990), provide for a substituted judgment basis for such decisions and/or the presentation of clear and convincing evidence to demonstrate the intentions of the person.

It has been suggested that in the case of incapacitated persons, particularly those who have not expressed an advance directive, the "clear and convincing" evidence standard for establishing the intent to discontinue artificial life

support is insufficient and incongruous. The insufficiency, it is argued, is because of the possibility of using information that is not accurate, complete or even honest. The incongruity is related to the "beyond a reasonable doubt" standard that serves as the basis for decisions to convict and then execute capital felons.

If persons unable to speak for themselves have decisions made on their behalf by guardians or family members, the potential for abuse, barring clear protections, could lead to a "slippery slope" of actions to terminate the lives of disabled and incompetent persons. And it is not difficult to imagine bad decisions being made in order to make life easier for a family or to avoid spending funds remaining in the estate on the maintenance of a person.

There is, of course, the other side of that slippery slope, which would be to keep people in a situation they would never dream of: unable to die, unable to communicate, dependent for everything, and unaware, being maintained principally or entirely through state resources--and for reasons that may relate to guilt, fear, needs or wants of family members, rather than what the person's best wishes might otherwise have been.

And there is the chillingly practical, other public policy matter of the cost of maintaining persons diagnosed in persistent vegetative states and terminal conditions alive for potentially indefinite periods of time--at what inevitably becomes public expense. Here the "reasonable person" standard, with respect to how one would want to be treated were they in Theresa's shoes affects the discussion. This is not easy stuff, and should not be.

In withholding or withdrawing life support, or in keeping a person alive, there is the risk of transposing intentions and values. The reasoned, even substituted judgment decisions of guardians or loved ones may be based upon either a "quality of life determination", or the desires of family members. This remains a risk in a system that does not require an explicit, advance directive.

Cruzan and the Role of States in Guidelines for Medical Decisions

A legal analysis of the tens of thousands of pages of documents in the case file, against the statutory legal guidelines and the supporting case law, leads the GAL to conclude that all of the appropriate and proper elements of the law have been followed and met. The law has done its job well. The courts have carefully and diligently adhered to the prescribed civil processes and evidentiary guidelines, and have painfully and diligently applied the required tests in a reasonable, conscientious and professional manner. The disposition of the courts, four times reviewed at the appellate level, and once refused review by the Florida Supreme Court, has been that the trier of fact followed the law, did its job, adhered to the rules and rendered a decision that, while difficult and painful, was supported by the facts, the weight of the evidence and the law of Florida.

A prevailing legal sentiment is that matters such as those in Theresa's case are best addressed by states, their legislatures and their courts--rather than by the federal judiciary.

Justice Scalia has admonished us to rely upon and accept the role of state lawmakers and laws to address issues of this very nature. Though his point of reference was Missouri law relative to an evidentiary standard, his message remains that it is up to states to establish the rules and guidelines in these matters.

I would have preferred that we announce, clearly and promptly, that the federal courts have no business in this field; that American law has always accorded the State the power to prevent, by force if necessary, suicide--including suicide by refusing to take appropriate measures necessary to preserve one's life; that the point at which life becomes "worthless," and the point at which the means necessary to preserve it become "extraordinary" or "inappropriate," are neither set forth in the Constitution nor known to the nine Justices of this Court any better than they are known to nine people picked at random from the Kansas City telephone directory; and hence, that even when it is demonstrated by clear and convincing evidence that a patient no longer wishes certain measures to be taken to preserve her life, *it is up to the citizens of Missouri to decide, through their elected representatives, whether that wish will be honored.* It is quite impossible (because the Constitution says nothing about the matter) that those

citizens will decide upon a line less lawful than the one we would choose; and it is unlikely (because we know no more about "life-and-death" than they do) that they will decide upon a line less reasonable. (emphasis added) *Cruzan v. Director, MDH*, 497, U.S. 261 (1990)

And while he might not agree with a particular state's method for addressing a matter--he not only defers to the states--but further admonishes us to avoid the politicization of legislation in these matters:

I am concerned, from the tenor of today's opinions, that we are poised to confuse that [497 U.S. 261, 293] enterprise as successfully as we have confused the enterprise of legislating concerning abortion--requiring it to be conducted against a background of federal constitutional imperatives that are unknown because they are being newly crafted from Term to Term. That would be a great misfortune. *Cruzan v. Director, MDH*, 497, U.S. 261 (1990)

In this context, it is vital to realize that Florida Statutes, Florida Rules of Evidence, Florida Rules of Civil Procedure and Florida case law were the basis for the past 13 years of litigation and conclusions of law in Theresa's case.

Florida carefully and intentionally crafted its laws about death and dying and decisions about how persons, situated similarly to Theresa, might be treated by the law. While Florida remains among a minority of states that has provisions for proxy and/or surrogate decision making in matters of removal of artificial feeding when there is no written living will--it is fair to say that this was a conscious, deliberate process within the Florida legislative arena. This process actively involved a broad cross section of political, philosophical and religious interests, public hearings, and the deliberate sharing of very specific language with vested parties, within and outside of government. Based upon Justice Scalia's admonition, one should exercise caution in re-crafting state laws from term to term.

Speaking with the majority in *Cruzan*, Justice Stevens further admonishes us to accept state legislation in matters of death and dying:

"Choices about death touch the core of liberty... [N]ot much may be said with confidence about death unless it is said from faith, and that alone is reason enough to protect the freedom to conform choices about death to individual conscience." Our salvation is the Equal Protection Clause, which requires the democratic majority *to accept for themselves and their loved ones what they impose on you and me*. This Court need not, and has no authority to, inject itself into every field of human activity [497 U.S. 261, 301] where irrationality and oppression may theoretically occur, and if it tries to do so, it will destroy itself. (emphasis added) *Cruzan v. Director, MDH*, 497, U.S. 261 (1990)

Justice O'Connor reinforces the High Court's view that it is to the states and their legislative process that the Supreme Court turns to grapple with these matters:

Today we decide only that one State's practice does not violate the Constitution; the more challenging task of crafting appropriate procedures for safeguarding incompetents' liberty interests is entrusted to the "laboratory" of the States, *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting), in the first instance. *Cruzan v. Director, MDH*, 497, U.S. 261 (1990)

And even if we are not happy with the result in a case--or the application and interpretation of the law, we are reminded by Chief Justice Requist, writing for the Court that general rules of law--indeed, even the law itself, is neither flawless nor faultless:

But the Constitution does not require general rules to work faultlessly; no general rule can. *Cruzan v. Director, MDH*, 497, U.S. 261 (1990)

In *In re Guardianship of Browning*, 568 So. 2d 4 (Fla. 1990) the Florida Supreme Court highlighted a privacy

interest in the decision regarding the removal of a feeding tube in an elderly, sick woman. The reasoning and methods deployed in that case have served as one of the foundations for the Florida courts' actions and conclusions in Theresa's case, including the proxy power of the court to make decisions about discontinuation of artificial life support. And while Browning can be distinguished from Theresa's case, it was adopted by the trial court and the court of appeal reasonably and rationally.

But the law has failed to provide Theresa a conclusion and resolution.

The elements of the law include specific provisions for decision making regarding the removal of artificial life support when explicit, written, advance directives have not been executed by a person.

Not all states deploy the specific guidelines and measures adopted by Florida. Many states refuse to accept anything but advance, written directives of the person as a basis for removal of artificial life support. Florida has chosen to employ guidelines that include surrogate decisions by the bona fide legal guardian and/or clear and convincing evidence as to the intentions of the person.

In Theresa's case, evidence regarding her intentions consisted of admitted hearsay regarding conversations between Theresa and her spouse and spousal relatives. The context and nature of this hearsay were deemed sufficiently probative, competent and reliable to serve as a basis for admission, and was determined to be sufficiently clear and convincing. The court then served as proxy decision maker, essentially assuming the role of legal guardian. The privacy interests of the person, as established in the Florida Constitution, and as articulated with specificity in Browning (*In re Guardianship of Browning*, 568 So. 2d 4 (Fla. 1990)) served as the legitimate legal bases for the court's conclusions to withdraw life support consistent with Florida Statute, 765.

Evidence regarding the persistent vegetative state consisted of highly credible medical testimony and documentation reflecting both early and recently performed neurological examinations and a case history that included early swallowing studies conducted multiple times nearly ten years ago.

The Swallowing Test and Neurological Function

The review of the medical and clinical evidence in the case goes directly to the issues of the feasibility and value of swallowing tests and swallowing therapy, and to the relationship between neurological function and swallowing food and liquid.

Three, independent sets of swallowing tests were performed early in Theresa's medical treatment: 1991, 1992 and 1993. Each of these determined that Theresa was not able to swallow without risk of aspiration (and consequent infection).

Swallowing tests and swallowing therapy address many of the core issues in contention. If Theresa can swallow, then she can take nutrition and hydration orally, and it is argued that she would not elect to stop eating. But to orally eat and drink, Theresa must possess cognitive capacity beyond mere reflex, or she will not only fail to ingest, but could easily aspirate substances into her lungs and be subjected to infections and subsequent death.

If Theresa were capable of orally taking nutrition and hydration, this GAL suggests that Theresa's reasoned best wishes might be not to choose to stop eating, depending upon the difficulty, burden to others and costs involved. The conduct of swallowing tests by an independent, competent clinician, shielded from the public process, would provide competent, scientifically based medical evidence as to Theresa's ability to swallow and whether swallowing therapy could improve her capability to orally eat and hydrate.

Three general methods of swallowing test can be performed to assess swallowing capacity and swallowing potential. A bedside test examines cranial nerve function, speech potential and trials of certain food textures through spoons, syringes, straws and cups. It is relatively non-invasive and low risk, with the exception of silent aspiration --

which is the unnoticed sucking of food or water into the lungs, rather than transporting it down the throat.

The second is also bedside based test, call Flexible Endo Exam Swallowing (FEES). A nasal tube is inserted and spontaneous swallowing is observed, again using various textures of liquid and foods. This is a bit more objective and also has the advantage of being done at the bedside.

The recognized gold standard test is the modified barium swallowing test, generally done in a hospital or at a facility that has radiology equipment. Theresa's three previous tests were barium swallowing tests.

Swallowing therapy, if swallowing potential is identified, may consist of posture management (head and neck positioning), training to focus on the food ingestion process, holding utensils and other activities. Electrical stimulation therapy has been promoted, but there is no objective, scientific evidence as to its effectiveness or value.

The ability to orally ingest food and water--to swallow substances other than saliva, is predicated on a level of cognitive capacity. Without cognitive capacity, the intentional act of oral nutrition and hydration is likely to lead to aspiration. Eating and drinking are not unconscious processes. Therefore, Theresa's neurological status is directly linked to her ability to swallow.

Early in Theresa's care, neurological examinations were performed to assess her cognitive capacity. Competent medical practitioners determined that Theresa was in what has been consistently defined as a persistent vegetative state--a finding that throughout the litigation was not disputed by either side. Quite recently, the Schindlers have disputed that Theresa is in a persistent vegetative state, and in the alternative, they have argued that even if she is, she deserves to live and be maintained via artificial nutrition and hydration.

Like the law, which offers prescriptive guidelines to be applied on a case by case basis, Neurology, a nationally recognized specialty within Medicine, has sought to define the elements of disease states for purposes of treatment. The persistent vegetative state has been accepted as a formal diagnosis in modern American medical practice and it is recognized by American Academy of Neurology as:

The vegetative state is a clinical condition of complete unawareness of the self and the environment, accompanied by sleep-wake cycles, with either complete or partial preservation of hypothalamic and brain stem autonomic functions. In addition, patients in a vegetative state show no evidence of sustained, reproducible, purposeful, or voluntary behavioral responses to visual, auditory, tactile, or noxious stimuli; show no evidence of language comprehension or expression; have bowel and bladder incontinence; and have variably preserved cranial-nerve and spinal reflexes. We define persistent vegetative state as a vegetative state present one month after acute traumatic or nontraumatic brain injury, or lasting in least one month in patients with degenerative or metabolic disorders or developmental malformations.

The Multi-Society Task for on PVS, *Medical Aspects of the Persistent Vegetative State*, New England Journal of Medicine, 330:1499-1508, May 26, 1994.

A particularly disarming aspect of persons diagnosed with persistent vegetative state is that they have waking and sleeping cycles. When awake, their eyes are often open, they make noises, they appear to track movement, they respond to deep pain, and appear startled by loud noises. Further, because the autonomic nervous system those brain related functions are not affected, they can often breathe (without a respirator) and swallow (saliva). But there is no purposeful, reproducible, interactive, awareness. There is some controversy within the scientific medical literature regarding the characterization and diagnosis of persons in a persistent vegetative state. Highly competent, scientifically based physicians using recognized measures and standards have deduced, within a high degree of medical certainty, that Theresa is in a persistent vegetative state. This evidence is compelling.

Terri is a living, breathing human being. When awake, she sometimes groans, makes noises that emulate laughter

or crying, and may appear to track movement. But the scientific medical literature and the reports this GAL obtained from highly respected neuro-science researchers indicate that these activities are common and characteristic of persons in a persistent vegetative state.

In the month during which the GAL conducted research, interviews and compiled information, he sought to visit with Theresa as often as possible, sometimes daily, and sometimes, more than once each day. During that time, the GAL was not able to independently determine that there were consistent, repetitive, intentional, reproducible interactive and aware activities. When Theresa's mother and father were asked to join the GAL, there was no success in eliciting specific responses. Hours of observed video tape recordings of Theresa offer little objective insight about her awareness and interactive behaviors. There are instances where she appears to respond specifically to her mother. But these are not repetitive or consistent. There were instances during the GAL's visits, when responses seemed possible, but they were not consistent in any way.

This having been said, Theresa has a distinct presence about her. Being with Theresa, holding her hand, looking into her eyes and watching how she is lovingly treated by Michael, her parents and family and the clinical staff at hospice is an emotional experience. It would be easy to detach from her if she were comatose, asleep with her eyes closed and made no noises. This is the confusing thing for the lay person about persistent vegetative states.

Theresa's neurological tests and CT scans indicate objective measures of the persistent vegetative state. These data indicate that Theresa's cerebral cortex is principally liquid, having shrunk due to the severe anoxic trauma experienced thirteen years ago. The initial oxygen deprivation caused damage that could not be repaired, and the brain tissue in that area continued to devolve. It is noteworthy to recall that from the time of her collapse, and for more than three years, Theresa did receive active physical, occupational, speech and even recreational therapy. There is evidence early in her records of care that she said "no" during physical therapy session. That behavior did not recur and was not further referenced.

In recent months, individuals have come forward indicating that there are therapies and treatments and interventions that can literally re-grow Theresa's functional, cerebral cortex brain tissue, restoring part or all of her functions. There is no scientifically valid, medically recognized evidence that this has been done or is possible, even in rats, according to the president of the American Society for Neuro-Transplantation. It is imaginable that some day such things may be possible; but holding out such promises to families of severely brain injured persons today may be a profound disservice.

In the observed circumstances, the behavior that Theresa manifests is attributable to brain stem and forebrain functions that are reflexive, rather than cognitive. And the substantive difference according to neurologists and neurosurgeons is that reflexive activities of this nature are neither conscious nor aware activities. And without cognition, there is no awareness. (Descartes addressed this in his proposition that it is our awareness, our consciousness that defines our being: "Cogito, ergo sum". This logic would imply that unless we are aware and conscious, we cease to be.)

By all measures in the literature, Theresa has beaten the odds in terms of surviving her persistent vegetative state condition. While younger persons fare better than older victims, life spans rarely, according to the American Academy of Neurology, exceed ten years following the onset of the condition. Persons who have been comatose have worse outcomes than those who have not. But Theresa has also far outlived any documented periods from which persons in persistent vegetative states have emerged in any functional capacity. The reasonable degree of medical certainty associated with her diagnosis and prognosis is very high.

Overcoming the Enmity and Disagreement Regarding the Medical Outcome

The parties cooperated completely with the GAL during the thirty day investigation, analysis and report preparation. The issue of feasibility and value, raised in the court charge, and discussed throughout this report, provided

the basis for very serious discussions among the parties regarding an agreement to pursue an alternative process in order to resolve the disputes in this matter and gain closure for Theresa.

During the final days of this investigation, an agreement, designed and titled a "platform of understanding" for an agreement in principle, was sculpted. Elements of the platform were acceptable and there was preliminary and contingent agreement in principle to the intent and much of the content of the drafts. All three parties, the Schindlers, Michael Schiavo, and the Office of the Governor, through their respective attorneys, participated actively in this process. The agreement was based, in good part, on the trusting relationship that evolved between the GAL and the parties during the investigation. It was expected that the parties would make a joint request to the court to allow and facilitate the agreement to be carried out.

The evening before the deadline for the submission of this report, the negotiations surrounding the agreement broke down, and the parties were not able to achieve what would have been an agreement in principle to engage in a new and different process. The outline of this agreement is in Appendix I.

Summary of Guardian Ad Litem Recommendations

Restatement of Questions and Recommendations

1. Should the Governor lift the stay that he previously entered relative to Theresa Schiavo's feeding tube?
 - a. Yes. The Governor should lift the stay, if valid, independent scientific medical evidence clearly indicates that Theresa has no reasonable medical hope of regaining any swallowing function and/or if there is no evidence of cognitive function and no hope of improvement.
 - b. No. The Governor should not lift the stay if valid, independent scientific medical evidence clearly indicates that Theresa has a reasonable medical hope of regaining any swallowing function and/or if there is evidence of cognitive function with or without hope of improvement.
2. Is there feasibility and value in swallowing tests and swallowing therapy given the totality of circumstances?
 - a. Yes. There is feasibility and value in swallowing tests and swallowing therapy being administered if the parties agree in advance as to how the results of these tests will be used with respect to the decision about Theresa's future. If the parties do not agree in advance as to how the tests will be used, then the court must be prepared to once again make a final judgment on the matter. Given the history of the case, this would not, in and of itself, assure a resolution, and is not, therefore, deemed either feasible or of value to Theresa Schiavo without prior agreement.

The GAL concludes from the medical records and consultations with medical experts that the scope and weight of the medical information within the file concerning Theresa Schiavo consists of competent, well documented information that she is in a persistent vegetative state with no likelihood of improvement, and that the neurological and speech pathology evidence in the file support the contention that she cannot take oral nutrition or hydration and cannot consciously interact with her environment. n1

n1 But that is not enough. This evidence is compromised by the circumstances and the enmity between the parties. Until recently, while both Michael Schiavo and the Schindlers agreed that Theresa was in a persistent vegetative state, they could not agree as to the matter

of discontinuation of life support. Recently, the Schindlers have adopted what appears to be a position that Theresa is not in a persistent vegetative state, and/or that they do not support the fact that such a medical state exists at all. Yet throughout the nearly ten years of litigation, it is the issue of her ability to swallow, ingest food and hydration, and the findings regarding any residual cognitive ability that have marked the medical substance of this dispute.

Of the Schindlers, there has evolved the unfortunate and inaccurate perception that they will "keep Theresa alive at any and all costs" even if that were to result in her limbs being amputated and additional, complex surgical and medical interventions being performed, and even if Theresa had expressly indicated her intention not to be so maintained. During the course of the GAL's investigation, the Schindlers allow that this is not accurate, and that they never intended to imply a gruesome maintenance of Theresa at all costs.

Of Michael Schiavo, there is the incorrect perception that he has refused to relinquish his guardianship because of financial interests, and more recently, because of allegations that he actually abused Theresa and seeks to hide this. There is no evidence in the record to substantiate any of these perceptions or allegations.

Until and unless there is objective, fresh, mutually agreed upon closure regarding measurable and well accepted scientific bases for deducing Theresa's clinical state, Theresa will not be done justice. There must be at least a degree of trust with respect to a process that the factions competing for Theresa's best interest can agree. To benefit Theresa, and in the overall interests of justice, good science, and public policy, there needs to be a fresh, clean-hands start.

The Schindlers and the Schiavos are normal, decent people who have found themselves within the construct of an exceptional circumstance which none of them, indeed, few reasonable and normal people could have imagined. As a consequence of this circumstance, extensive urban mythology has created toxic clouds, causing the parties and others to behave in ways that may not, in the order of things, serve the best interests of the ward.

The GAL concludes that the trier of fact and the evidence that served as the basis for the decisions regarding Theresa Schiavo were firmly grounded within Florida statutory and case law, which clearly and unequivocally provide for the removal of artificial nutrition in cases of persistent vegetative states, where there is no advance directive, through substituted/proxy judgment of the guardian and/or the court as guardian, and with the use of evidence regarding the medical condition and the intent of the parties that was deemed, by the trier of fact to be clear and convincing.

The GAL concludes the Guardian Ad Litem appointment be extended until a resolution is concluded in the matter of Theresa Maria Schiavo.

The rules were adhered to and they are the laws of this state. Again, Justice Renquist in *Cruzan*: "But the Constitution does not require general rules to work faultlessly; no general rule can." *Cruzan v. Director, MDH*, 497, U.S. 261 (1990)

We remain in Theresa Schiavo's shoes.

1 December 2003

APPENDIX I PLATFORM OF UNDERSTANDING

Good faith efforts marked the Guardian Ad Litem's investigation, interviews and research process. All parties were professional, civil and helpful. It is noted that the Governor's amicus brief to the federal district court served as a guidepost for the GAL's crafting of the platform. In that amicus brief, the Governor implied the importance of obtaining valid, scientifically-based medical information in order to address certain unresolved matters affecting Theresa. The platform that was developed remains a template that can afford the parties a vehicle for achieving a common ground upon which to resolve the central disputed matters that have precluded closure for Theresa Schiavo. Perhaps more time is needed. The elements of the platform of understanding, as last discussed are presented below.

As of the deadline for submission of this report, the parties are deeply engaged in the vicissitudes of a constitutional challenge to the law that afforded the Governor the authority to stay the removal of Theresa's artificial feeding tube. The parties have had little or no opportunity or inclination, during the nearly ten years of legal hostilities, to effectively seek an alternative approach to their dispute. As a consequence, uncertainties remain on all sides of the issue. And there is now a third side: the Governor.

The constitutional challenge may take weeks, if not months to wind its way through the Florida circuit, appeals and supreme court processes. The Governor's involvement has added a new and unexpected dimension to the litigation. It is reasonable to expect that the exquisite lawyering will continue, and the greatly enhanced public visibility of the case may increase the probability of more litigation, more parties entering as intervenors, and efforts to expand the case into federal jurisdiction.

Given this scenario, it is possible that continued delay could afford the Florida Legislature the opportunity to amend certain provisions of F.S. 765 to make the law more consistent with the majority of states that require written advance directives. The GAL believes this would be unfortunate. But were this to occur before the case resolved in the courts, it is possible that the evidentiary basis used in Theresa's previous cases would become unacceptable, and new litigation could arise around a new law's application. In this scenario, the litigation process could continue for months, if not years. This would leave Theresa in the continued netherworld of the unresolved, unless Mr. Schiavo determined that he would no longer pursue the matter.

In the alternative, the constitutional challenge could be addressed expeditiously by the court system, and in the event the law is deemed unconstitutional by the circuit court and affirmed at the district court of appeal and the supreme court, the entire process could end there. In this scenario, and given the well articulated position of the majority of the U.S. Supreme Court, it is possible that the case would not be accepted for review. It would be a good example, given the opinions in *Cruzan*, to leave matters such as this to the states and their legislative and judicial processes.

That scenario, if played out with reasonable speed, would lead to a final determination that Theresa's artificial nutrition should be terminated. For the third time, she could have the tube clamped or removed. She would then die within a week to ten days. Unless, some new legal maneuver intervened again--resulting in a new stay.

PLATFORM OF UNDERSTANDING FOR ARRIVING AT A RESOLUTION IN THE MATTER OF THERESA MARIE SCHIAVO

(Abandoned 30 November 2003)

All parties agree that the legal, medical and political issues surrounding Theresa Schiavo have made it difficult to come to any meeting of the minds among the parties regarding what is best for her.

All parties agree that their intention is to do what is best for Theresa.

All parties agree that the current circumstance has created the need for clarity and focus with respect to what is best for Theresa - to the extent possible, outside the press and even open court.

All parties agree that core issues persistently raised with respect to Theresa's condition that have been subject to the most consistently stated contest are:

- . Whether Theresa can take nutrition and hydration orally
- . Whether Theresa's neurological condition:
 - Includes cognitive functioning and/or capability
 - Provides a basis, given good science and medicine, to be improved to permit her to interact more with her environment

All parties agree that the legal process to date, while following statutory guidelines and rules of evidence, has not resulted in a conclusion that is, in the eyes of each of the parties, in Theresa's best interests;

to wit: those advocating for her rights to privacy and to die according to her wishes have not been successful in

reaching closure; and

those advocating for her right to live, regardless of the nature of her illness, injury, disability or condition, have not been successful in excluding termination of life support as an immediate possibility.

In the informed opinion of the GAL, following the directive guidelines of the Court, no "feasible and valuable" recommendations can be made that will be in Theresa's best interests and best wishes until and unless there are changes in the status quo among the parties. These changes are best approached incrementally.

In order to create a common ground among the parties, essential to feasibly and valuably addressing the best interests of Theresa, the parties agree in principle as follows:

1. The GAL is accepted and trusted by all the parties as having clean hands and acting exclusively in the interests of Theresa.
2. The GAL's judgment regarding the best interests of Theresa and his ability to objectively, fairly, scientifically and caringly represent these interests is accepted by all the parties.
3. The GAL will select competent, neutral, clinical specialists to make a formal determination about the feasibility and value of swallowing tests and therapy for Theresa. The specialists' identities will be kept confidential from the public. The specialists' determination will have value to the process of gaining a common and agreed-upon understanding among the parties.
4. The GAL will select competent, neutral, clinical specialists to conduct appropriate examinations and tests to make a formal determination about neurological capacity and prognosis. The specialists' identities will be kept confidential from the public. The specialists' determination will have value to the process of gaining a common and agreed-upon understanding among the parties.
5. The GAL should be permitted and authorized to move forward with a plan, designed to gain the data regarding swallowing tests/therapy and neurological capacity in a manner consistent with items 3 and 4, above, with and through the advice and input of the parties' counsels and the Court.
6. The parties agree in principle to establish in advance, parameters for their respective actions based upon the outcomes of the examinations and tests. These parameters will be developed, through the auspices of the GAL, within 10 days of the presentation of this report to the Governor, and said parameters, agreed upon by the parties, shall serve as the predicate for proceeding with the initiation of the testing and examination.
7. The successful recruitment and deployment of the clinical experts to perform the exams will be under the direction, supervision and discretion of the GAL, with advisement proffered to the attorneys for each of the parties.
8. Barring unforeseen events, the recruitment, deployment and reporting to the parties on the results of the tests will occur within 45 days of the specification referenced above in item 6 regarding the parameters.
9. In fairness, and because of the significant public policy issues involved, the costs associated with the recruitment and deployment of experts to perform the examinations and tests should be born by the State.
10. The parties respectfully request that the Court accept and honor this understanding in the interests of justice and with the expectation of achieving a feasible and valuable solution in a complex

and challenging matter that has acquired a high level of public policy significance.

In the event the GAL is unable to achieve agreement on a matter, the issue will either be respectfully set aside, with the acquiescence of the parties, or, if it is deemed to be of such a critical and vital nature, it may serve to stall or terminate the good faith process. At that juncture, the GAL will report on the failure of the process and the reason for the impasse.

Within ten days of the presentation of this report, the GAL will provide the Governor and the Court with a written status update along with the details of an implementation plan.

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SUMMARY: ABSTRACT: As exemplified in the Affordable Care Act, healthcare reform aims to combat fraud and abuse and promote new payment and delivery models. However, these aspects of reform are fundamentally incompatible, as the existing fraud and abuse regime, designed to protect care delivery in a fee-for-service (FFS) environment, is inhospitable to new integrated delivery models. To achieve balanced reform, the government must transform its enforcement approach to both protect against fraud and abuse and promote a fertile environment for delivery system innovations. Through its expansive use of its waiver authorities in connection with the Medicare Shared Savings Program (MSSP), the government has granted accountable care organizations (ACOs) unique regulatory treatment. This article discusses the extension of this regulatory approach to other initiatives, such as bundled payment models and patient-centered medical homes (PCMHs), to create a bifurcated system of fraud and abuse whereby integrated delivery models and traditional FFS-based arrangements are subject to distinctive regulatory treatment. The bifurcated model would advance the fraud and abuse goals of deterrence and proportionality while ensuring the success and sustainability of integrated delivery models envisioned in the Affordable Care Act.

KEYWORDS: Waivers, Fraud, ACOs, Healthcare Reform, Integrated Models**TITLE: NOTE AND COMMENT:** Fostering Healthcare Reform through a Bifurcated Model of Fraud and Abuse Regulation

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TEXT:**Introduction**

The Patient Protection and Affordable Care Act n1 (ACA) is the legal realization of recent healthcare reform efforts' triple aims: enhancing quality of care, improving the health of populations, and reducing per-capita costs. n2 To further these overarching goals, the ACA contains provisions designed to: (i) strengthen laws combating fraud and

abuse, and (ii) promote new healthcare payment and delivery models. However, despite their shared background, these two aspects of reform contain incompatible features that could jeopardize their respective agendas. The ACA's anti-fraud provisions, which embrace more traditional methods of preventing fraud and abuse in a fee-for-service (FFS) setting, threaten to impede the development of integrated delivery models. As the ACA is implemented through various rulemakings, healthcare reformers face the task of modifying the existing fraud and abuse regulatory structure to foster innovative payment and delivery schemes. Their efforts will be consequential to the overhaul of the healthcare system.

n1 Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, 124 Stat. 119 (2010) [hereinafter *Affordable Care Act*].

n2 Donald M. Berwick et al., *The Triple Aim: Care, Health, and Cost*, 27 *Health Aff.* 759, 760 (2008).

This article addresses anti-fraud and delivery system reforms as conceived in the ACA, its implementing regulations, and the surrounding healthcare debate. Special attention is applied to the U.S. Department of Health and Human Services' (HHS) use of its waiver authorities for the Anti-Kickback Statute (AKS), the Stark Law, and the Civil Monetary Penalties (CMP) Statute, and how industry commenters have framed the issues pertaining to the coordination of anti-fraud laws and integrated delivery models. With the issuance of the Interim Final Rule regarding accountable care organization (ACO) waivers for the Medicare Shared Savings Program (MSSP), the government revealed that it will undertake a unique enforcement approach that accounts for the distinctive characteristics of the ACO model.

Through its bold exercise of its ACO waiver authority, the government has taken the first steps in creating a bifurcated model of fraud and abuse regulation that distinguishes between integrated delivery models and traditional FFS-based arrangements. Such a model would create an enforcement gradient that would attract provider participation and ensure the success and sustainability of the ACA's delivery system reforms. In addition, it would permit the government to incorporate private payor involvement in integrated reforms, potentially leading the way for dramatic, industry-wide change. The bifurcated model would recognize that integrated models, particularly ACOs, are subject to heightened regulations that include enrollment, program integrity, data reporting, and compliance measures--internal safeguards that protect against fraud and abuse. Accordingly, under the bifurcated system, the government would view integrated models as largely self-correcting, and would permit enforcement authorities to focus their resources upon fraud in the FFS-based sphere. In this manner, the bifurcated model would be an efficacious means for achieving the desired policy balance between promoting participation in integrated delivery models and bolstering efforts to combat systemic fraud and abuse.

Healthcare Delivery and Fraud and Abuse Under the FFS System

The provision of healthcare services in the United States is governed not by a uniform system, but instead by a pastiche of independent or loosely affiliated provider components that incidentally arrange for care. Supporting today's fragmented model is the dominant FFS payment methodology with services reimbursed on an unbundled basis. Because volume determines payment, physicians have little incentive to control the amount of services provided. Due to growth in medicine costs and Medicare enrollment, n3 today's FFS model has contributed to overall cost escalation. Analysts predict that without reform, Medicare and Medicaid expenses will consume half of the federal budget by 2020. n4

n3 Charles Hugh Smith, *Is Fee-for-Service What Ails America's Health Care System?*, DAILY FIN.: AN AOL MONEY & FINANCE SITE, Jan. 18, 2010, www.dailyfinance.com/2010/01/18/is-fee-for-service-what-ails-americas-health-care-system/ (noting that the entrance of Baby Boomers into the Medicare system will increase enrollment in Medicare from 45 million beneficiaries to over 67 million by 2020).

n4 *Id.*

Problems in the healthcare sector also spring from the disconnect between hospitals and physicians founded on

Medicare's divergent payment methods. Hospitals are reimbursed primarily through the diagnosis-related group (DRG) system, whereby single bundled payments are provided for all inpatient hospital costs related to a specific diagnosis. Physicians, on the other hand, are reimbursed under the physician fee schedule (PFS), which allocates predetermined payments for each service rendered. As a result, the hospitals' motivation to reduce costs under DRG reimbursement conflicts with physicians' ability to receive volume-based payment under PFS. Because of these misaligned incentives, there is no financial impetus for physicians to work with hospitals or other physicians to seek efficiencies. n5 The PFS methodology tends to pay more for newer procedures than it does for older procedures or cognitive services. These factors have contributed to provider competition and the growth of physician entrepreneurship, n6 with the increased physician use of in-office diagnostic and therapeutic procedures and the growth of ambulatory surgery centers and specialty hospitals--all to the detriment of hospitals' finances and contributing to higher overall costs. n7

n5 Barry S. Collier, *Realigning Incentives to Achieve Health Care Reform*, 306 J. AM. MED. ASS'N 204, 204 (2011).

n6 Hoangmai H. Pham & Paul B. Ginsburg, *Unhealthy Trends: the Future of Physician Services*, 26 HEALTH AFF. 1586, 1591 (2007).

n7 Robin Locke Nagele, *Hospital-Physician Relationships After National Health Reform: Moving From Competition to Collaboration*, 82 PA. B. ASS 'N Q. 1, 2 (2011); see also Atul Gawande, *The Cost Conundrum: What a Texas Town Can Teach Us About Health Care*, NEW YORKER, June 1, 2009 ("[T]here are the physicians who see their practice primarily as a revenue stream . . . They take a Doppler ultrasound course, buy a machine, and start doing their patients' scans themselves, so that the insurance payments go to them rather than the hospital.").

The existing anti-fraud legal enforcement framework is designed to protect healthcare delivery in a FFS environment. The AKS, the Stark Law, and the CMP Statute are the product of lawmakers' FFS-related concerns about the restriction of patient choice and quality and the improper utilization of healthcare services. n8 Overutilization is an issue under the FFS framework because physician compensation primarily is based on the amount of services provided. On the other hand, the pressure for hospitals to economize under DRG-based reimbursement encourages underutilization. Paid referrals and kickbacks also are suspect because they inject financial considerations into medical decisionmaking. Such considerations may influence physicians to limit disclosures to patients, thereby restricting patients' abilities to make informed choices about their healthcare needs. Finally, the fraud and abuse laws, like the antitrust laws, are aimed at reducing activities that adversely impact competition in the healthcare sector.

n8 Carrie Valiant, *Accountable Care Organization, Clinical Laboratories and Fraud and Abuse--What's Old is New Again*, G-2 COMPLIANCE REP., at 2 (Mar. 2011).

Existing anti-fraud laws and enforcement policies powerfully reinforce fragmentation. The laws are designed to discourage unique financial arrangements between providers that are not at arms-length or based on fair market values. Consequently, provider coordination is deterred, leading, in turn, to the creation of isolated care "silos" that have no incentive under FFS payment--nor any ability under the fraud and abuse laws--to work together to achieve efficiencies.

The ACA authorizes important and dramatic changes in healthcare delivery and the fraud and abuse laws. Due to their close interrelationship, modifications of the fraud and abuse regulations should impact delivery system reforms greatly, and vice versa. Unless lawmakers and regulators coordinate these two paths of reforms, the prospects for optimal healthcare delivery reform in the United States may be undermined.

The ACA's Modifications of the Fraud and Abuse Laws

Although controversy and debate have surrounded many aspects of healthcare reform, a broad consensus has formed on the need to intensify the campaign against healthcare fraud and abuse. n9 Fraud is perceived as a central

driver of ballooning costs, as the government estimates that between 3 and 10 percent of total healthcare expenditures are comprised of fraudulent billings. n10 In fiscal year 2010, government health programs made over \$ 70 billion in improper payments, with approximately \$ 48 billion of that amount paid by Medicare. n11

n9 Kirk Ogosky & Daniel A. Kracov, *The Impact of Reform on Health Care Fraud Enforcement*, 40 THE BRIEF 42 (2010).

n10 FED. BUREAU OF INVESTIGATION, FINANCIAL CRIMES REPORT TO THE PUBLIC 2007: OCTOBER 1, 2006 - SEPTEMBER 30, 2007, available at www.fbi.gov/stats-services/publications/fcs_report2007.

n11 See *Medicare and Medicaid Fraud, Waste and Abuse: Effective Implementation of Recent Laws and Agency Actions Could Help Reduce Improper Payments*, Hearing Before the Subcomm. on Fed. Fin. Mgmt. Gov't Info., Fed Servs. & Int'l Security, S. Comm. on Homeland Security & Gov't Aff., 1 (Mar. 9, 2011) (statement of Kathleen M. King, Director, Health Care, and Kay L. Daly, Director, Financial Management and Assurance), available at www.gao.gov/new.items/d11409t.pdf.

The 1996 Health Care Fraud and Abuse Control (HCFA) Program launched a new era of concerted action against healthcare fraud and abuse. New laws, programs, and resources have been marshaled to bolster healthcare anti-fraud efforts as a law enforcement priority. On May 29, 2009, President Obama signed the Fraud Enforcement and Recovery Act (FERA) n12 and established the Health Care Fraud Prevention and Enforcement Action Team (HEAT), a working group focused on combating fraud. Created within HEAT is the Medicare Strike Force, a joint effort of agents from the FBI, the Office of Inspector General (OIG), regional Medicaid Fraud Control Units, and the Department of Justice (DOJ), now operating in nine U.S. cities to investigate and prosecute fraudulent Medicare billings. The ACA's passage in 2010 was the latest event in this progression, with more than thirty-two sections devoted to fraud and abuse and program integrity reforms.

n12 Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, 123 Stat. 1617 (May 20, 2009).

Although attention to healthcare fraud has reached new heights in recent years, related reforms, particularly those in the ACA, do not change the fundamental nature of the government's enforcement approach. To deter and combat healthcare fraud and abuse, the government primarily relies on a handful of statutes, namely, the AKS, the Stark Law, the CMP Law, and the False Claims Act. The ACA affirms the central role that these laws enjoy in today's enforcement framework by dramatically increasing their force and reach.

The Anti-Kickback Statute

Enacted in 1972 and subsequently amended, the AKS n13 prohibits the payment or receipt of remuneration in exchange for referrals or the purchase of any item or service that may be covered under a federal healthcare program. The AKS is intended to eliminate the practice of extending "kickbacks" or provider inducements, which can give rise to conflicted medical decisionmaking and the provision of unnecessary services that inflate healthcare costs. n14 In light of these concerns, the AKS allows for significant civil and criminal penalties--a single violation invites fines of up to \$ 25,000, imprisonment for up to five years, n15 and mandatory exclusion from federal healthcare programs. n16 An AKS violation also may serve as a basis for significant civil money penalties of up to \$ 50,000 for each improper act and damages of up to three times the amount of remuneration at issue. n17

n13 42 U.S.C. § 1320a-7b(b).

n14 *United States v. Ruttenberg*, 625 F.2d 173, 177 (7th Cir. 1980) ("The potential for increased costs if such 'fee' agreements become an established and accepted method of business is clearly an evil with which the court was concerned and one Congress sought to avoid . . .

.").

n15 42 U.S.C. § 1320a-7b(b).

n16 *Id.* § 1320a-7(a).

n17 *Id.* § 1320a-7a(a)(7).

Through an expansive construction of the statute's prohibition of "remuneration," the government has used the AKS to challenge a range of business and marketing activities, including doctor recruitment, rental arrangements, and home health management deals. The statute's reach is unquestionably broad--any payment for which one purpose conceivably could be construed as a referral implicates the statute. n18 To ensure compliance, providers must look to statutory exceptions or regulatory "safe harbors" relating to certain identified business and financial arrangements. n19 Although failure to satisfy a safe harbor does not mean a practice is illegal, n20 providers are very cautious about arrangements that implicate the AKS due to its harsh penalties, making transactions in the healthcare sector more complex, costly, and risky for providers. n21

n18 *Id.* § 1320a-7b(b)(3).

n19 The Medicare and Medicaid Patient and Program Protection Act of 1987, Section 14 of Public Law 100-93, directed the creation of "safe harbor" provisions to "limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial and innocuous arrangements." *See Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions*, 56 Fed. Reg. 35952, 35952 (July 29, 1991) (codified at 42 C.F.R. pt. 1001).

n20 *See Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbors for Protecting Health Plans*, 61 Fed. Reg. 2122, 2124 (Jan. 25, 1996) ("[t]he failure [of] compl[iance] with a safe harbor means only that the practice or arrangement does not have the absolute assurance of protection from anti-kickback liability.").

n21 Stanley A. Twardy & Michael P. Shea, *Anti-Kickback Anxiety: How a Criminal Statute is Shaping the Health-Care Business*, ABA Section of Bus. L., Bus. L. Today, available at <http://apps.americanbar.org/buslaw/blt/blt00may-kickback.html> (2000).

Courts have struggled to resolve uncertainties in the AKS's reach and applicability, including the law's scienter requirement, under which a party must be found to have "knowingly and willfully" n22 engaged in prohibited conduct. The Ninth Circuit interpreted this language as requiring the government to prove that the defendant knew that the AKS prohibited the conduct at issue and the defendant engaged in the conduct with specific intent to disobey the law. n23 Although other courts were not receptive to this reading, n24 it allowed for inconsistent interpretations.

n22 42 U.S.C. § 1320a-7b(a).

n23 *Hanlester Network v. Shalala*, 51 F.3d 1390, 1400 (9th Cir. 1995).

n24 *See, e.g., United States v. Neufeld*, 908 F. Supp. 491 (S.D. Ohio 1995).

The ACA brings closure by amending the AKS to state that a violation may be shown without establishing actual knowledge of an AKS violation or specific intent to violate the statute. n25 The ACA confirms that a violation of the AKS constitutes a "false or fraudulent claim" under the False Claims Act (FCA). This eases the government's ability to allege an AKS violation as a predicate for asserting a cause of action under the FCA. Previously, some courts had

concluded that liability under both statutes could only arise when there was a false assertion of compliance with the AKS. n26 The changes in the ACA also may increase downstream liability for entities insofar as they may be alleged to have "caused the submission of a false claim." n27

n25 *Affordable Care Act* § 6402(f)(2), 124 Stat. at 759.

n26 *See, e.g., United States ex rel. Thomas v. Bailey*, No. 4:06CV00465 JLH (E.D. Ark. Nov. 6, 2008). The AKS amendment in the ACA was specifically intended to restrict the adoption of the rationale expressed in *U.S. ex rel. Thomas v. Bailey*.

n27 *See, e.g., United States ex rel. Hutcheson et al. v. Blackstone Med., Inc.*, 647 F.3d 377, 389 (1st Cir. 2011) ("When the defendant in an FCA action is a non-submitting entity, the question is whether that entity knowingly caused the submission of either a false or fraudulent claim or false records or statements to get such a claim paid. The statute makes no distinction between how non-submitting and submitting entities may render the underlying claim or statements false or fraudulent.") (citing 31 U.S.C. §§ 3729(a)(1) & (2)).

The Federal False Claims Act

The FCA, law enforcement's weapon of choice for unearthing and penalizing fraud perpetrated against the United States, has been employed in various government contracting settings and is especially prevalent in the healthcare context. Briefly stated, the law prohibits the "knowing" submission of "false or fraudulent" claims in order to receive payment from the government. n28 Upon a finding of civil liability, the FCA authorizes penalties between \$ 5,500 and \$ 11,000 per claim plus three times the amount of damages sustained by the government as a result. The statute also contains qui tam provisions that encourage whistleblowers, or "relators," to bring suit on behalf of the government by granting them a stake in any eventual recovery.

n28 31 U.S.C. § 3729(a).

Significant revisions have been made to the FCA to expand its impact and scope. FERA made important substantive changes to the law. Critically, the FCA intent requirement was eliminated, meaning that violations can arise whenever a false statement is made that is "material to a false or fraudulent claim"; n29 no longer must a defendant be shown to have used a false statement "to get" a false claim "paid or approved by the Government." Under the revised FCA, providers may be held liable for "knowingly and improperly avoid[ing] or decreas[ing] an obligation to pay or transmit money or property to the government." n30 "Obligation" was defined further to include "the retention of any overpayment" n31 from the government. As a result, liability may attach even in the absence of an affirmative act if a provider retains an overpayment from the government. Finally, the statutory term "claim" was amended to mean "any request or demand, whether under contract or otherwise, for money or property and whether or not the United States has title to the money or property." n32 This means that a violation results even when the false claim is not presented directly to the government, but instead to a government intermediary or third party such as a Medicare administrative contractor disbursing money on the government's behalf.

n29 31 U.S.C. § 3729(a)(1)(B). Through this revision, FERA overturned the Supreme Court's holding in *Allison Engine Co. v. United States ex rel. Sanders*, 128 S. Ct. 2123 (2008) that a false statement claim must be based on proof of intent to defraud.

n30 31 U.S.C. § 3729(a)(1)(G).

n31 *Id.* § 3729(b)(3).

n32 *Id.* § 3729(a)(1)(G).

FERA also made significant procedural changes to the FCA by increasing the government's authority to obtain information through civil investigative demands and to share information obtained with third parties, including relators and their counsel and any "consultants and experts." The law now provides that when the government intervenes in an FCA action or amends a relator's complaint, the statute of limitations will relate back to the date of the original complaint. n33 Finally, FERA extended whistleblower anti-retaliation protections to cover contractors and agents, **company** employees, n34 and actions intended to stop an FCA violation. n35 Prior to FERA, whistleblower protections only applied to **company** employees for actions directly relating to an FCA action or investigation.

n33 *Id.* § 3731(c).

n34 *Id.* § 3730(h)(1).

n35 *Id.*

Implemented less than a year later, the ACA made additional changes to the FCA that built on the FERA amendments. With respect to the newly minted FCA liability for overpayments, the ACA imposed a requirement whereby identified overpayments must be reported and returned within 60 days to the government; any retention of an overpayment beyond the 60-day period creates an "obligation" under the FCA. n36 As a result, a provider may be held liable under the FCA for any delayed retention of a known overpayment.

n36 *Affordable Care Act* § 6402(a), 124 Stat. at 755.

The ACA also expanded whistleblowers' ability to assert actions by restructuring the FCA's "public disclosure" bar, which prevented qui tam actions based on publicly disclosed information, unless the relator was the "original source" of the information. First, the scope of the original source exception was broadened by eliminating the direct knowledge requirement. To qualify as an original source, a relator needs to have only "knowledge that is independent of and materially adds to the publicly disclosed allegations." n37 Second, the public disclosure bar now is limited to federal disclosures and proceedings; state proceedings and private litigation no longer constitute public disclosures. Third, the ACA provides that if the qui tam suit is based on publicly-disclosed information and the relator is not an original source, then the "the court shall dismiss [the action], unless opposed by the government." n38 This grants the United States discretion to waive application of the public disclosure bar, meaning that the bar will no longer be automatic or jurisdictional.

n37 *Id.* § 10104(j)(2), 124 Stat. at 902.

n38 *Id.* at 901.

As a result of FERA and the ACA, the FCA will continue to play a primary role in the government's campaign against healthcare fraud. The FCA's qui tam provisions, which were enhanced through the reduction of the public disclosure bar and the liberalized statute of limitations period, will be more effective in conscripting private individuals to assist law enforcement efforts. Healthcare providers now must be wary of attracting FCA liability through retention of overpayments as technology advancements permit the government to analyze data for billing errors and overutilizations. As a result, large providers such as hospitals will need to shoulder increasing compliance burdens.

The Stark Law

The Ethics in Patient Referrals Act (the Stark Law) prohibits physician referrals of Medicare patients for certain "designated health services" to any entity with which the physician (or the physician's immediate family member) has a financial relationship. n39 The law prohibits the submission of payment claims to Medicare for services provided as a result of a prohibited referral. A *financial relationship* is defined expansively as "a direct or indirect ownership or investment interest" or a direct or indirect "compensation arrangement" that includes the physician's personal financial relationships or those of the physician's immediate family members. The Stark Law provides for strict liability, meaning that if a financial relationship does not meet the elements of a specified exception, n40 it is subject to civil sanctions including payment denials, mandated returns of payments received, civil monetary penalties, and exclusion from participation in Medicare. n41

n39 42 U.S.C. § 1395nn.

n40 *See id.* §§ 1395nn(b)--1395nn(e).

n41 The Stark Law and the AKS share structural characteristics (broad prohibitions and specified exceptions/safe harbors) and frequently target the same underlying conduct. Nevertheless, significant differences between the laws' respective prohibitions and safe harbors exist that manifest a "clear expression of legislative intent to keep enforcement under the anti-kickback statute separate from enforcement under [the Stark Law]. . ." Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35957 (July 29, 1991) (codified at 42 C.F.R. pt. 1001).

The ACA amended the Stark Law by modifying some of its exceptions and adding a Medicare self-disclosure protocol. It amended the so-called "whole hospital" exception in a manner that will curtail the creation of new physician-owned hospitals and limit the extent of physician ownership in existing hospitals. n42

n42 The new "whole hospital" rules also are made to apply to the exception relating to physician-owned hospitals in rural areas.

The ACA authorized a Medicare self-disclosure protocol pertaining to actual or potential Stark Law violations. The subsequently released Self-Referral Disclosure Protocol grants HHS discretion to resolve Stark violations and to reduce the amount levied against providers for violations after consideration of the nature of the violation, the disclosure's timeliness, the provider's cooperation, the matter's litigation risk, and the disclosing party's financial position. The self-disclosure protocol was welcomed by the provider community as a step in the right direction given that the Stark Law was drafted to hold physicians strictly liable for technical violations, even those that are minor or unintentional.

Despite the changes noted above, from the point of view of Stark Law detractors, the ACA is perhaps most noteworthy for the changes it did not make. No amendment or clarification assuages the Stark Law's manifold complexities, its correlation with the AKS, or its rigid structure that does not marry with healthcare industry dynamics. On balance, the ACA amendments serve to increase the practical risks associated with the Stark Law due to its role as a predicate for government and qui tam actions brought under the FCA. Amendments to the FCA suggest that the retention of payments received for services provided via a Stark-prohibited referral will support FCA liability. n43 The close connection between the two statutes is worrisome because the Stark Law's complexity frequently leads to technical violations, which can redound into draconian sanctions under the FCA. n44

n43 AM. HEALTH LAWYERS ASS'N, PUB. INTEREST COMM., A PUBLIC POLICY DISCUSSION: TAKING THE MEASURE OF THE STARK LAW 8 (2009), available at www.healthlawyers.org/hlresources/PI/Policy/Documents/Stark%20White%20Paper.pdf.

n44 *Id.* at 5--6.

The Civil Monetary Penalties Statute

The CMP Statute (Section 1128A of the Social Security Act) authorizes the Secretary of HHS to assess civil monetary penalties for various types of conduct. Among other things, it contains a "Gainsharing CMP" that prohibits hospitals from knowingly extending a payment, directly or indirectly, to a physician as an inducement to reduce or limit healthcare services to Medicare or Medicaid beneficiaries. n45 Like the AKS and the FCA, the CMP Statute's reach is expansive, as it includes any incentive that affects a physician's delivery of care regardless of whether the reduction in care is medically necessary. *Any* payment to a physician that has the potential to lead to a reduction in care is illegal--the payment need not be associated with an actual diminution in care. Finally, the CMP Statute creates a less flexible regulatory enforcement system, with no associated exceptions or safe harbors for its provisions; indeed, HHS's position is that it has no authority to create exceptions under the statute for this CMP. n46

n45 42 U.S.C. § 1320a-7a(b)(1).

n46 OFFICE OF INSPECTOR GEN., DEPT OF HEALTH & HUMAN SERVS., SPECIAL ADVISORY BULLETIN: GAINSHARING ARRANGEMENTS AND CMPS FOR HOSPITAL PAYMENTS TO PHYSICIANS TO REDUCE OR LIMIT SERVICES TO BENEFICIARIES (July 1999), *available at* <http://oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm>.

The ACA amends the CMP Statute by adding several new CMPs and modifying others. Of note, the ACA amended the definition of remuneration under the beneficiary inducement provisions to exclude remuneration that promotes "access to care and poses a low risk of harm to patients and Federal healthcare programs." n47 In addition, the ACA allows for CMPs totaling \$ 50,000 for false claims or statements made to any federal healthcare program and authorizes the OIG to impose CMPs of \$ 15,000 per day for those who delay providing access during audits, evaluations, or investigations. n48

n47 *Affordable Care Act* § 6402, 124 Stat. at 758. The beneficiary inducement provision prohibits offers and transfers of remuneration to federal healthcare program beneficiaries if the offeror knows or should know that the remuneration is likely to influence the individual's choice of healthcare provider.

n48 *Id.* §§ 6408(a)(2)--(3), 124 Stat. at 771.

Program integrity provisions

In addition to its amendments of the principal fraud and abuse statutes, n49 the ACA prescribes new program integrity measures that focus on the prevention and detection of fraudulent activities. For example, to improve oversight and to pinpoint fraud and abuse activities, the Centers for Medicare & Medicaid (CMS) integrated data repository will be expanded to include information from the several federal healthcare programs, and HHS is required to establish data-sharing and matching agreements with the heads of various agencies. n50 The ACA also includes enhanced screening and enrollment requirements, including background checks, for providers participating in Medicare, Medicaid, and the Children's Health Insurance Program; by 2013, all providers will be required to undergo enhanced screening prior to enrollment. n51 To identify and recover overpayments, the authority of the recovery audit contractors is extended to Medicaid, Medicare Advantage, and Medicare Part D programs. n52 Finally, pursuant to the ACA, many Medicare and Medicaid providers are now required to establish internal compliance programs designed to, among other things, educate employees about fraud and abuse laws, establish reporting mechanisms for fraudulent activity, and direct continual audits of billing and referral practices. n53

n49 The ACA also amends the Health Care Fraud Statute, 18 U.S.C. § 1347, which makes it unlawful to knowingly and willfully

defraud or attempt to defraud a healthcare benefit program, to ensure that criminal liability may apply even in the absence of actual knowledge or specific intent to violate the statute. *See Affordable Care Act* § 10606(b), 124 Stat. at 1008.

n50 *Affordable Care Act* § 6402, 124 Stat. at 753.

n51 *Id.* § 6401, 124 Stat. at 747.

n52 *Id.* § 6411, 124 Stat. at 773.

n53 *Id.* § 6102, 124 Stat. at 702 (requiring skilled nursing facilities to implement compliance programs as a condition of participation in federal health programs); *id.* § 6401, 124 Stat. at 747 (requiring the government to issue compliance programs for all types of healthcare providers).

Law Enforcement's Campaign Against Healthcare Fraud

Alternatively described as the "cops and robbers" or "pay and chase" approach, the current legal system is calibrated to recover improperly obtained money after it has been dispensed. Observers have criticized this after-the-fact approach as inefficient and ineffective. Much of the fraud perpetrated on the federal healthcare programs is seen as tied to their "trust-based" nature, where participation is treated as a right instead of a privilege--a system that is characterized by "low barriers to entry, lucrative targets, and the perception of low risk of detection and penalty." n54

n54 *A Perspective on Fraud, Waste, and Abuse Within the Medicare and Medicaid Programs: Hearing Before the Subcomm. on Health Care, District of Columbia, Census and the National Archives of the H. Comm. on Oversight & Government Reform, 112th Cong. 7* (Apr. 5, 2011) (statement of Gerald T. Roy, Deputy Inspector General for Investigations, Office of Inspector General, U.S. Department of Health & Human Services), available at http://oig.hhs.gov/testimony/docs/2011/Roy_Testimony_04052011.pdf.

Through the ACA's program integrity provisions, the government has taken important steps in assuming a novel approach to fighting healthcare fraud. The enrollment and screening initiatives are prophylactic measures that will keep wrongdoers out of the programs in the first place. The data analytics and audit oversight measures will promote transparency and hasten the ability to detect and address fraudulent activity. Together, these reforms place greater emphasis on the need for front-end protections rather than tracking the money down after it has already left the door. n55

n55 *Preventing Health Care Fraud: New Tools and Approaches to Combat Old Challenges: Hearing Before the S. Comm. on Finance, 112th Cong. 3--4* (2011) (statement of Peter Budetti, Deputy Administrator and Director, Center for Program Integrity, Centers for Medicare and Medicaid Services), available at www.hhs.gov/asl/testify/2011/03/t20110303a.html.

However, viewed from a broader perspective, the program integrity provisions are sideshows in the overall anti-fraud agenda. The ACA dramatically reinforces the traditional pay-and-chase mode of enforcement by enhancing existing legal tools, resources, and penalties. For instance, the law devotes an additional \$ 350 million for consolidated government-wide anti-fraud efforts through the HCFAC account for fiscal years 2011 through 2020. The U.S. Sentencing Guidelines were amended to increase offense levels by 20 to 50 percent for healthcare crimes that involve more than \$ 1 million. By sharpening the prevailing arsenal of statutes (the FCA, the AKS, the Stark Law, and the CMP Statute), the ACA does not signal a major shift in healthcare fraud enforcement; instead, the law upholds and furthers the status quo.

The latest statistics reflect how the government is using its new tools and resources to make the fight against healthcare fraud a top priority. n56 In November 2010, Attorney General Eric Holder remarked that the United States has taken the "fight against health care fraud to a new level." n57 Under the auspices of the HCFAC and through the

coordinated activities of HEAT and the Medicare Fraud Strike Force, federal law enforcement obtained a record \$ 4 billion in civil, criminal, and administrative recoveries in fiscal year 2010. n58 In the past 3 years, it has recovered nearly \$ 7 for every dollar spent on healthcare enforcement efforts. n59 Spurred by these successes, enforcement efforts have achieved an unprecedented momentum, as federal healthcare fraud prosecutions in the first 8 months of 2011 were on track to rise 85 percent over 2010. n60

n56 Press Release, U.S. Dep't of Justice, Office of Pub. Affairs, Justice Department Recovers \$ 2.4 Billion in False Claims Cases in Fiscal Year 2009; More than \$ 24 Billion Since 1986 (Nov. 19, 2009), *available at* www.justice.gov/opa/pr/2009/November/09-civ-1253.html.

n57 Press Release, Dep't of Justice, Office of Pub. Affairs, Departments of Justice and Health and Human Services Team Up to Crack Down on Health Care Fraud (Nov. 5, 2010), *available at* www.justice.gov/opa/pr/2010/November/10-ag-1256.html.

n58 *Fighting Fraud and Waste in Medicare and Medicaid, Hearing Before the Subcomm. on Labor, Health and Human Services, Education, and Related Agencies, S. Comm. on Appropriations*, 112th Cong. (Feb. 15, 2011) (statement of Tony West, Assistant Att'y Gen., Civil Division, Department of Justice), *available at* <http://appropriations.senate.gov/ht-labor.cfm?method=hearings.download&id=736b3bc1-3aa2-47a7-86ff-880d453d6b07>.

n59 *Id.*

n60 Kelly Kennedy, *Health Care Fraud Prosecutions on Pace to Rise 85%*, USA TODAY, Aug. 29, 2011.

The FCA has been front and center in the government's anti-fraud campaign. The DOJ recorded \$ 3 billion in FCA civil settlements and judgments in fiscal year 2010, with 83 percent of the year's total resulting from healthcare fraud recoveries. n61 Whistleblowers under the FCA's qui tam provision brought most of the successful cases, netting over \$ 2.3 billion in recoveries, with \$ 385 million earmarked for private plaintiffs. n62 The government has not heeded the U.S. Supreme Court's concern that the FCA is becoming an "all-purpose anti-fraud statute." n63 Instead, through the ACA, Congress modified the FCA, the AKS, and the Stark Law specifically to enhance their compatibility to extend the FCA's reach deep into the healthcare industry's remote recesses. Recent prosecutions have revealed how the DOJ wields enormous leverage through its combined use of the FCA and the AKS. n64

n61 Press Release, U.S. Dep't of Justice, Office of Pub. Affairs, Department of Justice Recovers \$ 3 Billion in False Claims Cases in Fiscal Year 2010 (Nov. 22, 2010), *available at* www.justice.gov/opa/pr/2010/November/10-civ-1335.html.

n62 *Id.*

n63 *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008).

n64 The AKS was cited as a predicate offense in an FCA action that resulted in a \$ 108 million settlement--the largest recovery ever under the AKS for a single hospital's conduct. Press Release, U.S. Dep't of Justice, Office of Pub. Affairs, The Health Alliance of Greater Cincinnati and the Christ Hospital to Pay \$ 108 Million for Violating Anti-Kickback Statute and Defrauding Medicare and Medicaid (May 21, 2010), *available at* www.justice.gov/opa/pr/2010/May/10-civ-602.html. In December 2010, the government reached a \$ 41 million settlement and deferred prosecution agreement with Kos Pharmaceuticals to resolve charges brought under the FCA and the AKS for alleged illegal kickback activities. Press Release, U.S. Dep't of Justice, Office of Pub. Affairs, Kos Pharmaceuticals to Pay More Than \$ 41 Million to Resolve Kickback and Off-Label Promotion Allegations (Dec. 7, 2010), *available at* www.justice.gov/opa/pr/2010/December/10-civ-1402.html.

Moreover, recent patterns indicate a growing emphasis on individual as well as corporate liability. DOJ prosecutions of healthcare executives have begun to surface as front page news. n65 As of early 2011, the Strike Force

was successful in charging more than 990 individuals for false Medicare billings totaling more than \$ 2.3 billion. n66 In addition, the Food and Drug Administration announced that it will use the "responsible corporate officer" doctrine to hold industry executives strictly liable for misdemeanor regulatory offenses under the Food, Drug, and Cosmetic Act. n67 In October 2010, the OIG identified nonbinding factors that will inform its consideration of whether to seek program exclusion under Section 1128(b)(15) of the Social Security Act for officers of excluded or convicted entities. n68 The guidance is viewed as communicating the OIG's intention to increasingly use its exclusion sanction--commonly referred to as "the death penalty"--against healthcare executives. n69

n65 For example, in February 2011, 111 defendants were charged in the largest federal healthcare fraud takedown for alleged participation in schemes involving more than \$ 225 million in false billing under Medicare. Press Release, U.S. Dep't of Health & Human Servs., HHS Press Office, Medicare Fraud Strike Force Charges 111 Individuals for More than \$ 225 Million in False Billing and Expands Operations to Two Additional Cities (Feb. 17, 2011), *available at* www.hhs.gov/news/press/2011pres/02/20110217a.html.

n66 *Preventing Health Care Fraud: New Tools and Approaches to Combat Old Challenges: Hearing Before the S. Comm. on Finance*, 112th Cong. 13 (2011) (statement of Peter Budetti, Deputy Administrator and Director, Center for Program Integrity, Centers for Medicare and Medicaid Services), *available at* www.hhs.gov/asl/testify/2011/03/t20110303a.html.

n67 Letter from Margaret Hamburg, Comm'r of Food & Drugs, Food & Drug Admin., Dep't of Health & Human Servs., to The Honorable Charles E. Grassley, Ranking Member, Senate Fin. Comm. (Mar. 4, 2010), *available at* www.grassley.senate.gov/about/loader.cfm?csModule=security/getfile&pageid=25529.

n68 *See* OFFICE OF INSPECTOR GEN., DEPT OF HEALTH & HUMAN SERV., GUIDANCE FOR IMPLEMENTING PERMISSIVE EXCLUSION AUTHORITY UNDER SECTION 1128(b)(15) of the Social Security Act (Oct. 20, 2010), *available at* http://oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf.

n69 Eliza Andonova et al., *Risky Business: The Pursuit of Healthcare Industry Executives and Managers*, 8 HEALTH LAW. WKLY. 1 (Nov. 12, 2010).

The Prevailing Fraud and Abuse Regulations and the Challenges to Coordinated Care

In the wake of recent reform efforts, the prevailing fraud and abuse regulations retain their longstanding character. This continuity reflects the government's recognition that even with the institution of new delivery system reforms, FFS payment methodologies will continue to predominate. However, while traditional fraud and abuse concerns will persist, to improve the status quo through integrated delivery model development fundamental changes will have to be made in the fraud and abuse laws.

The AKS, the Stark Law, and the CMP Statute set broad prohibitions that implicate integrated designs. To receive protection, stakeholders must satisfy prescribed safe harbors or exceptions or accept some level of risk--a process that can require a delicate dance, considering, for instance, that many exceptions and safe harbors between the AKS and the Stark Law do not correlate completely. The laws' application may evolve over time through periodic modifications or the creation of new exceptions or safe harbors. The exceptions and safe harbors tend to be narrowly drawn, and their revisions over time have made the regulatory picture increasingly complex. The CMS and OIG advisory opinion processes provide some legal guidance; however, the opinions only apply to specific factual circumstances and do not have general precedential force. As a result, stakeholders seeking to develop innovative financial arrangements face considerable difficulties in navigating the regulatory waters.

The OIG's historic treatment of gainsharing arrangements illustrates regulators' restrictive views of the fraud and abuse laws and how such views evolve--if at all--in a narrow and piecemeal manner. "Gainsharing" refers to "an arrangement in which a hospital gives physicians a percentage share of any reduction in the hospital's costs for patient care attributable in part to the physicians' efforts." n70 Gainsharing may be used to align physician and hospital

incentives--an attractive tool considering that hospitals' cost-reduction pressures under DRG-based reimbursement are not shared by physicians paid separately under PFS.

n70 OFFICE OF INSPECTOR GEN., SPECIAL ADVISORY BULLETIN: GAINSHARING ARRANGEMENTS AND CMPS FOR HOSPITAL PAYMENTS TO PHYSICIANS TO REDUCE OR LIMIT SERVICES TO BENEFICIARIES (July 1999), *available at* www.oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm.

Momentum built behind gainsharing in the 1990s until the OIG issued a Special Advisory Bulletin in 1999 announcing its position that gainsharing arrangements were generally prohibited under the Gainsharing CMP. n71 The OIG advised that parties desiring gainsharing should seek legislative relief, and that any existing arrangements should be terminated. However, since 2005, the OIG has tempered its approach through several advisory opinions in which it abstained from taking enforcement action against certain arrangements. n72

n71 *Id.* (addressing the application of sections 1128A(b)(1) and (2) of the Social Security Act to gainsharing arrangements).

n72 *See* Office of Inspector Gen., Dep't of Health & Human Servs., OIG Advisory Opinion No. 05-01 (Feb. 4, 2005), *available at* <http://oig.hhs.gov/fraud/docs/advisoryopinions/2005/ao0501.pdf>; *id.* No. 05-02 (Feb. 17, 2005), *available at* <http://oig.hhs.gov/fraud/docs/advisoryopinions/2005/ao0502.pdf>; *id.* No. 05-03 (Feb. 17, 2005), *available at* <http://oig.hhs.gov/fraud/docs/advisoryopinions/2005/ao0503.pdf>; *id.* No. 05-04 (Feb. 17, 2005), *available at* <http://oig.hhs.gov/fraud/docs/advisoryopinions/2005/ao0504.pdf>; *id.* No. 05-05 (Feb. 25, 2005), *available at* <http://oig.hhs.gov/fraud/docs/advisoryopinions/2005/ao0505.pdf>; *id.* No. 05-06 (Feb. 25, 2005), *available at* <http://oig.hhs.gov/fraud/docs/advisoryopinions/2005/ao0506.pdf>; *id.* No. 07-21 (Jan. 14, 2008), *available at* <http://oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-21A.pdf>; *id.* No. 07-22 (Jan. 14, 2008), *available at* <http://oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-22A.pdf>.

Although these favorable decisions suggest that the OIG changed its view of gainsharing, they were modest in scope. Most of the approved arrangements were only one year in duration and involved limited cost savings opportunities such as product substitution, standardization, and the limitation of devices to an "as needed" basis. The advisory opinions were tethered closely to their unique factual scenarios, which involved relationships between acute care hospitals and physician groups that performed nearly all of the hospitals' services within a specified field. The opinions suggest that although it will no longer take an absolutist approach, the OIG will authorize only limited gainsharing arrangements with extensive safeguards. Because of this narrow guidance, and due to the time and cost required to undergo the advisory opinion process, gainsharing remains more the exception than the rule in the healthcare sector.

Gainsharing is only one example of how provider coordination efforts are inhibited under the fraud and abuse laws. Many joint venture models, including physician-hospital organizations and management services organizations, n73 face similar challenges in complying with Stark exceptions that allow group practices to distribute payments for ancillary services performed within the group. n74 These models are permitted to operate insofar as they fit within the regulatory structure's narrow confines, which generally condone only joint ventures that are tightly knit, bona fide professional and non-professional relationships; loosely affiliated relations invite enforcement scrutiny. As a result, providers must be hypervigilant of compliance issues when forming or maintaining collaborative financial relationships.

n73 Carrie Valiant, *Meeting Fraud and Abuse Challenges in the Brave New World of Health Reform--What's in Store for ACOs?*, 14 HEALTH CARE FRAUD REP. 1043 (2010).

n74 *See* Stark Law, in office ancillary services exception and the group practice definition, and related regulations. Social Security Act §§ 1877(b)(2), (h)(4); 42 C.F.R. §§ 411.355(b), 411.352.

To comply with the AKS and the Stark Law, financial relationships must be conceived in arm's length transactions and adhere to strict fair market value considerations because regulators presume that payments exceeding the Medicare fee schedules are intended to induce referrals. n75 Even once protections are extended, they can be withdrawn in the future, injecting further uncertainty. In recent years, seemingly secure hospital-physician safe harbors have been rescinded, as evidenced in the October 2009 issuance of the revised "under arrangements" regulations relating to the Stark Law. CMS effectively ended the practice of hospital and physician contractual joint ventures by holding that physician owners are included within the definition of the billing entity even when the hospital is submitting the billing. n76 Additionally, in the ACA lawmakers effectively disassembled the "whole hospital" exception, which had validated physician ownership and investment in hospitals. n77

n75 See OIG Special Fraud Alert: Clinical Laboratory Fraud Alert (Dec. 1994), 94 Fed. Reg. 31157, available at <http://federalregister.gov/a/94-31157> ("Whenever a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral of business."). Recent enforcement actions underscore how inattention to detail or fair market value miscalculations can prove costly. For example, in 2008, the Condell Health Network entered into a \$ 36 million settlement with the United States and the State of Illinois to avoid FCA liability after voluntarily disclosing potential Stark and anti-kickback violations that it discovered in due diligence that preceded its sale to another hospital. Among other things, Condell was alleged to have leased space in medical office buildings it owned to physicians at below fair market value and was cited for paying physicians for performing services at the hospital without written agreements. Although the hospital contended that its activities were not fraudulent, it acknowledged that the absence of a signed agreement raised a possible technical violation of the Stark Law. The hospital also noted that it failed to use a valuation expert to confirm that its deals complied with fair market values. See *After Self-Disclosing to Feds, Hospital Pays \$ 36 Million for Alleged Sweetheart Deals*, 17 REP. ON MEDICARE COMPLIANCE 1, 2 (2008).

n76 42 C.F.R. § 411.351 (Definition of "Entity") (effective Oct. 1, 2009).

n77 *Affordable Care Act* § 6001, 124 Stat. at 684-89.

The current fraud and abuse enforcement scheme creates a hazardous environment for efforts at establishing collaborative modalities. Observers believe that the only well-established and comprehensive form of integrated delivery is the physician employment model, a closely knit arrangement specifically sanctioned under the fraud and abuse laws. n78 A handful of major hospitals, including the Mayo Clinic and the Cleveland Clinic, have resorted to full physician employment to bolster clinical integration and eliminate individual physician financial incentives. More innovative approaches to integration, especially on a large scale and among loosely affiliated providers, continue to carry uncertainty as to the risk of violating the fraud and abuse laws.

n78 See Robin Locke Nagele, *Hospital-Physician Relationships After National Health Reform: Moving From Competition to Collaboration*, 82 PA. B. A'SSN. Q. 1, 11 (2011) (noting that employment is allowed under the AKS's statutory exception and is further protected by an employment "safe harbor"); see 42 U.S.C. § 1320a-7b(b)(3)(B); 42 C.F.R. § 1001.952(i).

Therefore, history does not augur well for delivery system reformers' aspirations. Systematic reform of healthcare delivery will take root only if corresponding systematic changes are made to the prevailing fraud and abuse enforcement approach. However, because the FFS methodology will continue to play a central role for the foreseeable future, considerable inertia supports the status quo. As a result, the ACA equips an already aggressive enforcement campaign with more tools and resources, thereby raising the risks of noncompliance for even the most well-meaning efforts at integrated reform. On the other hand, the ACA grants HHS the authority to modify the existing fraud and abuse laws to facilitate the development of integrated models such as ACOs. In so doing, lawmakers reserved the difficult task of reconciling the fraud and abuse and delivery system reforms for the rulemaking process. The goal is to achieve the proper balance that will promote integrated delivery reforms without neglecting the traditional fraud and abuse concerns that underlie the FFS-based system.

The ACA's Delivery System Reforms

As revealed in the ACA, two prominent aspects of recent reform efforts are the expansion of insurance coverage and the restructuring of healthcare payment and delivery. Delivery system reform--although less controversial than health insurance issues--is about the fundamental restructuring of how healthcare is provided and paid for in the United States. The project is ambitious, but it is underwritten by public supportⁿ⁷⁹ and political will--an uncommon phenomenon in today's highly partisan environment. Therefore, although much of the ACA remains threatened by political and legal attacks, it is fair to say that delivery system reform--at least in some manifestation--is here to stay.

ⁿ⁷⁹ See SABRINA K.H. HOW ET AL., COMM'N ON A HIGH PERFORMANCE HEALTH SYSTEM, THE COMMONWEALTH FUND, PUBLIC VIEWS ON U.S. HEALTH SYSTEM ORGANIZATION: A CALL FOR NEW DIRECTIONS (Aug. 2008), available at <http://tinyurl.com/7dkz9ol> (describing survey results finding that 8 of 10 respondents believe that the healthcare system needs a fundamental change or complete rebuilding).

Delivery system reform is aimed at integrating the various healthcare delivery components to better coordinate patient care and reduce systemic costs. Part and parcel of this agenda is modifying or replacing the FFS payment methodology with new pay-for-performance (P4P) initiatives that promote quality and cost savings. To lay the groundwork for P4P, several quality reporting programs, including the Hospital Inpatient Quality Reporting (IQR) Programⁿ⁸⁰ and the Physician Quality Reporting System,ⁿ⁸¹ have been instituted to increase transparency in the Medicare payment system. To enable further quality reporting, providers have been pushed to invest in health information technology through incentive programs aimed at promoting the "meaningful use" of electronic health recordsⁿ⁸² and the ability of clinicians to utilize quality e-prescribing systems.ⁿ⁸³

ⁿ⁸⁰ The Hospital Inpatient Quality Reporting Program (formerly known as the Reporting Hospital Quality Data for Annual Payment Update) was established as authorized by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 § 501(b), Pub. L. No. 108-173, 117 Stat. 2066 (2003), and extended by the Deficit Reduction Act of 2005 § 5001(a), Pub. L. No. 109-171, 120 Stat. 4 (2006).

ⁿ⁸¹ The Physician Quality Reporting System (formerly known as the Physician Quality Reporting Initiative) was created by the Tax Relief and Health Care Act, Div. B § 101(b), Pub. L. No. 109-432, 120 Stat. 2922 (2006), and subsequently extended by the Medicare, Medicaid and State Children's Health Insurance Program Extension Act of 2007, Pub. L. No. 110-173, § 101(b), 121 Stat. 2492 (2008), and the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), Pub. L. No. 110-275, § 131(b), 122 Stat. 2494 (2008).

ⁿ⁸² The American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, § 4201(a)(1), 123 Stat. 489 (2009).

ⁿ⁸³ The Electronic Prescribing (eRx) Incentive Program was authored by MIPPA, Pub. L. No. 110-275, § 132, 122 Stat at 2527-31.

The Hospital Value-Based Purchasing (VBP) Program builds on quality reporting and health information technology initiatives and represents the hallmark of the "payment approach" to reform under Medicare. Mandated by ACA Section 3001 and adopted by final rule published on May 6, 2011, Hospital VBP directs incentive payments to hospitals based on their ability to achieve and improve on certain performance metrics. Although many of the quality measures relate to clinical processes of care and patient experience, an efficiency measure, called the "Medicare Spending per Beneficiary Measure," will be incorporated in both the Hospital IQR and the Hospital VBP programs to control payment determinations for fiscal year 2014.ⁿ⁸⁴ Hospital VBP is budget neutral and will be funded by Medicare's withholding of 1 percent of DRG hospital payments in fiscal year 2013, increasing to a 2 percent reduction by fiscal year 2017. The money withheld, estimated to be \$ 850 million, will be redistributed to hospitals that excel on the quality measures and denied to hospitals that fail to demonstrate improvements.

ⁿ⁸⁴ Ctrs. for Medicare & Medicaid Servs., Dep't of Health & Human Servs., Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2012 Rates, 76 Fed. Reg. 25788, 25927 (May 5, 2011).

The institution of Hospital VBP marks the advent of a true P4P system in Medicare, n85 by actually conditioning payment and penalties on quality and efficiency. Through the use of quality reporting and VBP initiatives, the Medicare program is being reconfigured from a passive to an active payor of healthcare services, with the goal of simultaneously improving patient outcomes while mitigating long-term costs.

n85 There has been considerable experimentation with P4P programs in the private sector, with well over 100 programs of varying size and characteristics that have been administered by private payors. Anne B. Claiborne et al., *Legal Impediments to Implementing Value-Based Purchasing in Healthcare*, 35 AM. J.L. & MED. 442, 484 (2009).

The ACA also authorizes the implementation of bundled payment models and the creation of shared savings programs such as ACOs (see Accountable Care Organizations) and patient-centered medical homes (PCMHs). To further these plans, ACA Section 3021 authorizes the establishment of the Center for Medicare and Medicaid Innovation (CMMI) within CMS to research, develop, and test innovative payment and delivery models.

Accountable Care Organizations

An ACO is a healthcare delivery model that is comprised of an integrated network of physicians, hospitals, and other providers that work together with the aim of furnishing quality healthcare services in a cost-effective manner for a defined patient population. n86 Any achieved savings attained through ACO operations are distributed as rewards among the ACO's constituent providers and suppliers. n87 Designed to address the care needs for entire communities, ACOs may provide the framework for smaller scale delivery system reforms such as bundled payments and PCMHs. n88

n86 See generally Posting of Chris Fleming to Health Aff. Blog, *Health Policy Brief: Accountable Care Organizations*, <http://healthaffairs.org/blog/2010/07/27/health-policy-brief-accountable-care-organizations/> (Jul 27, 2010).

n87 *Id.*

n88 See ACCOUNTABLE CARE ORG. LEARNING COLLABORATIVE, REFORMING PROVIDER PAYMENT: MOVING TOWARD ACCOUNTABILITY FOR QUALITY AND VALUE 1, 2, available at http://accountablekidneycare.com/files/AKCC-Brookings_Dartmouth-Brief.pdf ("If adopted within a framework of overall accountability for cost and quality as is envisioned in the ACO model, both the medical home and bundled payment reforms would have added incentives to support not only better quality, but also lower overall spending growth . . .").

ACA Section 3022 sets forth the MSSP, which is designed to encourage providers and suppliers to form ACOs that will serve Medicare beneficiaries. n89 The MSSP's details are developed through the rulemaking process, which received feverish attention in advance of the program's deadline launch date of January 1, 2012. If successfully realized through the MSSP, ACOs are liable to reshape the medical landscape and become a central fixture in healthcare delivery. As a result, physicians, hospitals, interest groups, and other industry stakeholders see financial gain and opportunity in ACO development. States have been encouraged to develop models for their Medicaid programs, n90 and there has been significant interest among private insurers.

n89 *Affordable Care Act* § 3022, 124 Stat. at 395.

n90 See Press Release, U.S. Dep't of Health and Human Services, Sebelius Continues Work to Implement Health Reform, Announces First Steps to Establish Temporary High Risk Pool Program (Apr. 2, 2010), available at www.hhs.gov/news/press/2010pres/04/20100402b.html.

On March 31, 2011, CMS proposed implementing regulations for the MSSP that outlined the ACO's basic operational and structural elements including, among other things, participation eligibility, legal structure, beneficiary assignment, quality standards, and incentive payment calculations. n91 Accepted applicants are invited to enter into participation agreements with CMS for a three-year period and are required to serve at least 5,000 Medicare beneficiaries. Under the MSSP, ACO participants continue to receive payment under the traditional FFS-based Medicare program and also are eligible to receive shared savings depending on their ability to: (i) satisfy a quality performance standard, and (ii) demonstrate achieved savings against a benchmark of projected per capita Medicare expenditures. ACO participants must uphold stringent programmatic responsibilities involving, among others, extensive disclosure of internal governance, processes of care, and protocols for distributing shared savings; implementation of strict program integrity and compliance control mechanisms; and satisfaction of health information technology requirements. Finally, ACOs are subject to monitoring and oversight through financial and quality measurement data reviews, site visits, audits, and analysis of beneficiary complaints.

n91 Ctrs. for Medicare & Medicaid Servs., Dep't of Health & Human Servs., Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 19528 (Apr. 7, 2011).

Although significant excitement initially surrounded the ACO concept, n92 much of this interest quickly dissipated after the release of the Proposed Rule. n93 Observers perceived the quality performance standard as too difficult and the model's potential financial benefits as outweighed by its operating costs, administrative complexities, and the threat of financial penalties. Skepticism also developed concerning the ability of physicians and hospitals to align interests and collaborate, due to infrastructure constraints, weak shared savings incentives, separations in types of care, and residual mistrust between hospital managers and physicians. n94 In addition, the investment risks and infrastructure costs required for developing ACOs under the MSSP were more challenging than originally anticipated; smaller providers were dismayed by CMS estimates of start-up costs of around \$ 1.8 million per organization. Finally, questions about the economic viability of the ACO model arose from disappointing results of the Physician Group Demonstration Program (PGDP), in which only half of participating groups earned sufficient shared savings payments to meet the required \$ 1.7 million in start-up costs. n95 The PGDP results were doubly discouraging for ACO observers because the experimental model did not include penalties for excessive spending, making it less risky than the double-sided ACO model set forth in the Proposed Rule. n96

n92 See Stephen M. Shortell et al., *How the Center for Medicare and Medicaid Innovation Should Test Accountable Care Organizations*, 29 HEALTH AFF. 1293, 1294 (July 2010), (noting that "70 percent of hospitals, leaders believe that their institution could be a part of an accountable care organization within the next five years").

n93 See generally Letter from Richard A. Correll, President & CEO, Coll. of Healthcare Info. Mgmt. Executives (CHIME), and Dr. Lynn Vogel, Chair, CHIME Bd. of Trustees, Vice President & Chief Info. Officer, Univ. of Tex. M.D. Anderson Cancer Ctr., to Donald Berwick, Adm'r, Ctrs. for Medicare & Medicaid Servs., Dep't of Health & Human Servs., Re: CMS Notice of Proposed Rulemaking for Accountable Care Organizations (May 10, 2011), available at www.cio-chime.org/advocacy/CHIME_comments_on_CMS_NPRM_for_ACOs.pdf.

n94 Jeff Goldsmith, *Accountable Care Organizations: The Case for Flexible Partnerships Between Health Plans and Providers*, 30 HEALTH AFF. 32, 33-36 (Jan. 2011).

n95 See Trent T. Haywood & Keith C. Kosel, *The ACO Model--A Three-Year Financial Loss?*, NEJM.ORG, Apr. 7, 2011, www.nejm.org/doi/full/10.1056/NEJMp1100950; see also Amy Goldstein, *Experiment to Lower Medicare Costs Did Not Save Much Money*, WASH. POST, June 1, 2011.

n96 Posting of Megan McArdle to The Atlantic, *Medicare Pilot Program Fails to Achieve Significant Cost Control*, www.theatlantic.com/business/archive/2011/06/medicare-pilot-program-fails-to-achieve-significant-cost-control/239830/ (June 2, 2011),

13:05 EST).

After assessing industry concerns, expressed in part through over 1,300 public comments to the Proposed Rule, CMS released the ACO Final Rule on October 20, 2011. Although using the same basic programmatic framework set forth in the Proposed Rule, the Final Rule included "significant modifications" aimed at reducing the "burden and cost for participating ACOs." n97 The changes were designed to endow ACO participants with greater flexibility with respect to eligibility, governance, and operations. n98 Provider participation was encouraged by reductions in the stringency and complexity of the quality reporting burden and performance standard. The Final Rule also offered a reimbursement track without down-side risk for the first agreement period. Finally, to promote participation of smaller ACOs, on October 20, 2011, CMS announced the Advance Payment ACO Model to supplement the MSSP. In this new model, ACO participants are eligible for payments to support start-up and infrastructure costs. n99

n97 Ctrs. for Medicare & Medicaid Servs., Dep't of Health & Human Servs., Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67802, 67804 (to be codified at 42 C.F.R. pt. 425).

n98 These changes reflected CMS's consideration of comments criticizing the overly detailed, narrow, and prescriptive approach taken by CMS in the proposed regulations as indicative of agency "micromanagement." *See, e.g.*, Letter from Delos M. Cosgrove, Chief Executive Officer & President, Cleveland Clinic, to Donald M. Berwick, Adm'r, Ctrs. for Medicare & Medicaid Servs. 2-3, Re: CMS-1345-P, Medicare Shared Savings Program: Accountable Care Organizations (May 26, 2011), *available at* www.modernhealthcare.com/Assets/PDF/ClevelandClinicACOletter.pdf.

n99 Ctrs. for Medicare & Medicaid Servs., Dep't of Health & Human Servs., Medicare Program; Advance Payment Model, 76 Fed. Reg. 68102 (Oct. 20, 2011).

The Final Rule successfully rekindled much of the enthusiasm that had originally surrounded the ACO concept in the provider community. By addressing many of the operational concerns related to the MSSP, CMS went a long way toward encouraging participation in advance of the program's launching dates, scheduled for April 1 and July 1, 2012. Industry observers also were encouraged by CMMI's May 2011 introduction of the Pioneer ACO model, designed to evaluate how experienced provider groups can coordinate care with private payors to achieve cost savings and quality outcomes. n100 Many stakeholders see the ability to incorporate commercially insured providers, as well as Medicare beneficiaries, as critical to their designs to pursue integrated delivery through the ACO model. n101 However, notwithstanding these operational adjustments, the most consequential factor in promoting the MSSP's success will be the government's use of its waiver authorities with respect to the fraud and abuse laws.

n100 CTR. FOR MEDICARE & MEDICAID INNOVATION, CTRS. FOR MEDICARE & MEDICAID SERVS., DEPT OF HEALTH & HUMAN SERVS., Pioneer Accountable Care Organization (ACO) Model Request for Application, *available at* <http://innovations.cms.gov/wp-content/uploads/2011/05/Pioneer-ACO-RFA.pdf>; Press Release, Ctrs. for Medicare & Medicaid Servs., Dep't of Health & Human Servs., Pioneer Accountable Care Organization Model (May 23, 2011), *available at* <http://innovations.cms.gov/documents/pdf/Pioneer%20FSG%2005%2023%202011.pdf>.

n101 *See* Fed. Trade Comm'n & Dep't of Justice, Antitrust Div., Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 21894, 21895 (Apr. 19, 2011) (noting stakeholder interest in incorporating commercially insured patients in ACO plans).

The Relationship Between ACOs and the Fraud and Abuse Laws

As noted above, ACOs, like other delivery system reforms, involve financial arrangements that are often not permitted or even contemplated under the existing fraud and abuse enforcement framework. Therefore, Congress authorized HHS, under ACA Section 3022(f), to waive application of the anti-fraud statutes to facilitate the development of the MSSP. The debate surrounding the development of the ACO model and waivers illustrates the

framework of issues concerning the relationships between delivery system reforms and fraud and abuse.

Proposed waivers

Simultaneous to the release of the MSSP Proposed Rule, CMS and the OIG introduced three statute-specific waivers for the Stark Law, the AKS, and certain provisions of the CMP Statute that were designed "to support beneficial ACO development under the Medicare Shared Savings Program, while still **protecting** patients and programs from harms caused by fraud and abuse." n102 The proposed waivers' narrow purpose and scope were readily apparent. For instance, the Stark Law and AKS waivers protected shared savings distributions only if made internally among ACO participants; distributions by and between outside parties, such as referring physicians, were permitted only if tied to activities "necessary for and directly related to" ACO business. The proposed CMP Statute waiver concerning shared savings pertained to distributions made by a hospital to a physician, provided that: (i) the payments are not made knowingly to induce the physician to reduce or limit medically necessary items or services; and (ii) the hospital and physician are ACO participants, or were ACO participants during the year in which the ACO earned the shared savings. n103 The AKS and CMP Statute waiver components concerning financial relationships were restricted to the term of the ACO's agreement. Described by CMS as "limited exceptions," these waivers only immunized financial arrangements under the AKS and CMP Statute if the arrangements complied with the Stark Law.

n102 Medicare Program; Waiver Designs In Connection With the Medicare Shared Savings Program and the Innovation Center, 76 Fed. Reg. 19655, 19659 (Apr. 7, 2011).

n103 *Id.*

CMS and the OIG recognized the limited nature of the proposed waivers, noting that they did not "cover all of the possible financial arrangements involved with setting up and operating an ACO." n104 However, they justified this cautious approach with the observance that under the MSSP, "providers and suppliers will continue to be paid on a fee-for-service basis, even under the two-sided risk model." n105 Therefore, from the agencies' point of view, careful steps needed to be taken to ensure that "ACO arrangements are not misused for fraudulent or abusive purposes that harm patients of Federal health care programs." n106 To address concerns about the scope of the proposed waivers, CMS solicited public comments on waiver design considerations.

n104 *Id.* at 19658.

n105 *Id.* at 19659.

n106 *Id.* at 19655.

Suggested modifications

Many stakeholders criticized the proposed waivers as unduly narrow. n107 Besides shared savings paid by CMS, the proposed waivers did not address other financial arrangements, such as those needed to cover the payment (and repayment) of significant start-up, training, hiring, and infrastructure costs related to ACO formation n108 or investment-related distributions necessary for ACO functioning. Concerns were expressed over the proposed waivers' duration, which only covered an ACO's term of participation. Protection was sought for activities relating to ACO formation n109 and post-termination distributions of shared savings and remuneration. n110

n107 While many providers expressed concern about the narrow scope of the waivers, some commenters applauded the limited

approach. *See, e.g.*, Am. Clinical Lab. Ass'n, Comments of the American Clinical Laboratory Association on the Medicare Program; Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center; Notice with Comment Period (CMS-1345-NC2) (June 6, 2011), *available at* www.acla.com/sites/default/files/ACLA%20comments%20on%20ACO%20proposed%20F-A%20waivers.pdf; Letter from Gary Bacher, Senior Vice President & Julie S. Miller, Deputy Gen. Counsel, Am.'s Health Ins. Plans (AHIP), to Ctrs. for Medicare & Medicaid Servs., Re: Medicare Program; Waiver Designs in Connections With the Medicare Shared Savings Program and the Innovation Center (Waiver Notice) (CMS-1345-NC2) (June 6, 2011) [hereinafter AHIP Letter], *available at* www.ahipcoverage.com/wp-content/uploads/2011/06/AHIP-Letter-ACO-Antifraud-and-Waiver.pdf.

n108 *See* Letter from David B. Hoyt, Executive Dir., Am. Coll. of Surgeons, to Donald M. Berwick, Adm'r, Ctrs. for Medicare & Medicaid Servs., and Daniel R. Levinson, Inspector Gen., Office of Inspector Gen., Re: Medicare Program; Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center; Notice with Comment Period 3 (June 3, 2011), *available at* <http://www.facs.org/ahp/aco-shared-savings-fraudabuse-waivers-proposal.pdf> (noting that many physician practices are burdened with investments in other initiatives such as the PQRS, Medicare E-Prescribing Program, and Medicare and Medicaid Electronic Health Record Incentive Programs. As a result, it is very likely that ACOs will need to extend significant resources to physicians during the formation process.).

n109 Letter from Steven M. Schlossberg, Health Policy Chair, Am. Urological Ass'n, to Donald M. Berwick, Adm'r, Ctrs. for Medicare & Medicaid Servs., & Daniel R. Levinson, Inspector Gen., Office of Inspector Gen., Re: Medicare Program; Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center: CMS-1345-NC2 3 (June 6, 2011), *available at* www.auanet.org/content/legislative-and-regulatory/washington-news/comments-and-testimony/news/ACOWaiverfinsig.pdf [hereinafter AUA Letter] (noting need to protect pre-formation activities that include market studies, business planning, and demographic analysis).

n110 Letter from Michael D. Maves, Executive Vice President, Am. Med. Ass'n, to Daniel R. Levinson, Inspector Gen., Office of Inspector Gen., U.S. Dep't of Health & Human Servs., & Donald M. Berwick, Adm'r, Ctrs. for Medicare & Medicaid Servs. 3-4 (June 3, 2011), *available at* www.ama-assn.org/resources/doc/washington/aca-comment-letter-3june2011.pdf [hereinafter AMA Letter] (remarking that coverage for post-termination distributions would assist independent practicing physicians and physician organizations that may take more time to realize shared savings).

Commenters noted that waiver protection should apply to a wider array of ACO operations. For instance, the waivers should protect ACO interaction with non-participating outside providers, such as independent contracting physicians and specialists, n111 as well as with private payors. n112 Waiver protection was warranted for referral relationships between ACO participants and non-participating facilities and specialists n113 and for ACO-related investments in medical information technologies. n114 Finally, because Medicare beneficiaries have freedom to select providers, stakeholders sought coverage for beneficiary incentives aimed at encouraging beneficiaries to use providers in the ACO and adhere to care recommendations. n115 Accordingly, it was requested that the CMP Statute waiver be extended to outreach and intervention practices, such as those that offer free supplemental services (e.g., transportation, counseling, and in-home visits) to beneficiaries. n116

n111 *Id.*, at 3.

n112 *AUA Letter*, at 3. *But see AHIP Letter*, at 8 ("... it is vital that any waivers proposed to apply to the Pioneer Program or other CMMI initiatives be limited in scope (similar to the proposed waiver under the MSSP) ...").

n113 *Id.*

n114 Letter from Elizabeth A. Ryan, President & CEO, N.J. Hosp. Ass'n, to Donald M. Berwick, Adm'r, Ctrs. for Medicare & Medicaid Servs., Dep't of Health & Human Servs., Re: CMS-1345-P, Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations Proposed Rule 6 (June 1, 2011), *available at* www.njha.com/Reform/Pdf/NJHACommentLettertoCMSregardingACOregulations.pdf (requesting that existing AKS safe harbors and Stark Law exceptions permitting medical technology be broadened to extend through the lifetime of the MSSP).

n115 *AUA Letter*, at 3.

n116 Letter from Temple Sellers, Ga. Hosp. Ass'n, to Donald M. Berwick, Adm'r, Ctrs. for Medicare & Medicaid Servs., & Daniel R. Levinson, Inspector Gen., Office of Inspector Gen., at 3 (June 6, 2011) [hereinafter GHA Letter]; Letter from Charles W. Bailey, Senior Vice President, Gen. Counsel, Tex. Hosp. Ass'n, to Donald M. Berwick, Adm'r, Ctrs. for Medicare & Medicaid Servs., & Daniel R. Levinson, Inspector Gen., Office of Inspector Gen., Re: CMS-1345-NC-2; Request for Comments, Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center 2 (May 31, 2011), *available at* www.tha.org/HealthCareProviders/Advocacy/CommentLetters/THA%20Comments%20-%20CMS%20-%20OIG%20Waivers%20%205-31-11.pdf.

Some prominent commenters, including the American Hospital Association, voiced more fundamental concerns over the proposed waiver rules' compartmentalized and statute-based approach. n117 To provide meaningful protection for ACOs operating seamlessly across a variety of settings, several commenters proposed an ACO waiver applicable to all ACO-related activities from formation through the end of participation. Precedent for this approach is found in the AKS safe harbors that permit managed care organizations (MCOs) to conduct activities within a "protected zone." n118 In creating these MCO safe harbors, lawmakers acknowledged MCOs' built-in protections that neutralized the cost-sharing concerns underlying the AKS. Although ACO participants will continue to receive FFS-based payment under Medicare, ACOs have adequate internal safeguards that address many of the concerns underlying the fraud and abuse laws. Thus, observers have advocated for a tailor-made waiver to both promote the success of the ACO model and ensure adequate protection against fraud and abuse.

n117 See *GHA Letter*, at 2-3.

n118 There are six safe harbors relating to risk-sharing agreements that are designed to facilitate managed care arrangements. A statutory exception is contained in 42 U.S.C. § 1320a-7b(b)(3)(F) and four additional criminal safe harbors are found in 42 C.F.R. § 1001.952, subsections (l), (m), (t), and (u). Finally, 42 U.S.C. § 1395nn(b)(3) sets forth a civil statutory safe harbor for physician risk-sharing agreements.

Aside from the specific criticisms noted above, industry stakeholder disappointment in the wake of the proposed waiver rules was based on the government's general reluctance to significantly transform the fraud and abuse laws. Instead of making broad allowances through its waiver authority, the proposal merely layered the traditional fraud and abuse framework on top of the ACO program. This regulatory inertia was all the more discomfiting considering daily headlines highlighting the government's aggressive campaign against fraud and abuse. It had become clear that unless the government made more dramatic changes in its fraud and abuse approach in the ACO setting, wide-spread delivery system reforms were endangered.

The final waiver rule

Along with its release of the final MSSP rule on October 20, 2011, CMS and the OIG issued an Interim Final Rule with comment period, providing five separate fraud and abuse waivers for MSSP participants (here, "final waiver rule"). n119 The final waiver rule replaced the statute-based format of the proposed waiver rules with the following repertoire of arrangement-based waivers:

1. An "ACO pre-participation" waiver of the Stark Law, the AKS, and the Gainsharing CMP covering ACO-related start-up arrangements in anticipation of participating in the MSSP, subject to limitations on, among other things, the duration of the waiver and the types of parties covered;
2. An "ACO participation" waiver of the Stark Law, the AKS, and the Gainsharing CMP, broadly covering ACO-related arrangements during the course of the ACO's participation agreement under the MSSP--and for a specified time thereafter;
3. A "shared savings distributions" waiver of the Stark Law, AKS, and Gainsharing CMP, covering distributions and uses of shared savings payments earned;
4. A "compliance with the Physician Self-Referral Law" waiver of the AKS and the Gainsharing

CMP, for ACO arrangements that implicate the Stark Law and meet an existing exception; and

5. A "patient incentive" waiver of the Beneficiary Inducements CMP and the AKS, for medically related incentives offered by ACOs to beneficiaries to encourage preventative care and compliance with treatment regimens.

n119 Medicare Program; Final Waivers in Connection With the Shared Savings Program, 76 Fed. Reg. 67992 (Nov. 2, 2011).

The Final Rule clarifies that while there is significant overlap between the waivers' scope, parties are required to meet only the criteria for a single waiver. n120 On the other hand, failure to meet one of the proposed waivers under the AKS does not necessarily render an arrangement illegal. In addition, the waivers are self-implementing, meaning that parties are not required to obtain pre-authorization. n121 Because they relate to several legal authorities and to ensure consistency in the event of subsequent modification, the waivers were not codified in the Code of Federal Regulations, but instead may be referenced on CMS and OIG websites. The government added that it will monitor the efficacy of the waivers and, if necessary, narrow their protections upon a finding that the waivers are being abused to the detriment of Medicare patients or program funds. n122

n120 *Id.* at 67994.

n121 *Id.* at 67999.

n122 *Id.* at 68008.

The final waiver rule incorporated several modifications aimed at increasing the waivers' scope and ease of application. The "shared savings distributions" and "compliance with the Physician Self-Referral Law" waivers--both contained in the Proposed Rule--were expanded so that the former now covers distributions made after an ACO's participation agreement expires, and the latter applies to any arrangement, not just those involving distributions of shared savings. n123 In addition, the final waiver rule provides that the waivers apply uniformly to ACOs, ACO participants, and ACO providers/suppliers as the terms are defined in the MSSP, thus involving a wide array of healthcare entities and agents. n124 The waivers employ the phrase "reasonably related to the purposes of the Shared Savings Program" as a substitute for the initially proposed phrase, "necessary for and directly related to ACO purposes." n125 Unlike most Stark Law exceptions and AKS safe harbors, the waivers do not require a showing that certain arrangements meet fair market value and commercially reasonable standards. Finally, and most fundamentally, the final waiver rule establishes broad "ACO pre-participation" and "ACO participation" waivers. n126 The government thereby heeded industry requests for blanket waivers to ensure meaningful leeway for providers to engage in ACO formation and participation confidently.

n123 *Id.* at 68005-68007.

n124 *Id.* at 67999.

n125 In turn, the phrase "purposes of the Shared Savings Program" is expansively defined to include: (1) the promotion of accountability for the quality, cost, and care for Medicare beneficiaries; (2) the management and coordination of care for Medicare FFS beneficiaries through an ACO; and (3) the encouragement of investment in infrastructure and redesigned care processes for high quality and efficient service delivery.

n126 76 Fed. Reg. at 68002-68003.

The final waiver rule represents the determination of CMS and the OIG that waiver protection must be comprehensive to encourage ACO participation. This judgment reflects consideration of industry concerns relating to existing fraud and abuse laws that are overly complex and inimical to integrated delivery reforms. Together with the MSSP Final Rule, the final waiver rule creates a regulatory framework that is flexible, navigable, and protective. On the other hand, the waivers are not blank checks; their protections are earned only by meeting prerequisite fraud and abuse safeguards. For example, the ACO "pre-participation" and "participation" waivers prescribe, among other things, detailed and contemporaneous documentation and public disclosure requirements. Moreover, the waivers require good standing under the MSSP and satisfaction of its prerequisite program integrity provisions; screening requirements; and governance, leadership, and management criteria. These incorporated MSSP rules prohibit, among other things, limiting or restricting referrals to ACO participants and ACO providers/suppliers. At bottom, the final waiver rule reflects the government's determination that broad waivers and rigorous program integrity safeguards together achieve the correct policy balance that serves to encourage ACO participation and prevent fraud and abuse.

Bundled Payments

ACA Section 3023 is another central avenue of delivery reform that directs HHS to establish a national pilot program on payment bundling by January 1, 2013. n127 *Payment bundling* refers to the process of providing a single payment of predetermined amount to cover all goods and services furnished to a beneficiary for a single episode of care. n128 The payment is shared among all providers involved in treating the episode of care, making them jointly accountable for any gains or losses realized. This arrangement encourages providers to better coordinate their provision of services, even across different care settings. n129

n127 *Affordable Care Act* § 3023, 124 Stat. at 399.

n128 CTR. FOR MEDICARE & MEDICAID INNOVATION, BUNDLED PAYMENTS FOR CARE IMPROVEMENT INITIATIVE REQUEST FOR APPLICATION 2 (Aug. 22, 2011), *available at* www.innovations.cms.gov/documents/payment-care/Request_for_Application_v2.pdf [hereinafter Request for Application].

n129 *Id.*

In August 2011, CMS announced the bundled payments for care improvement initiative (BPCII) and invited providers to help test and develop four separate bundling models that are scheduled to launch in 2012. n130 In the proposed models, the bundled payments are predetermined at a discount compared to the historical total payment for the episode; in exchange, participating providers are granted the opportunity to share gains achieved from efficient administration of care. Applicants are invited to propose their own bundled payment plans with episode definitions and target prices for episodes; preference will be given to applicants offering greater discounts to Medicare. In addition, CMS advised that gainsharing among BCPPII participants will be permitted on satisfaction of criteria designed to ward against fraud and abuse concerns. n131 CMS recognized that the models would require regulatory changes with respect to gainsharing, and it proposed to "consider exercising [its] waiver authority with respect to the fraud and abuse laws . . . as may be necessary to develop and implement" the BPCII. n132

n130 Ctrs. for Medicare & Medicaid Servs., Dep't of Health & Human Servs., Bundled Payments for Care Improvement Initiative: Request for Applications, 76 Fed. Reg. 53137 (Aug. 25, 2011).

n131 REQUEST FOR APPLICATION, at 24 (noting that the criteria are "designed to ensure that care is not inappropriately reduced, that the quality of care remains constant or is improved, that there are not inappropriate changes in utilization or referral patterns, and to guard against fraud, waste, and abuse.").

n132 *Id.* Under Section 3021 of the ACA, the Secretary is authorized to waive requirements of Titles XI and XVIII, including Sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A)(iii), as necessary to the testing of new models such as the BCPII.

The BPCII largely is informed by successful private sector experiments as well as three Medicare bundled payment demonstrations and two gainsharing demonstrations, which CMS championed as meeting (mostly preliminary) savings and quality measures. n133 CMS intends to build on the BCPII as part of a "broader shift toward bundled payments" with the hope that bundled payments will be incorporated into future prospective payment models. n134 In the nearer future, CMS plans to extend the concept further by creating a chronic care model. n135

n133 *Id.* at 4. CMS identified the Medicare Participating Heart Bypass Center demonstration, the Medicare Cataract Surgery Alternate Payment demonstration, the Medicare Acute Care Episode demonstration, the Physician Hospital Collaboration demonstration, and the 2005 Deficit Reduction Act Medicare Gainsharing demonstration.

n134 *Id.* at 5.

n135 *Id.* at 5.

Generally speaking, the proposed payment bundling models have been received positively in the provider community. Observers approve of the BCPII's broad eligibility standards that invite participation from providers of various sizes, types, and capacities. n136 By inviting applicants to propose unique plans, the program permits flexibility in the definition of care bundles, specific financial terms, and the beneficiaries' risk adjustment. Observers believe that these measures will be effective in attaining quality of care goals and cost-savings resulting from, among other things, the prevention of hospital readmissions and unnecessary or expensive post-acute care. n137 The new gainsharing arrangements also will afford hospitals the opportunity to correlate financial incentives with physicians. Such mutually beneficial relationships could serve to attract physician talent, giving participating hospitals a recruiting advantage over non-participating competitors. n138

n136 Posting of Vince Kuraitis to e-CareManagement blog, *Six Quick First Impressions of CMS' Bundled Payment for Care Improvement Initiative (BPCII)*, <http://e-caremanagement.com/six-quick-first-impressions-of-the-cms-bundled-payments-for-care-improvement-initiative-bpcii/> (Aug. 23, 2011).

n137 Posting of James Arvantes to AAFP News Now, *Bundled Payment Initiative May Provide Opportunities for Family Medicine: Program Focuses on Reducing Expensive Hospitalizations*, <http://www.aafp.org/online/en/home/publications/news/news-now/practice-professional-issues/20110831bundledpayment.html> (Aug. 31, 2011, 17:20 EST).

n138 Chas Roades, Chief Research Officer, Advisory Bd. Co., *Initial Thoughts on the CMS Bundling Program: Key Takeaways for Providers Weighing Participation*, DAILY BRIEFING, Aug. 24, 2011, www.advisory.com/Daily-Briefing/2011/08/24/Initial-thoughts-on-bundling.

The bundled payment model of instituting joint accountability is similar to methods proposed in PCMH and ACO models. However, because bundled payments reforms are focused at the level of an individual patient's care, rather than at the provider group or population level, they are perceived as less risky and more manageable. To participate in the BCPII, providers are not required to make massive up-front investments or to restructure their business models fundamentally. BCPII participation is not an all-or-nothing endeavor--hospitals and other providers may limit the extent of their participation, permitting experimentation over time. For these reasons, bundled payment reform, as proposed in the BCPII, is seen as a promising means for achieving delivery reform on a graduated basis.

Patient-Centered Medical Homes

The PCMH is a care delivery model conceptualized nearly two decades agoⁿ¹³⁹ that recently has emerged as a vital solution for delivery system reform. The defining characteristic of a PCMH is the use of a personal physician who is responsible for managing overall patient wellness. The personal physician interacts with the patient's family and with a team of practitioners to provide continuous and coordinated care across medical specialties, hospitals, and **nursing homes**. Personalized care is reinforced and facilitated through after-hours access to health practitioners, effective care coordination, and the use of health information technology.ⁿ¹⁴⁰ To encourage interaction, reformers envision the use of subscription fees, per capita "care coordination" payments, as well as the implementation of P4P and shared savings programs.ⁿ¹⁴¹

ⁿ¹³⁹ Ad Hoc Task Force on Definition of the Medical Home, Am. Acad. of Pediatrics, *The Medical Home*, 90 PEDIATRICS 774 (1992).

ⁿ¹⁴⁰ See Daniel Fields et al., Driving Quality Gains and Cost Savings Through Adoption of Medical Homes, 29 HEALTH AFF. 819, 823-25 (2010) (discussing some of the final features of medical homes).

ⁿ¹⁴¹ See Katie Merrell & Robert A. Berenson, *Structuring Payment for Medical Homes*, 29 HEALTH AFF. 852, 854-57 (2010) (discussing alternative payment approaches that may be used to support the medical home model).

Hopes for the PCMH model have been buoyed by private-sector medical home experiments run by the Geisinger Health System, Intermountain Healthcare, and the Group Health Cooperative of Puget Sound, that have achieved impressive results with respect to patient satisfaction, care coordination, and cost savings.ⁿ¹⁴² As a result, public-sector experimentation with PCMHs has surged in recent years, as 12 states oversee PCMH programs that involve multiple payors and 31 states are planning pilots within Medicaid and the Children's Health Insurance Program.ⁿ¹⁴³ The Department of Veterans Affairs plans to have transitioned its clinics fully to the medical home model by 2015.

ⁿ¹⁴² Stephen M. Shortell et al., *United States Innovations in Health Care Delivery*, 32 PUB. HEALTH REVIEWS 190, 193-94 (2010).

ⁿ¹⁴³ Amanda Cassidy, *Patient-Centered Medical Homes: A New Way to Deliver Primary Care May be More Affordable and Improve Quality. But How Widely Adopted Will the Model Be?*, HEALTH POL'Y BRIEF, HEALTH AFF. (Sept. 14, 2010), available at www.healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_25.pdf.

Several ACA provisions are devoted to the establishment of pilot programs to test the development of PCMH models (e.g., Section 2703 authorizes Medicaid medical home pilots to create health homes for individuals exhibiting certain risk factors or chronic conditions; Section 3502 creates and funds community health teams to support primary care practices and PCMHs; Section 3021 assigns the CMMI with the task of developing innovative PCMH models).ⁿ¹⁴⁴ Since the ACA's passage, the government has begun developing and implementing some of these programs. For example, on November 1, 2011, CMS began directing approximately \$ 42 million to 500 community health centers under the Federally Qualified Health Center (FQHC) Advanced Primary Care Practice demonstration project, which is aimed to test the effectiveness of the PCMH model.ⁿ¹⁴⁵ Under the three-year project, teams of doctors and health professionals will administer care for up to 195,000 Medicare patients, many of whom suffer from chronic conditions.ⁿ¹⁴⁶

ⁿ¹⁴⁴ *Affordable Care Act* §§ 2703, 124 Stat. at 319, 3502, 124 Stat. at 513, 3021, 124 Stat. at 389.

ⁿ¹⁴⁵ See Press Release, U.S. Dep't of Health & Human Services, *Affordable Care Act to Help Improve Care for Medicare*

Beneficiaries (Oct. 24, 2011), available at www.hhs.gov/news/press/2011pres/10/20111024a.html.

n146 See Press Release, U.S. Dep't of Health & Human Services, New Affordable Care Act Support to Improve Care Coordination for Nearly 200,000 People with Medicare (June 6, 2011), available at www.hhs.gov/news/press/2011pres/06/20110606a.html.

The ACO Model and the Promise and Challenges of Coordinated Care

The prevailing fraud and abuse enforcement framework, which remains closely moored to its fee-for-service roots, is incompatible with new integrated delivery models intended to coordinate the provision of care to enhance quality and reduce costs. These concerns, as well as increasing pressures to reduce healthcare costs, are motivating HHS and lawmakers to make bolder changes in anti-fraud enforcement. The final MSSP rules signal the government's recognition that, given the enormous risks and start-up costs of developing ACOs and other innovative reform models, a critical mass of support will not take hold in the provider community until more sweeping regulatory changes are made. The ACO-related waivers provide a beachhead of regulatory protection for providers seeking to undertake innovative delivery reform. In time, the government may expand special regulatory treatment to cover a wider array of delivery system initiatives, such as Pioneer ACOs, PCMHs, and bundled payment models. n147 This progression would result in the creation of two independent fraud and abuse enforcement systems--a traditional one that will continue to govern FFS-based arrangements and a new one that will apply to integrated delivery models.

n147 In its Interim Final Rule on waivers, the government noted that the waivers did not apply to other demonstration programs operated by CMMI, such as the Pioneer ACOs. Waiver reforms that apply to these programs will be separately addressed.

Debate over ACOs has consumed much of a broader discussion over delivery system reform. The attention is merited, as the relative success of the ACO model will have a profound influence on the fate of delivery reform generally. The ACO, the PCMH, and the payment bundling initiative are fundamentally compatible--all of the models spread accountability for quality and cost containment among participants at three different overlapping levels of care, with the ACO aimed at the population level, the PCMH designed for provider groups, and bundled payments focused on episodes of care. The models are interdependent and configured to fit together like a Russian nesting doll, with the PCMHs and bundled payment arrangements operating within an ACO shell to achieve quality and cost synergies. ACOs are envisioned to be founded on a corps of primary physicians that may be organized as PCMHs. n148 On the other hand, PCMHs will be largely dependent on ACOs, as many PCMHs likely will not survive as stand-alone entities due to challenges in obtaining start-up resources, information technology, economy of scale, and management capacity that are needed to provide up-to-date services. n149 Therefore, although VBP is slated to develop on its own accord, the prospects for PCMHs and bundled payment models will depend largely on the ACO's acceptance as a sustainable delivery model.

n148 Stephen M. Shortell et al., *How the Center for Medicare and Medicaid Innovation Should Test Accountable Care Organizations*, 29 HEALTH AFF. 1293 (July 2010).

n149 See Jeff Goldsmith, *Analyzing Shifts in Economic Risks to Providers in Proposed Payment and Delivery System Reforms*, 29 HEALTH AFF. 1299, 1302 (2010) ("A major concern . . . is whether the medical home concept is becoming so logistically complex that only large group practices or hospital systems can afford the requisite information technology systems and overhead."); Dennis Grantham, *Is "Accountable Care" in Trouble? After Critics Hammered Initial ACO Rules, Will the Fed's Rewrite Succeed?*, BEHAVIORAL HEALTHCARE (ONLINE EXCLUSIVE), available at www.behavioral.net/ME2/dirmod.asp?type=Publishing&mod=Publications::Article&mid=64D490AC6A7D4FE1AEB453627F1A4A32&tier=4&id=A5894AA0 Stephen M. Shortell et al., *United States Innovations in Health Care Delivery*, 32 PUB. HEALTH REVIEWS 190, 194 (2010).

Fostering Integrated Delivery System Reform through a Bifurcated Model of Fraud and Abuse Regulation

Reformers face the challenge of creating a fraud and abuse structure that will promote integrated delivery reform

while maintaining sufficient controls against concerns such as overutilization, underutilization, referrals, and kickbacks that underlie the FFS-based system. One potential solution to this challenge is the creation of a bifurcated model of fraud and abuse regulation.

The government has taken a bold step in this direction through sweeping use of its waiver authorities under the ACA to limit the scope of the Stark Law, the AKS, and the CMP Statute as they apply to ACOs. The waivers afford protection to a wide range of participants and apply to most, if not all, arrangements necessary for the creation and administration of ACOs under the MSSP. In particular, the ACO pre-participation and participation waivers offer blanket coverage permitting ACOs to operate within a "protected zone," wherein referrals, gainsharing, distributions of shared savings, and investment payments would receive substantial leeway.

While the current MSSP waivers are laudable, further improvements could be made to deepen the exceptional enforcement treatment afforded to ACOs. First and foremost, attention should be paid to state fraud and abuse laws that may pose a substantial threat to ACOs, particularly those serving beneficiaries who are dually eligible for Medicare and Medicaid. Many states have adopted laws that prohibit kickbacks and self-referrals; these laws vary in scope and do not parallel related federal laws, thus presenting complex and costly compliance issues for ACOs planning to work across state lines. To assuage such concerns, the federal government should consider preempting parallel state laws to the greatest extent possible. At the very least, states should be encouraged to modify their laws to ensure alignment with federal ACO regulations. In addition, to the extent that unique and esoteric regulatory issues remain unresolved under the MSSP, HHS could create a fast-track advisory opinion process to provide guidance, further reducing the complexity and uncertainty of participating in the MSSP.

Most importantly, the exceptional enforcement treatment highlighted in the MSSP waivers could also be extended to cover related integrated delivery system reforms. In its final waiver rule, CMS and the OIG noted that the MSSP waivers do not apply to other CMMI-sponsored demonstration programs, which will be addressed separately. While these programs merit individual attention, many industry observers hope the government will assume a similar regulatory approach in crafting additional waivers. The first obvious candidate is the Pioneer model ACO. Through the application of unique regulatory treatment to ACOs, PCMHs, bundled payment plans, and other related demonstration programs, HHS would create an enforcement gradient--a clear line of separation between traditional FFS-based delivery modalities and collaborative arrangements. The greater the enforcement gradient (i.e., the difference between the traditional and new regulatory frameworks), the faster providers will enroll in integrated delivery models, and the greater the chances for the new models' success. In time, these events would give rise to a bifurcated system of fraud and abuse regulation in the healthcare sector.

Purpose and effect

The purpose and effect of creating a bifurcated model is not to reward integrated models with more lenient treatment. Instead, it would be the natural result of a distinction in *enforcement approach*. In recognition of the integrated models' unique operational design, incentive structure, and governing regulations, the government would accordingly modify its regulatory treatment especially to meet these models' specifications. This context-specific handling leads to a new form of enforcement that is different in kind--but not extent--from the traditional FFS-based system of fraud and abuse enforcement. A different regulatory climate is deserving of a tailor-made enforcement system to promote deterrence and proportionality. Finally, a new system would provide a more balanced and efficacious means of attaining fraud and abuse goals in a manner that does not compromise the ability of integrated models to work in the first place. Although the MSSP remains essentially an FFS-based system, traditional fraud and abuse concerns do not have the same currency under the MSSP. ACOs specifically are designed to ensure heightened transparency and internal safeguards; it would be short-sighted to smother their development with crude laws calibrated to the FFS setting. The final waiver rule reflects the government's embrace of a unique ACO-specific enforcement approach based upon its faith in the ACO model's self-correcting mechanisms.

The new fraud and abuse system would account for the fact that integrated models, such as ACOs, PCMHs, and

bundled payment plans, will be subject to greater regulation. The ACO model set forth in the MSSP is instructive. ACO applicants are subjected to higher enrollment, verification, and application requirements--front-ended measures aimed at ferreting out illegitimate actors before payments are extended. The MSSP requires participating ACOs to include internal safeguards, such as program integrity and compliance measures. ACOs are designed ultimately to become risk-bearing entities, with operational and financial success tied to the achievement of stringent quality and cost thresholds. Furthermore, because of enhanced reporting requirements, integrated delivery models will serve as examples of transparency. Data on financial and quality measurements and beneficiary feedback will be easily accessible and scrutinized through enhanced health information technology, and ACOs will be subject to frequent site visits and audits. All of these safeguards have been designed to reduce fraud and abuse concerns relating to underutilization, overutilization, and referrals that are readily apparent in the traditional FFS-based environment. Finally, such heightened regulations will deter many potential wrongdoers from participating in newer models, leading to a process of self-selection. Strict checks and balances thereby make ACOs accountable both in name and in reality.

FCA influence

Although the waiver authority granted under the ACA applies in the first instance to the AKS, the Stark Law, and the CMP Statute, it is important to consider the influence of the False Claims Act in a bifurcated fraud and abuse system. As FCA activities are projected to increase substantially in the near future, it is likely that FCA enforcement trends will change as well. VBP and other quality-based payment and reporting initiatives will further bind Medicare payment to reporting, meaning that FCA scrutiny will apply to the accuracy of such reporting. Additionally, ACOs and other integrated models will be subject to additional FCA vulnerability, as they must certify compliance with program requirements to obtain shared savings. To counterbalance these trends, deep waivers in the AKS, the Stark Law, and the CMP Statute are justified in the integrated delivery setting to lessen the chance that violations of these statutes will serve as the basis of FCA actions. Although ACO participants would remain susceptible to FCA liability for fraudulent reporting, they would be granted appropriate latitude to experiment with innovative financial arrangements without inviting regulatory punishment.

There may be some residual reluctance among DOJ, CMS, and the OIG to rearrange enforcement efforts with respect to certain types of provider arrangements. On the other hand, the bifurcated model would permit these agencies to focus efforts and resources on fighting fraud within the traditional FFS sphere. To the extent that fraudulent activities occur in integrated delivery models, such activities would be more easily uncovered and proven with increased reporting and data analysis, making them especially vulnerable to FCA penalties. If lawmakers believe that greater deterrence is warranted in this setting, they could increase the penalties (but not the anti-fraud restrictions) for misconduct within integrated models. The agencies' pursuit of individual liability through criminal and civil prosecutions and program exclusions would appropriately apply to egregious misconduct. Because ACOs and other integrated models operate in a stricter regulatory environment, participating physicians and corporate officers would have fair notice of the consequences of malfeasance. Thus, higher penalties for willful misconduct and individualized liability would serve as coiled threats that would promote proportionality and deterrence by punishing willful offenders, while sparing honest providers for inadvertent violations.

Private payors

The creation of a bifurcated fraud and abuse system would serve to enhance combined public-private approaches to integrated delivery reform. In calling for a national movement to reform healthcare, HHS Secretary Kathleen Sebelius remarked:

Our health care system remains fragmented and disorganized. Even the strongest private sector plans don't have the reach to bring on wholesale change. And until now, the public sector has been slow to act. In fact, in many ways our public programs are operating in the 20th Century while much of the private sector is using 21st Century technology and innovation to drive change. n150

n150 Press Release, U.S. Dep't of Health and Human Services, *Sebelius Outlines How the Affordable Care Act is Improving the Quality of Care* (Dec. 7, 2010), available at www.hhs.gov/news/press/2010pres/12/20101207a.html [hereinafter *Sebelius Outlines How the Affordable Care Act is Improving the Quality of Care*].

Industry observers agree that many innovative achievements involving P4P and disease management have been spearheaded by private-sector efforts. n151 Private health plans and medical groups, such as Kaiser Permanente, the Group Health Cooperative of Puget Sound, the Geisinger Health System, the Cleveland Clinic, the Mayo Clinic, and the Intermountain Health System, have been embraced as exemplars for integrated delivery. n152 Private-sector initiatives have proven more nimble and innovative in large part because they do not implicate the fraud and abuse restrictions. Although these initiatives have not achieved the sort of scale obtainable through Medicare sponsorship, private-sector integration is beginning to drive utilization trends in areas outside the prohibitive reach of the fraud and abuse laws. In recognition of the public/private disconnect, Secretary Sebelius stated that the ACA provides "all of the stakeholders, public and private" with the "support to work together not just to coordinate care, but to align payment policies and public policy." n153

n151 See, e.g., Paul B. Ginsburg, *Private Payer Roles in Moving to More Efficient Health Spending*, in *RESTORING FISCAL SANITY 2007: THE HEALTH SPENDING CHALLENGE* 153, 157 (Alice Rivlin & Joseph Antos eds., 2007).

n152 See, e.g., Stephen M. Shortell et al., *United States Innovations in Health Care Delivery*, 32 *Pub. Health Reviews* 190, 196 (2010); Alain C. Enthoven & Laura A. Tollen, *Competition in Health Care: It Takes Systems to Pursue Quality and Efficiency* W5-420, W5-421, *Health Aff. (Web Exclusive)*, (2005).

n153 *Sebelius Outlines How the Affordable Care Act Is Improving the Quality of Care*.

The ACO model represents the government's boldest effort at integrated delivery reform, with potential application to both the private and public spheres for profound and industry-wide change. The Pioneer ACO model, which will operate concurrently with the MSSP, is designed to incorporate private payors to promote care coordination on an unforeseen scale. However, public-private Medicare-based ACO initiatives will replicate private-sector successes only if they are permitted to operate within a designated zone of protection under the AKS, the Stark Law, and the CMP Statute. Through the replication of special enforcement treatment to the Pioneer ACO model, the government would begin to invite private payor involvement and shape integrated delivery on its own terms.

Conclusion

With the passage of the Affordable Care Act, the government announced far-reaching reforms in healthcare that are aimed at battling fraud and abuse and restructuring payment and delivery systems. In acknowledgement of the fundamental incompatibility of these two lines of reform, the ACA granted HHS waiver authority under the AKS, the Stark Law, and the CMP Statute. In the course of exercising this authority, HHS heeded industry concerns with its robust final waiver rule that permits ACOs to develop and operate within a generous protective zone. In so doing, the government has taken the first steps in creating a bifurcated system of fraud and abuse regulation. To further this progression, the government should consider extending exceptional regulatory treatment to other related reforms, such as the Pioneer ACO, bundled payment models, and PCMHs to encourage enrollment in integrated models while maintaining an adequate bulwark against fraud and abuse. Bifurcated treatment would be further promoted by, among other things: seeking alignment with state laws; creating an advisory opinion process; targeting fraudulent reporting as an FCA enforcement priority; expanding waivers to encourage private payor participation; increasing penalties for willful violations in integrated models; and pursuing individual liability for egregious misconduct. The bifurcated model would empower the government to define the paradigm for comprehensive delivery system reform and thereby remake the healthcare landscape in a balanced and efficacious manner.

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TITLE: A Critical Look at Recent Developments in Tax Exempt Hospitals [+]

[+] The views expressed herein are those of the authors and do not necessarily represent the position of the Internal Revenue Service.

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TEXT:

I. INTRODUCTION

The last ten years have not been kind to nonprofit hospitals. Stripped of the ability to rely on generous charitable contributions, cost-based reimbursement, and cost shifting among payers, these hospitals have been forced into the domain of commercial enterprise. Declining demand for inpatient services has obliged voluntary, nonprofit institutions to learn how to compete -- with one another, with for-profit hospitals, and increasingly, with free standing health care providers.

Nonprofit, tax exempt hospitals are adapting to this new environment, often choosing strategies as competitive as those of their investor-owned counterparts. One response appears to be a reduced emphasis on treating patients without regard to their ability to pay. For this and other reasons, access to care for the poor and the uninsured is again a topic of national debate. At the same time, hospitals are desperately seeking patients who can pay. Nowhere is this more evident than in their innovative efforts to recruit, retain, and reward physicians in order to gain access to the patients those physicians control.

This Article explores two issues currently of concern: (1) the continued relevance of the community benefit standard used to determine hospitals' qualification for tax exemption, and (2) the evolving relationships between nonprofit hospitals and physicians and their potential effect on a hospital's exemption. As will be seen, hospital attempts to avoid providing needed emergency care, and their attempts to financially reward physicians for patient referrals may violate federal laws administered by the Department of Health and Human Services. The authors

conclude that these same activities may jeopardize a hospital's tax exempt status.

II. HOSPITALS RESPOND TO A CHANGED ENVIRONMENT

It would be difficult to overstate the extent of change affecting hospitals in the last decade. After many years in which government regulations designed to control costs were its worst headache, the hospital industry awoke in the early 1980s to a far more threatening environment. Almost overnight, hospitals found themselves in a revenue squeeze imposed by third party payers. For-profit or not, hospitals struggled with rapidly increasing labor and technology costs accompanied by declining inpatient revenues. As if this were not enough, they also encountered aggressive new competition from unexpected adversaries. It soon became apparent that only the strongest and most efficient would survive.

Heading the list of contributors to this new environment is the federal government's switch to prospective payment. The reimbursement system, used by the Health Care Financing Administration since 1983 to pay for Medicare-covered inpatient hospital care, is based on fixed payments, determined in advance, for each episode of care. ⁿ¹ Payments are established objectively based on diagnosis without regard to treatment choices or the actual cost of an individual patient's care. Designed to control costs, Medicare's Prospective Payment System (PPS) gives each hospital ⁿ² an incentive to increase admissions, shorten its average length of stay per admission, and reduce the consumption of ancillary services. Because payments are now fixed, hospitals can no longer increase their Medicare revenues by providing more services or longer hospitalization to each patient. Under PPS, they fare better by providing fewer services to more patients.

Other payers have also contributed to the new environment. The rapid growth of alternative health care delivery systems has been a mixed blessing for hospitals. Although health maintenance organizations (HMOs) and preferred provider organizations (PPOs) offer access to large numbers of referrals, these organizations have also imposed strict cost and utilization limits on the hospital care they pay for.

Alternative delivery systems have flourished largely because of increasing private sector cost sensitivity. Employers, who pay for much of the nation's private health insurance, are demanding cost containment through beneficiary cost-sharing and improved management of utilization and fees. Today, almost sixty percent of privately insured Americans are covered by managed care plans, including HMOs, PPOs, and fee-for-service plans requiring advance authorization for hospital stays. ⁿ³ The result of these pressures, combined with the switch to outpatient settings for many common procedures, has been empty hospital beds and declining revenues. ⁿ⁴ Moreover, the ability to shift costs from one payer to another -- long a means of financing care for the indigent -- has been severely curtailed.

Hospital net revenues, perhaps the best indicator of financial health, have declined dramatically. The average hospital's operating margin shrank by fifty percent between 1987 and 1988, to a mere 0.5 percent in the first half of 1988. ⁿ⁵ Moreover, hospitals are closing at a record rate. The American Health Lawyers Association reports that eighty-one acute care hospitals closed in 1988; forty-one of those were nonprofit. ⁿ⁶

If hospitals overbuilt in the 1960s and early 1970s, when third party payers covered much of the cost, today they are paying the piper. The extent of overcapacity dictates that more will fail. A government study of hospitals which closed during 1987 found no single reason for closure. Rather, the closed hospitals were gradually weakened by a number of factors, including (1) declining admissions due to lack of physician availability or confidence in the institution, changing patient preferences, and greater mobility; (2) lagging revenues due to cost containment efforts and uncompensated care burdens; and (3) rising costs due to aging physical plants, nursing shortages, and new technology. ⁿ⁷ To remain financially strong, and thus in existence, nearly every hospital is striving to achieve operating efficiencies, control costs, attract new admissions, and secure additional sources of revenue. ⁿ⁸

Nonprofit hospitals quickly recognized that they, as well as for-profit hospitals, must be managed efficiently and must become more competitive to survive. At its heart, efficiency involves controlling costs, often an elusive goal in

the present health care economy. Competition, on the other hand, has been aimed at generating additional revenues. With many hospital costs fixed, managers know the importance of maintaining a sufficient volume of business to cover them. Thus, some of the increased competition hospitals are experiencing is merely the result of stepped-up efforts by neighboring facilities to preserve or improve their own market share.

Making matters worse for many hospitals is the arrival of new competitors who threaten to skim off traditionally profitable diagnostic and treatment activities. Ironically, hospitals increasingly find their toughest competitors for outpatient services to be their own medical staff physicians. Physician-owned ambulatory surgery centers, urgent care centers, and diagnostic facilities now provide a convenient alternative to hospital services in many suburban areas.

Specific hospital responses to these challenges have been many. Both for-profit and nonprofit hospitals have banded together into chains and alliances, with varying degrees of centralized control. Diversification into nontraditional activities quickly became the norm. A few of these activities, including some entered via joint ventures with physicians and suppliers, have proven successful; others have resulted in financial disaster.ⁿ⁹ Financial managers have assumed more important roles with the advent of computerized data systems designed to maximize revenues under PPS. Recognizing the conflict between their fixed PPS payments and physicians' continued fee-for-service reimbursement, many hospitals have established physician incentive plans to reward efficient treatment.

While the changes in the hospital environment and the challenges they present affect nonprofit and for-profit hospitals in many of the same ways, the remainder of this Article deals only with nonprofit, tax exempt hospitals. The law extending the benefits of tax exemption to hospitals imposes restrictions and requirements that may be at odds with some otherwise effective responses to competition. The purpose of these restrictions and requirements is not to place nonprofit hospitals at a competitive disadvantage vis-a-vis for-profit hospitals, but to ensure that the advantages of tax exemption are justified by the public benefits they provide.

III. THE COMMUNITY BENEFIT STANDARD IN 1990

Judicial analysis of the tax exempt status of nonprofit hospitals has evolved over the years as hospitals themselves responded to changes in community needs, technology, private insurance, and the role of the government in relation to health care.ⁿ¹⁰ The requirements set forth by the Internal Revenue Service (Service) for tax exemption under section 501(c)(3) also have evolved in response to these changes and will continue to do so.ⁿ¹¹ This section of the Article considers whether the community benefit standard, used to determine a hospital's qualification for exemption, remains relevant in light of the radical changes reshaping the health care environment. The authors conclude that the community benefit standard, by design, is flexible enough to ensure that tax exempt hospitals meet the needs of their communities.

A. From Charity Care to Community Benefit

Analysis of the federal tax exemption of hospitals logically begins with the requirements of the Internal Revenue Code and Treasury Regulations. Any applicant seeking recognition of exemption under section 501(c)(3) must establish that it is organized and operated exclusively for exempt purposes,ⁿ¹² that no part of its net earnings inures to the benefit of any private shareholder or individual, and that it does not conduct substantial lobbying or any political activities.ⁿ¹³ Regulations under section 501(c)(3) make clear that an organization is not organized or operated exclusively for exempt purposes unless it serves a public rather than a private interest.ⁿ¹⁴

Provision of health care is not one of the purposes enumerated in section 501(c)(3) or the regulations. Although the Service had long recognized the exemption of nonprofit hospitals as charitable organizations,ⁿ¹⁵ no specific standards for determining whether hospitals qualified for exemption were set forth until 1956. Rev. Rul. 56-185ⁿ¹⁶ established a number of requirements. First, the applicant must be organized and operated as a nonprofit charitable organization for the purpose of operating a hospital for care of the sick. Second, it must be operated to the extent of its financial ability for those not able to pay for the services rendered, and not exclusively for those able and expected to pay. Third, the

hospital must not restrict use of its facilities to a particular group of physicians, to the exclusion of all other qualified physicians. Finally, its earnings must not inure directly or indirectly to the benefit of any private shareholder or individual. n17

Rev. Rul. 56-185's second requirement, known as the "financial ability standard," required tax exempt hospitals to admit and treat patients who were unable to pay, either without charge or at rates below cost. This requirement reflected the Service's position at the time that providing health care, *per se*, was not charitable, and that to be charitable, health care activities must also relieve poverty. Therefore, a hospital not only had to operate on a nonprofit basis, it had to provide more than an insubstantial amount of uncompensated care to be recognized as exempt. Under this standard, if less than 5 percent of its patients were provided free service, a hospital could be found not to qualify for tax exempt status. The opposite result obtained where 6 to 8 percent were treated without charge. n18 In practice, the financial ability standard proved vague and difficult to apply. n19

Following issuance of Rev. Rul. 56-185, certain events indicated the need for reconsideration of the requirements for hospitals to qualify under section 501(c)(3). In 1959, the regulations under section 501(c)(3) were amended to state that the term charitable is used in the section in its generally accepted legal sense. n20 This made clear for the first time that section 501(c)(3) charitable purposes are not limited to those enumerated in the Code, but include other charitable purposes as established by judicial decision. n21

Other developments also militated against continuing an absolute requirement that hospitals provide a particular amount of uncompensated care. Growing availability of third party payments for hospital care, including employer provided insurance and government programs such as Medicare and Medicaid, led some to believe that the need for free care was disappearing. n22 In addition, widespread belief that the government had assumed responsibility for indigent care brought reduced private philanthropy for hospitals, as donors turned their support to other causes. n23 These factors, along with dramatic increases in hospital operating costs, contributed to a decrease in the amount of free care provided, n24 thereby fostering concern that some hospitals might lose their exemption because they were unable to provide sufficient uncompensated care to meet the requirement. n25

Recognizing these developments, the Service reconsidered the requirements for hospital exemption. In Rev. Rul. 69-545, n26 the agency modified Rev. Rul. 56-185 by removing the financial ability standard and substituting a new test, known as the "community benefit standard," n27 which focuses on a number of factors indicating that operation of the hospital benefits the community. Rev. Rul. 69-545 recognizes the general legal principle that promotion of health is itself a charitable purpose, n28 and removes the express requirement that hospitals relieve poverty by providing as much uncompensated care as they could afford. n29

The principal drafter of Rev. Rul. 69-545 subsequently described the community benefit standard as follows:

As Professor Scott has stated: "A trust is not charitable if the persons who are to benefit are not of a sufficiently large or indefinite class so that the community is interested in the enforcement of the trust. This is true even though the purpose of the trust is to promote health." In the case of a community hospital, this fundamental principle is translated into a rule or requirement which has been phrased in various ways -- it must admit "patients without regard to race, creed, or wealth;" or "[t]he rich should not be turned away because of their wealth nor the poor because of their poverty."

This language, when applied to the modern American hospital system can easily be misunderstood. It is therefore important to appreciate that its underlying rationale is that: (1) a charitable hospital must in fact benefit the community, and (2) the community may not be benefited if its needs are not met, i.e., if a substantial portion of its residents are turned away. n30

Rev. Rul. 69-545 recognizes there are many ways in which a hospital can demonstrate that it is operated for the benefit of the community and not to serve private interests. It requires that all relevant facts and circumstances be

weighed in each case. Rather than setting forth a definitive list of requirements, Rev. Rul. 69-545 illustrates the analysis under the community benefit standard by giving two examples, one hospital that qualified and one that did not.

The first hospital described (Hospital A) is controlled by a board of trustees composed of prominent civic leaders. Staff privileges are available to all qualified physicians in the area, and any member of the active medical staff may lease space in the hospital's medical office building at fair market rates. Hospital A also operates an active and accessible emergency room, with no one requiring emergency care denied treatment. Hospital A provides inpatient care to all in the community who are able to pay, either themselves or through third party reimbursement, including Medicare and Medicaid. However, indigent persons needing admission as inpatients ordinarily are referred to other hospitals in the community. Hospital A usually ends each year with an excess of receipts over disbursements, applying the surplus to expansion and replacement of facilities and equipment, amortization of indebtedness, improvement of patient care, and medical training, education, and research.

Rev. Rul. 69-545 reasons that, by providing hospital care on a nonprofit basis to its community, Hospital A furthers a charitable purpose. By operating an emergency room open to all, and providing hospital care for all those able to pay either themselves or through third parties, Hospital A promotes the health of a class of persons broad enough to benefit the community as a whole. In addition, by having a board composed of independent civic leaders, an open medical staff, and an active, open, and accessible emergency room, Hospital A operates to serve public, rather than private, interests. Accordingly, Rev. Rul. 69-545 concludes that Hospital A qualifies for exemption. n31

The second hospital (Hospital B) is a small facility originally owned by five physicians who continue to dominate its board of trustees and medical staff and who rent office space from the hospital at below market rates. Only four other physicians were granted staff privileges in the hospital's first five years of existence, although a number of other qualified physicians applied. Admission to Hospital B is restricted to patients of its staff physicians, and ordinarily is limited to those able to pay. Although Hospital B operates an emergency room (primarily for patients of its staff physicians), local ambulance services were instructed to take emergency cases to other area hospitals. Rev. Rul. 69-545 concludes that Hospital B operates for the private benefit of its original owners, rather than for the exclusive benefit of the community, because the former owners restricted the number of physicians admitted to the staff, entered into favorable rental agreements with the hospital, and substantially limited emergency room care and hospital admissions to their own paying patients. n32

Private citizens challenged Rev. Rul. 69-545 in federal court, arguing that the Service should continue to require tax exempt hospitals to provide free treatment to individuals unable to pay. n33 Plaintiffs argued that the ruling was invalid because it constituted an improper administrative alteration of the Code in contradiction of long-standing tax policy and judicial interpretation. The district court agreed, holding that Rev. Rul. 69-545 was contrary to the relevant judicial, legislative, and administrative history on the matter and was an unauthorized reversal of a long-established policy of requiring exempt hospitals to offer special consideration to persons unable to pay. n34 The United States Court of Appeals for the District of Columbia Circuit reversed, holding that the definition of charity was not limited to the relief of poverty and that an inflexible construction of the term "fails to recognize the changing economic, social and technological precepts and values of contemporary society." n35 The court reviewed the changes characterizing the health care field and concluded that "the rationale upon which the limited definition of 'charitable' was predicated has largely disappeared." n36 Therefore, the court held that the Commissioner was authorized to change the standards for hospital exemption and that Rev. Rul. 69-545 was founded on a permissible definition of charity and was not contrary to express congressional intent. Although the Supreme Court vacated and remanded solely on the issue of standing, the court of appeals decision generally has been regarded as upholding Rev. Rul. 69-545. [n37]

Though it removed the express charity care requirement, Rev. Rul. 69-545 was widely interpreted as requiring exempt hospitals to operate an emergency room open to all without regard to ability to pay. [n38] A revenue ruling issued in 1983, however, provides that under certain narrowly defined circumstances an emergency room is not required. [n39] Rev. Rul. 83-157 states that a hospital identical to Hospital A in Rev. Rul. 69-545, which does not operate an emergency room solely because a state health planning agency determined it would unnecessarily duplicate

emergency services and facilities adequately provided by another institution in the community, may continue to qualify under section 501(c)(3). In essence, the ruling requires an independent determination by the state that another emergency room would not benefit the community. According to the ruling, operation of a full-time emergency room serving all members of the public regardless of ability to pay is strong evidence of community benefit, but other significant factors may be sufficient to demonstrate that the hospital is organized and operated for the benefit of the community.

Rev. Rul. 83-157 also recognizes that certain specialized facilities, such as eye hospitals and cancer hospitals, treat conditions unlikely to need emergency care and do not, as a practical matter, maintain emergency rooms. These hospitals nevertheless may demonstrate through other activities that they are organized and operated for the benefit of the community. The Office of Chief Counsel, considering the ruling in proposed form, recommended it be expanded to emphasize that, where a hospital does not operate an emergency room open to all, careful consideration must be given to its other medical services and characteristics in determining whether it operates exclusively to benefit the community. [n40]

B. Responding to Changes in Need

Many members of the community, particularly indigents and the uninsured, do not have private physicians and, as a result, rely on hospital emergency rooms as their principal means of access to medical care. [n41] It follows that availability of a truly open emergency room is vital to the health of the community. As noted by a leading commentator, hospitals located near medically indigent populations may be required to undertake affirmative programs to serve the poor or uninsured, such as indigent care clinics. [n42] One might question whether they should be allowed, absent overwhelming justification, to close their emergency rooms to those from whom they cannot expect payment.

When the number of medically indigent people increases, as it has in the last decade, [n43] the importance to the entire community of uncompensated care, particularly emergency care, grows proportionally. Thus, caring for the indigent and operating an open emergency room, always meaningful indications of community benefit, [n44] remain two of the most important ways for a nonprofit hospital to demonstrate that it is organized and operated for the benefit of the community. [n45] Unfortunately, economic pressures on hospitals also mounted during the 1980s. As a result, there are indications that fewer hospitals are willing to provide medical care without expectation of payment. [n46]

In this regard, the community benefit standard allows the inference that hospitals not providing emergency care without regard to ability to pay may not be organized and operated exclusively for the benefit of the community, at least where they fall outside the circumstances described in Rev. Rul. 83-157. [n47] A truly open emergency room is just that. If a hospital tells ambulance drivers not to bring patients to its emergency room, as Hospital B did in Rev. Rul. 69-545, that suggests the facility is not organized and operated for the benefit of the community. [n48] Further, if a hospital routinely transfers uninsured or indigent emergency patients to another hospital because of inability to pay, a similar inference may be drawn. [n49]

Another community benefit requirement generally recognized after publication of Rev. Rul. 69-545 is nondiscriminatory treatment of Medicare and Medicaid patients. [n50] Hospitals often find Medicaid rates inadequate to cover costs. Nonetheless, where a hospital has a policy of turning away Medicaid patients, a question arises as to whether it truly is operated for the benefit of the community. Furthermore, a hospital that does not bid for Medicaid contracts on a good faith basis arguably no more serves its entire community than a hospital that routinely discriminates. [n51]

The businesslike attitudes and strategies now embraced by nonprofit hospitals have created the perception in some circles that the distinctions between nonprofit and for-profit hospitals are disappearing. [n52] One potential effect of such a perception is illustrated by the recent experience of Blue Cross-Blue Shield. When it discerned that the products and services offered by the Blues had become indistinguishable from those of commercial insurers, Congress took away their exempt status. [n53] In the hospital field, studies have been undertaken to determine whether and to what extent

the levels of uncompensated care in for-profit and nonprofit hospitals differ. [n54] Significantly, a congressional committee has asked the General Accounting Office to compare indicia of community benefit, including uncompensated care, in tax exempt hospitals with those in for-profits. [n55] The results are expected later this year.

As more information becomes available, Congress may consider whether remedial legislation is needed to ensure that all segments of the population, including the medically indigent, benefit from the tax exemption accorded hospitals. While charity care alone cannot solve the nation's access problems, it can be part of the solution. Many hospitals already do all they can. The few taking measures to avoid uncompensated care increase the burden on the rest, and thereby become part of the problem. [n56]

In the meantime, neither the Service nor its community benefit analysis need stand still. The latter was adopted in part because the earlier formalistic approach had not kept pace with changes in health care. By introducing flexibility into the determination, the community benefit standard allows the Service to adjust the requirements for exemption as needs change.

The authors believe that exempt hospitals, in order to justify continued exemption, should be required to demonstrate that they provide public benefits which are more substantial than those of their for-profit counterparts. [n57] As the Chair of the House Ways and Means Subcommittee on Health has stated, "[I]f tax exempt, not-for-profit hospitals are not providing enough service to the community to justify the costs to society of their tax exemption, then they should show their true colors, end the subsidy, and convert to for-profit." [n58] This is not to suggest the sole difference between nonprofits and for-profits is the amount of uncompensated care they provide. Nor do we advocate reinstatement of the financial ability standard of Rev. Rul. 56-185. [n59] Nonetheless, the chief advantage of the community benefit standard is that it allows particular factors, including those discussed above, to be emphasized as they assume greater significance in community need.

C. Responding to Changes in Law and Policy

Under the common law, the purpose of a charitable trust may not be illegal, and an organization is not exempt under section 501(c)(3), if its purposes or activities are illegal. [n60] Under certain circumstances, significant changes in the law could cause an organization previously recognized as exempt to no longer qualify.

The need for access to health care by all segments of society is once again receiving the attention of state and federal governments. [n61] Increasingly, nonprofit hospitals are transferring poor or uninsured patients to public hospitals and admitting only those able, either themselves or through third party payments, to shoulder the full cost of their care. [n62] This process, known as patient dumping, has resulted in legislative action making inappropriate transfers a violation of state law for many hospitals. [n63]

Congressional concern about access and dumping was expressed in legislation as far back as 1946, with passage of the Hill-Burton Act (Hill-Burton). [n64] Hill-Burton provided federal funds for construction and modernization of public and private nonprofit hospitals. [n65] In return for federal funds, hospitals were required to provide uncompensated care [n66] and to satisfy a community service obligation. [n67] The uncompensated care obligation requires that, for twenty years after receiving Hill-Burton funds, hospitals annually provide a prescribed amount of free or reduced-rate care to indigent patients. [n68] Under the community service obligation, hospitals must provide full services, including emergency services, on an ongoing basis to all patients in their community [n69] The latter obligation allows discharge or transfer to another facility for treatment only after appropriate personnel determine that the transfer will not subject the patient to a substantial risk of deterioration. [n70] A patient's inability to pay is not a valid reason for a Hill-Burton hospital to deny emergency services, nor is the fact that the person does not have a physician with privileges at the hospital. [n71]

Litigation and congressional hearings in the 1970s exposed widespread noncompliance with the Hill-Burton requirements, [n72] attributed in part to the fact that neither the statute nor the regulations impose effective sanctions for

violations. [n73] This situation apparently continues to the present. [n74]

In 1985, Congress again expressed concern about hospital treatment of the poor and uninsured, and this time included sanctions. In the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), [n75] Congress required all hospitals that participate in Medicare and have emergency departments to treat any patient in an emergency condition, whether or not covered by Medicare, and regardless of the patient's ability to pay. [n76]

COBRA requires hospitals to conduct a medical screening examination of each emergency room patient to determine if an emergency medical condition exists or the patient is in active labor. [n77] If such a condition exists, a hospital generally must provide treatment to stabilize the patient before he or she may be transferred to another facility. If a hospital knowingly and willfully, or negligently, fails to meet these requirements, the hospital may have its Medicare provider agreement terminated. In addition, hospitals and physicians that knowingly violate this provision are each liable for a penalty of up to \$ 50,000 per violation. Further, any individual suffering personal harm as a direct result of a COBRA violation can recover civil damages from the hospital. [n78]

In 1989, Congress passed new legislation strengthening the antidumping provisions by requiring hospitals to (1) adopt and enforce a policy to ensure compliance; (2) keep records regarding transfers for five years; and (3) maintain a list of physicians who are on call for duty after the initial examination to provide treatment necessary to stabilize an individual with an emergency medical condition. The new legislation also requires that each Medicare-participating hospital conspicuously post a sign in its emergency department specifying the rights of individuals to emergency treatment and indicating whether the hospital participates in Medicaid. [n79]

Like Hill-Burton, COBRA's antidumping provisions are administered by the Department of Health and Human Services (HHS). However, the Service has begun obtaining information from HHS regarding nonprofit hospital violations. [n80] When a hospital exhibits a pattern of violating COBRA's antidumping provisions, it arguably no longer qualifies for exemption. This is so because it is operating contrary to law, and is not operating for the benefit of the community. Thus, when considering the risks of dumping, hospitals should include potential loss of tax exemption.

IV. THE EVOLVING RELATIONSHIP BETWEEN HOSPITALS AND PHYSICIANS

Among the most remarkable developments in the health care field are those involving relations between hospitals and physicians. Expanded concepts of institutional liability have obliged hospitals to exercise more control over the selection, training, and discipline of their medical staffs. A more fundamental transformation, however, involves the new economic relationships being forged between the two as a result of PPS and the competitive pressures discussed above. Where these relationships allow physicians to share assets which otherwise would belong to the hospital, important tax and public policy issues are raised.

A hospital's ability to generate needed revenues depends heavily on its relations with its medical staff. Patients bring revenues to hospitals, but they rarely decide for themselves when or where to obtain care. For that, they rely upon physicians. A recent commentator notes:

[P]hysicians, not institutions, control the vast bulk of health care expenditures. Doctors determine when, how long, how intensively, and in what environment to treat patients. They order the laboratory tests, x-rays, pharmaceuticals, and surgery that determine the short-term institutional costs of treatment. . . . Although difficult to quantify with precision, informed estimates place 70 to 90 percent of health care expenditures within the control of individual practitioners. [n81]

Hospital managers understand this control. Accordingly, some of their most intense -- and inventive -- competitive efforts have focused on attracting, retaining, and motivating physicians.

Hospitals traditionally attracted physicians by offering modern treatment facilities, a prestigious reputation, or the latest medical equipment. Medicare and private insurers picked up many of the costs of the capital improvements and

assets involved. Constant upgrading proved expensive, but patients and the community could be counted among the primary beneficiaries.

Facilities that are financially able still woo physicians with bricks and technology. Increasingly, however, recruitment and retention efforts are shifting toward sophisticated financial arrangements through which the physicians can share in the revenues resulting from their patient referrals. [n82] These arrangements include recruiting incentives, hospital purchases of physician practices, and joint ventures between hospitals and physicians. The physicians enjoy a handsome economic benefit from these arrangements, sometimes described as bonding or enhancements. However, it is difficult in many cases to identify any benefit for patients or the community. Indeed, the resulting financial incentives for physicians could detract from the exercise of disinterested professional judgment on patients' behalf.

Despite the increasing criticism leveled at these arrangements from Congress, professional journals, and the press, [n83] nonprofit hospitals apparently still believe they are worthwhile. One explanation is that hospitals participate out of hope and fear. They hope that giving the physicians a financial stake will improve utilization and revenues, and fear that if they refuse, the physicians will change hospitals or establish competing providers to take advantage of their captive referrals. Thus, sharing hospital economic opportunities with physicians not only can attract referrals, it may forestall additional competition from those most able to capitalize on it.

A. Why the IRS is Concerned: Private Inurement, Private Benefit, and the Hospital-Physician Relationship

The Internal Revenue Code and the Service view tax-exempt hospitals as charitable trusts for the benefit of the public. Physicians and physician-owned entities, on the other hand, are taxable private interests. The entire regulatory scheme under which hospitals are exempt is designed to ensure that charitable assets are used for public purposes and not diverted into private hands. [n84] Some of the new hospital-physician economic arrangements may not withstand a strict application of that standard.

1. The First Deadly Sin: Private Inurement

Section 501(c)(3) exempts from taxation certain organizations "no part of the net earnings of which inures to the benefit of any private shareholder or individual. . . ." An organization is not operated exclusively for charitable or public purposes if its net earnings inure in whole or in part to the benefit of private shareholders or individuals. [n85] Simply stated, the inurement proscription "means that a private shareholder or individual cannot pocket the organization's funds except as reasonable payment for goods or services." [n86]

The inurement restriction prohibits inurement of an organization's assets to an "insider." [n87] Generally, an insider is a person who has a personal or private interest in or opportunity to influence the activities of an organization. [n88] The Office of Chief Counsel has stated: "[I]nurement is likely to arise where the financial benefit represents a transfer of the organization's financial resources to an individual solely by virtue of the individual's relationship with the organization, and without regard to accomplishing exempt purposes." [n89] This power to influence the organization from the inside often is referred to as control. [n90] As used in this context, however, control does not involve a measured amount of ownership or voting power. Instead, it refers to the opportunity to cause the organization to take or refrain from the action giving rise to the inurement. The clearest examples of insiders include trustees or board members, officers, managers, or an organization's founders.

Inurement need not take the form of a dividend and need not be direct. [n91] Moreover, the phrase "net earnings," as used in section 501(c)(3), includes more than just net profits, as shown on the books of the organization or by the difference between gross receipts and disbursements. [n92] The law seeks to prevent anyone in a position to do so from siphoning off any of a charity's assets for personal use. Finally, the fact that the amount involved may be small does not remove the prohibition against inurement. [n93]

The presence of even an insubstantial amount of private inurement will cause an entity to fail the operational test. Thus, the organization will no longer qualify for exemption and may have its exemption revoked.

2. The Second Deadly Sin: Private Benefit

An organization exempt under section 501(c)(3) must be organized and operated to serve public rather than private interests. [n94] This private benefit prohibition applies to everyone, not just insiders. However, its application is not as strict as the private inurement prohibition. Instead, the standard is that any private benefit must be incidental to the accomplishment of the public benefits (*i.e.*, exempt purposes) involved. [n95] This sometimes requires a balancing of the public versus private interests served by a given activity.[n96]

In General Counsel Memorandum (GCM) 37,789, [n97] the Service considered the meaning of "incidental" in the private benefit context, and concluded that a benefit is incidental only if both qualitatively and quantitatively so. To be qualitatively incidental, the benefit must be a necessary concomitant of the activity that benefits the public at large, *i.e.*, the activity can be accomplished only by benefiting certain private individuals. To be quantitatively incidental, the private benefit must not be substantial after considering the overall public benefit conferred by the activity. [n98] The balancing involves only the public benefit conferred by the activity at issue, not the overall good accomplished by the exempt organization.

Some private benefit is always present in typical hospital-physician relationships. Almost twenty years ago, a commentator observed: "The professional relationship between a physician and a hospital is such that some professional advantage always will accrue to the physician by reason of such association." [n99] To some extent, a hospital could be viewed as a workshop in which physicians are allowed to engage in the private practice of medicine. Exemption is not ruled out as long as the private benefit is incidental to the public benefits achieved. However, the presence of substantial private benefit will cause an organization to lose its exemption. [n100]

Private benefit is a broader concept than private inurement and has wider application. Both may be present on a given set of facts. Some courts and commentators treat inurement as a subset of private benefit, [n101] while others fail to distinguish the concepts at all. [n102] The Tax Court squarely addressed the distinction in the recent *American Campaign Academy* decision, stating that "while the prohibitions against private benefit and private inurement share common and overlapping elements, the two are distinct requirements which must independently be satisfied." n103 As the Service determines additional classes of individuals to be insiders for inurement purposes, the overlap becomes greater. Nonetheless, it is helpful in evaluating hospital-physician relationships to bear in mind the distinction. As noted above, inurement generally will not be found in the absence of an insider, while private benefit can involve anyone. Thus, a key question in the hospital field is whether physicians are insiders.

At the outset, we note that physicians' relationships with hospitals take many forms, often simultaneously. Some are independent contractors, enjoying only staff privileges at the hospital. While they may not perform services for the hospital, a contractor analysis is appropriate because their privileges make the medical staff bylaws an implied contract. Other physicians are full- or part-time hospital employees. n104 Still others serve as officers of the medical staff, as administrators, and even as members of the governing board.

When considering a hospital's physician recruiting program in 1986, the Office of Chief Counsel stated that "the recruited physicians as employees or as individuals with a close professional working relationship with the hospital are persons who have a personal and private interest in the activities of the hospital. Thus, such physicians are subject to the inurement proscription." n105 Eighteen months later, the Office of Chief Counsel considered the insider question in the context of a university-affiliated fund which paid incentive compensation to athletic coaches and concluded that employees are a class to whom the inurement proscription can apply. n106 In the latter GCM, the Office of Chief Counsel states: "It is our opinion that all persons performing services for an organization have a personal and private interest, and therefore possess the requisite relationship necessary to find private benefit or inurement." n107

Some might question whether this means every exempt organization employee, including the janitor, or even a new recruit who has not yet performed any services, is necessarily an insider. The Service's position appears to be, in effect, a presumption, *i.e.*, that employees as a class relate to an exempt organization in such a manner that significant potential

exists for inside influence. Similarly, physicians rendering services at a hospital, under any of the above-described relationships, are too likely as a class to enjoy considerable influence over the hospital to not apply the inurement analysis. It still may be possible for a hospital to demonstrate that all of its relationships with an individual physician are truly at arm's length and that the latter has had no opportunity to exercise inside influence, in which case private inurement would not be present (though more than incidental private benefit still may be). Of course, where the facts support a finding of unreasonable compensation or other unjustified economic benefit, such a showing would be very difficult to make.

It has been suggested that the Service's position represents a departure from precedent. n108 While the above GCMs were the first to squarely address the issue, the Service has traditionally applied the inurement analysis in determining reasonable compensation issues in the hospital setting. For example, in Rev. Rul. 69-383, n109 the Service considered a compensation arrangement under which a hospital paid a radiologist a percentage of the department's gross billings. Noting that percentage compensation may, under certain circumstances, constitute private inurement, the Service approved the arrangement because it found that (1) the radiologist did not control the hospital; n110 (2) the arrangement was negotiated at arm's length; and (3) the amount received was reasonable.

Also, it must be noted that hospital-physician relationships are changing. The influence physicians have over hospitals by virtue of participation in the organized medical staff, representation on the board of trustees, participation in economic joint ventures, and, increasingly, by virtue of their power over patient referrals, suggests the possibility of control. n111 Even physicians not yet on staff, but who are the subject of recruiting incentives, n112 may be able to exert the latter type of control. Thus, any time a hospital deals with a physician, it should be certain that the transaction is strictly arm's length and that the amounts received by the physicians are reasonable under the facts.

B. Most Hospitals Also are Subject to Laws Which Prohibit Paying for Referrals

Tax laws designed to prevent the private use of charitable assets are not the only restrictions affecting hospital-physician economic arrangements. Most hospitals also are subject to state n113 and federal laws that restrict their ability to financially reward physicians for admitting or referring patients. Hospitals participating in Medicare and Medicaid are governed by a strict statute designed to ensure that funds flowing from those programs are used only for permissible purposes. n114 The Medicare and Medicaid fraud and abuse law prohibits payment or receipt by a provider of any remuneration (including any kickback, bribe, or rebate) in return for or to induce referrals. n115 The intersection of these provisions in the hospital setting is readily apparent. When Medicare funds are paid to a hospital, they become charitable assets, available to accomplish the hospital's public purposes. If those funds are diverted to reward physicians for referrals, both the inurement proscription and the fraud and abuse law may be violated.

Providers have long decried the difficulty of complying with both the tax and the fraud and abuse laws. The Service requires exempt hospitals to demonstrate clearly the benefits they expect from, for example, novel compensation arrangements or joint ventures. In many cases, obtaining continued or additional referrals is the primary benefit a hospital expects to achieve. Attempting to show compliance with IRS standards by citing anticipated referrals places both hospital and physician at risk of severe fraud and abuse penalties. Moreover, this assumes that bargained-for patients could properly be used to demonstrate the absence of private inurement -- a point that is by no means clear.

The fraud and abuse statute is extremely broad (*e.g.*, "remuneration" is defined to include any direct or indirect economic benefit) and by its terms prohibits many arrangements which would be acceptable business practices in other settings were Medicare or Medicaid not involved. It was enacted before PPS recast the hospital environment, yet applies to today's arrangements. Moreover, in the few published decisions in this area, courts have not hesitated to apply the statute almost as broadly as it was drafted. The leading case construing the statute is *United States v. Greber*, n116 in which the United States Court of Appeals for the Third Circuit held that if one purpose of a payment is to induce future referrals, then, notwithstanding the presence of other permissible purposes, the statute has been violated.

The illegal remuneration provision comes into play most often in arrangements involving referral of patients. Typically, it is physicians, and not hospitals, nurses, insurers, etc., who are in a position to control patient referrals. Thus, just as with the tax exemption provisions, any prohibited economic benefits arising from hospital-physician arrangements generally flow from the hospital to the physician.

While the fraud and abuse law has existed for eighteen years, the stakes were recently raised. The greatest concern for hospitals and physicians today is the Secretary of HHS' newly expanded civil exclusion authority. n117 Until enactment of the Medicare and Medicaid Patient and Program Protection Act of 1987, n118 the provisions governing illegal remunerations were strictly criminal in scope. The necessity of convincing a United States Attorney that an alleged violation is severe enough to warrant criminal prosecution and the exacting criminal burden of proof effectively insulated many arrangements from prosecution. n119 Today, the Secretary can, on his own initiative, prosecute a provider civilly for violations of the illegal remuneration provision and exclude the provider from Medicare and Medicaid. n120

It has been widely expected that once the "safe harbor" regulations, also required by the 1987 Act, are finalized, enforcement of the illegal remuneration provision will intensify. n121 The safe harbor regulations, which identify a few specific types of arrangements that will not be considered illegal remunerations, were published in proposed form on January 23, 1989. n122 In the preamble to the proposed rules, the Secretary notes that his new exclusion authority "is intended to provide an alternative civil remedy, short of criminal prosecution, that will be a more effective way of regulating abusive business practices than is the case under criminal law." n123 Hospitals, which have benefited from prosecutors' reluctance to take on prominent community organizations, should be prepared for more aggressive enforcement once this new authority is implemented.

C. Hospital-Physician Activities That May Involve Private Inurement, Illegal Remunerations, or Both

1. Unreasonable Compensation Arrangements

Professor Treusch states that "[t]he most obvious forms of inurement include the bail-out of earnings by way of compensation for services performed for the organization." n124 Many of the compensation issues of greatest interest to the Service arise in tax exempt hospitals, a segment of the nonprofit community with a substantial number of highly compensated individuals. Similarly, the vast majority of illegal remuneration cases pursued by the Inspector General over the past two years have involved physician compensation, in part because cases involving disguised or exorbitant cash payments are relatively easy to prosecute successfully. n125

From a tax standpoint, it is well established that paying reasonable salaries to managers, officers, or other employees does not constitute inurement of net earnings to the recipient and does not defeat exemption of an otherwise exempt organization. On the other hand, excessive and therefore unreasonable compensation can result in a finding of prohibited inurement. n126 Reasonable compensation is "only such amount as would ordinarily be paid for like services by like enterprises under like circumstances." n127 This assumes that the compensated individual has provided something of value to the exempt organization. Thus, from a combined tax and fraud and abuse standpoint, the most important inquiries are (1) what is being paid for and (2) how does the amount paid compare to fair market value. n128

Determination of what is reasonable compensation necessarily involves a facts and circumstances test. Other important questions to ask are whether the agreed upon compensation results from arm's length negotiation between the parties and, closely related, whether the party receiving the compensation is in a position to exert control over the exempt organization. n129 Much the same test is used in determining the deductibility of a payment under section 162 in the case of a taxable employer. n130

Unreasonable compensation need not be in the form of salary or cash, and it can be for goods as well as services. Other common factual settings include goods or services provided to employees at less than fair market value, commercially unreasonable loans (either due to inadequate interest or inadequate security), n131 and below fair market

rentals.

a. Recruiting Incentives

Hospital recruiting activities have recently been a fertile ground for reasonable compensation issues. In an effort to attract physicians to their service areas, hospitals are offering them guaranteed practice incomes, below market loans, reduced or free office rent, and opportunities to participate in joint ventures with the hospital or an affiliate. These activities cannot be judged in a vacuum. They must be analyzed in view of their true purpose and actual community needs. Because recruited physicians rarely become common law employees who will render services directly to the hospital, the most important inquiry is what the hospital is paying for. A truthful answer probably would include some mix of relocation, services, and referrals.

As far back as 1973, the Service was asked to consider whether an organization formed to attract a physician to an isolated rural community totally lacking medical services could be exempt.ⁿ¹³² The organization was formed by locals to erect a medical office building and rent space at a below market rate in order to induce a physician to locate there. The physician agreed to serve the entire community, provide emergency services, and, within reasonable limits, care for those unable to pay. The compensation here, below market rent, was given in exchange for relocation and charity care, not referrals. The Service found no private inurement -- all arrangements were at arm's length, and the physician did not have an employment or close professional relationship with the organization. The private benefit to the physician was incidental to the public benefit of finally having a physician in the community.ⁿ¹³³

In a more recent GCM, the Office of Chief Counsel considered a charitable hospital's proposal to guarantee a newly recruited physician a minimum annual private practice income for two years.ⁿ¹³⁴ The physician would have no obligation to repay amounts paid under the guarantee except out of income earned in excess of the guaranteed annual income during the two year contract period. Significantly, there was no ceiling on the amount of subsidies to be paid or on other types of recruitment benefits to be offered the physician simultaneously.ⁿ¹³⁵ Moreover, the method for determining the amount of the subsidy bore no relation to the value of services the physician would render to the hospital. Since it was based on an unrelated factor -- the physician's private practice income -- there was no way the subsidy could be shown to be reasonable compensation for services to the hospital.

The GCM indicated that subsidized salary arrangements used as a recruiting device do not *per se* give rise to private inurement as long as the compensation resulting from the arrangement, viewed as a whole, is not unreasonable. An analysis of the entire compensation package and all the facts and circumstances is required. Because of the open-ended nature of the subsidies at issue, the Office of Chief Counsel concluded that it had not been demonstrated, nor was it possible to demonstrate in advance, that all possible subsidies under the recruiting program would be reasonable.ⁿ¹³⁶

This GCM is important in that it recognizes that a hospital may offer a one-time recruitment bonus or incentive which is determined not by reference to actual services the physician will render, but by reference to the value assigned to recruiting a particular physician to its service area. The hospital must be able to justify the amount of the bonus or incentive in terms of the benefits it expects to receive. Where the true justification lies chiefly in expected admissions, the hospital should be aware that its action probably violates the fraud and abuse law.

b. Incentive Compensation

The Service has abandoned an early view that certain incentive compensation arrangements necessarily result in a loss of exemption.ⁿ¹³⁷ Today, the Service's position is that the entire compensation arrangement must be examined to determine whether it is the result of arm's length bargaining and the compensation is reasonable in amount, or whether the arrangement converts the principal activity of the exempt organization into a joint venture or is a device to distribute profits to principals. The Office of Chief Counsel applied this analysis to two profit-sharing plans that rewarded hospital employees for cost containment and improved quality and patient satisfaction. Assuming that total

compensation was reasonable, the plans were approved. n138 The presence of a ceiling or reasonable maximum to avoid the possibility of a windfall benefit was an important factor.

In Rev. Rul. 69-383, n139 the Service ruled that computing a radiologist's compensation based on a fixed percentage of the department's gross income does not constitute private inurement where (1) the amount of compensation is reasonable in light of the responsibilities assumed, (2) the agreement was negotiated at arm's length, and (3) the physician does not control the hospital. The Service cautioned, however, that the presence of a percentage compensation arrangement will destroy exemption where it transforms the hospital's principal activity into a joint venture between it and a group of physicians, or is merely a device for distributing profits to persons in control. n140

Here again, it is vital to focus on what is being paid for. Today's incentive compensation plans are likely to have as their purpose rewarding physicians for certain behaviors that are important to the hospital under PPS. These include proper coding of patient diagnoses, efficient care delivery, and timely completion of records. However, they may also include payments which allow physicians to share in hospital profits achieved through early discharges or reduced utilization of ancillary hospital services. n141 Certain physician incentive arrangements may also serve as a disguised mechanism to reward a physician for referrals.

c. Rentals of Office Space, Equipment, etc.

A physician's right to use a hospital's property rent-free or for below market rent obviously constitutes private benefit, which may or may not be incidental depending on the facts. Absent substantial justification in terms of furthering the hospital's exempt purpose, such arrangements may rise to the level of inurement. As noted above, the IRS found the private benefit to be incidental where below market rent was used to attract the first physician to an isolated area totally lacking medical services. On the other hand, a few years later, the Office of Chief Counsel concluded that a hospital should lose its exemption for entering into a ninety-nine year ground lease for one dollar per year with physicians already on its staff. The private benefit in that case was more than incidental in both a qualitative and quantitative sense. n142

In GCM 39,598, n143 the Office of Chief Counsel considered a situation in which an exempt organization affiliated with a section 501(c)(3) hospital leased a medical office building from a partnership of physicians and then subleased the building to another partnership of the same physicians. The arrangement resulted in the exempt organization absorbing financial losses which otherwise would have been realized by the physician partners. The GCM reasoned there had been no showing that the organization's charitable purposes could only be accomplished by benefiting the physicians in this manner. Moreover, the losses which would have been experienced by the physicians absent the transaction with the exempt organization were not insubstantial. Accordingly, the GCM concluded the private benefit to the physician partners was neither qualitatively nor quantitatively incidental, and thus was prohibited. In addition, the funds of the subsidiary inured to the benefit of the physician partners. On the facts presented, the funds which inured to the physicians could not be traced to the hospital, or its exemption would also have been in danger. n144

In many cases, renting out hospital facilities or equipment may truly further exempt purposes; in others it may be a mechanism to induce referrals. Much depends on whether fair market value is paid, or if not, why not. Where a hospital rents nearby office space to members of its medical staff at fair rental, any private benefit probably is incidental. Where the rent is below market, that result may no longer obtain. While the safe harbor regulations concentrate on rental payments flowing to physicians, the Inspector General, too, has emphasized the importance of rental arrangements being at fair market value. n145

d. Hospital Purchase of a Physician's Practice

Perhaps the ultimate method of acquiring control of a physician's referrals is to purchase his or her practice. The rationale offered for this arrangement is improving market share, assuring a continued referral base, and preempting another hospital that might acquire the practice. Hospitals gain guaranteed access to the physician's patients, while

physicians enjoy an assured income and relief from the business aspects of practice. n146

Purchase by a hospital of a physician's practice at more than fair market value can result in a violation of the operational test or prohibited inurement. n147 The same would be true of a bargain resale or below market loan to a second physician to facilitate his purchase of the practice. Thus, valuation issues are likely to predominate. Once again, the crucial inquiry is what the hospital is paying for.

Often, the selling physicians continue to provide professional services to their former patients as employees or contractors of the hospital. Compensation of a physician employee based on a percentage of the net profits of the physician's hospital practice or at a level in excess of the fair market value of his services could violate the operational test or result in private inurement. n148

The Inspector General's proposed safe harbor regulations would protect physician purchases of a retiring physician's practice, but are critical of purchases by hospitals. According to the preamble, sales of practices to hospitals often involve much higher rates of compensation than would be the case if a retiring physician sold a comparable practice to another physician. The additional compensation reflects a payment for referrals. A variation on these arrangements involves periodic hospital payments for an "option" to buy the practice, which really amount to no more than disguised payments for referrals. n149

2. Joint Ventures

Hospitals increasingly are becoming involved in activities which fall outside their traditional role. Sometimes they have strong business justifications for entering into these activities. For example, a hospital may establish a home health care provider to assure a source of care for discharged patients and to diversify its revenue base. Such vertical integration has been a common response to the early discharge incentives created by PPS.

Frequently, hospitals establish joint ventures with their medical staff members to engage in non-inpatient care activities. These joint ventures may or may not have business justifications when viewed strictly in terms of the hospital's need to engage in the activity. Often, however, the key motivation for joint ventures is the hospital's desire to make or keep its physicians loyal, in order to ensure continued referrals. In these cases, the joint venture may be viewed as a device to distribute hospital profits to the physicians, strongly suggesting the presence of inurement. Once again, these activities can properly be judged only after a careful examination of what the hospital gets in return for conferring an economic benefit on the physicians.

Hospitals typically argue that physician participation is necessary to provide capital to finance the joint venture. Investment may or may not be formally restricted to physicians on staff or engaged in a particular specialty, but, as a practical matter, usually only these individuals are invited to participate. However, most physician-hospital joint ventures can hardly be described as capital intensive. Even those established to purchase and operate expensive equipment such as a magnetic resonance imager or lithotripter seem unlikely to be justifiable solely on the basis of raising capital, particularly where the manufacturer makes financing available.

Other justifications for physician participation may not be readily apparent. One is fear that, absent a joint venture, the physicians will establish a new service alone or at another hospital. The hospital loses immediate revenue and may lose physician loyalty, so that the physicians refer their patients elsewhere for other services as well. Giving physicians a stake in a joint venture, on the other hand, virtually assures loyalty and referrals, as long as the venture proves profitable for the physicians.

The status of joint ventures under the fraud and abuse law is less clear than that of direct kickbacks. Nonetheless, the Inspector General recently reaffirmed his belief that many of these arrangements violate the law, thereby effectively placed the health care community on notice. n150 Moreover, the proposed safe harbor regulations would afford no protection to most of these arrangements. n151

The tax treatment of joint ventures changed in the early 1980s. Historically, the Service took the position that an exempt organization could not be a general partner in a partnership with private entities. This position was grounded on the belief that the exempt organization would be assuming fiduciary obligations to the nonexempt partners that were inconsistent with its exempt status.

In *Plumstead Theatre Society v. Commissioner*, n152 the Tax Court held that an organization was exempt even though it was a general partner in a limited partnership with private individuals and a for-profit **company**.

The Service no longer contends that participation as a general partner in a joint venture with individuals or nonexempt entities in itself is grounds for revocation of exemption. However, the Service will carefully examine any joint venture between taxable and exempt parties for private inurement and private benefit. If the Service finds private inurement or too much private benefit resulting from the exempt party's participation, it can revoke its recognition of the organization's exemption. n153 The Service weighs all of the relevant facts and circumstances in each case, applying a "careful scrutiny" standard of review. n154

It may be analytically useful to divide the facts and circumstances test into two categories. As a threshold, the Service examines whether the partnership serves a charitable purpose or, more precisely, whether participation by the exempt entity furthers its exempt purpose. n155 Then, even where an exempt purpose would be furthered, the Service examines the arrangement to see if it permits the exempt party to act exclusively in furtherance of its exempt purposes. n156 The Service will disapprove of participation if it finds inadequate protection against financial loss by the exempt party or improper financial gain by private parties, *i.e.*, private inurement or greater than incidental private benefit. n157 Examples of instances in which the Service is likely to find the boundary exceeded include those in which (1) participation imposes obligations on the exempt organization that conflict with its exempt purposes; (2) there is a disproportionate allocation of profits and losses to the nonexempt partners, *i.e.*, physicians; n158 (3) the exempt partner makes loans to the joint venture that are commercially unreasonable (either because of inadequate security or too low an interest rate); (4) the exempt partner provides property or services to the joint venture at less than fair market value; or (5) a nonexempt partner receives more than reasonable compensation for the sale of property or services to the joint venture.

The interrelationship of the tax and fraud and abuse laws is well illustrated by the fact pattern in a recent private letter ruling. In Private Letter Ruling (LTR) 8820093, n159 the Service issued a favorable ruling to a hospital that planned to establish a limited partnership with members of its medical staff. A hospital-affiliated exempt corporation would serve as the general partner, and the physician/limited partners ultimately would own 50 to 90 percent of the venture. The limited partnership was set up to purchase the net revenue stream of the hospital's outpatient surgery and gastroenterology departments for the next five years, with an option for another five. The purchase price was established by an independent appraiser at fair market value, discounted to present value.

The hospital would continue to own and operate the facilities. In support of the proposal, the hospital stated it would receive cash at the outset and the transaction would increase utilization of its facilities. Because the price was established at fair market value, the limited partnership (physicians) would benefit only on the chance that net revenues increased.

This transaction can be analyzed in several different ways. It may well violate the fraud and abuse law. Participation is limited to medical staff members in a position to refer patients to the departments in question, and their interests are subject to substantial transfer restrictions and mandatory tender provisions. n160 Moreover, the hospital's chief reason for undertaking the transaction apparently was to obtain increased referrals. The arrangement also appears to involve private inurement. Viewed critically, it appears to be a vehicle for the distribution of hospital net earnings to private individuals falling within the definition of insiders. At the least, the transaction confers on the physician investors a private benefit which is difficult to characterize as qualitatively or quantitatively incidental. Finally, one must question whether the hospital affiliate's participation as the general partner furthers an exempt purpose sufficiently to meet the careful scrutiny standard discussed above.

There may be a distinction between transactions such as this, undertaken for the primary purpose of rewarding referrals, and joint ventures which truly confer a public benefit by, for example, establishing or operating a new health care provider. This joint venture is merely a shell, set up to facilitate physician investment. This is another factor making it suspect under the fraud and abuse law. n161 Hospitals contemplating similar transactions should be aware that the Service is re-examining LTR 8820093. n162

D. How Much Is Too Much?

From a purely economic standpoint, paying physicians for referrals may make sense for an individual hospital, as long as it is able to recover its costs, including the payment, for each patient. The hospital avoids competition, fills beds, achieves economies of scale, gains market share, and may be able to modernize or expand. Physicians may hospitalize less acutely ill patients, allowing a greater return from Medicare's fixed payments. However, if all hospitals follow suit, the advantage flowing to any one is greatly reduced, and the payments become an added cost of doing business. n163 Society, on the other hand, pays higher costs for care, risks unnecessary utilization, and has health care decisions influenced by pecuniary gain. In the end, only the physicians win.

Economics notwithstanding, the law so clearly prohibits direct payments for referrals that the activity has shifted to complex business arrangements which are thinly veiled attempts to reward referrals while avoiding prosecution. As these deals proliferate, individual hospitals give more and more to physicians to stay ahead of the competition, often totally relinquishing control over the amounts flowing to the physicians to avoid obviously violating the law. n164 It is not surprising, then, that while some hospitals willingly accede to increasing physician demands, others wonder when it all will stop. Absent a change in the law or its enforcement, however, it is a rare hospital that dares say no to its physicians.

The hospital-physician arrangements discussed above, and the justification offered for them, raise an important question of tax law -- is virtually anything justifiable in the name of survival? If, out of solicitude for nonprofit hospitals, the answer is yes, we must be prepared for an ever-expanding transfer of wealth from hospitals to physicians and further reductions in the assets available for charity care. Continued escalation in what could be called "revenue shifting" seems unavoidable as individual hospitals try to top what their neighbors are doing. This process cannot continue indefinitely without seriously undermining our health care system.

Like the COBRA antidumping provisions discussed above, the fraud and abuse provisions evince a strong legislative policy -- in this case, condemning payments for referrals. If paying for referrals is illegal, then obtaining continued or additional referrals cannot properly be used to justify sweetheart investments with or payments to private physicians. More fundamentally, if hospitals regularly violate the law through their dealings with physicians, continued exemption itself may be inappropriate. n165

When hospital-physician arrangements are being negotiated, only the hospital is likely to pay any attention to exemption issues. Physicians and their counsel are more apt to be informed about fraud and abuse issues because the physician, too, would be at risk for any violations. Because all risk is on the hospital in the exemption area, it bears the full responsibility for **protecting** its, and the community's, interests.

E. The Future: Proposed Legislation and Interagency Cooperation

Last year, Congressman Stark, Chairman of the House Ways and Means Subcommittee on Health, introduced H.R. 939, the Ethics in Patient Referrals Act of 1989. n166 This bill would provide a bright-line rule prohibiting nearly all Medicare referrals by physicians with a financial stake in the provider receiving the referral. In Rep. Stark's view, clever deal makers have exploited uncertainties surrounding the coverage of the existing statute by disguising referral schemes as legitimate business arrangements, most commonly as joint ventures. Under his proposal, providers of Medicare services would be prohibited from accepting referrals from physicians who have ownership interests or compensation arrangements with the provider.

In his introductory statement, Rep. Stark cited three evils of physician referrals induced or rewarded by financial benefit. First, there is a risk that physician partners may not refer patients to the facility that provides the best care. Second, patients may be referred for costly services that are unnecessary, driving up the costs of the Medicare Program. Finally, honest competition is undercut, while hidden payments become a cost of doing business. n167 The authors would add a fourth. The charitable assets of the hospital or other tax exempt provider may be diverted for the benefit of private parties and no longer available for exempt purposes.

Viewed strictly as a means of **protecting** hospitals' charitable assets, Rep. Stark's bright-line approach has appeal. Its near absolute prohibition of interested referrals would remove the incentive for most questionable hospital-physician financial arrangements. It would affect all hospitals equally. Moreover, it would help avoid some of the most threatening competition hospitals face, that from physician-owned entities. n168

A modified version of Rep. Stark's proposal was included in the House fiscal year 1990 budget reconciliation package, but only a narrow substitute provision was ultimately enacted. The Omnibus Budget Reconciliation Act of 1989 n169 includes a provision prohibiting, effective January 1, 1992, referrals to clinical laboratories with which the referring physician has a financial relationship. n170 Also, all Medicare providers will be required to report to the Secretary by December 19, 1990, regarding ownership arrangements involving referring physicians, and Medicare Part B claims will be required to carry the name and provider number of the referring physician. n171 Presumably, this new information will facilitate further study of physician ownership. The Act also requires the Comptroller General to conduct a study of physician ownership and self-referrals and report to Congress by February 1, 1991. This study is to include the types of ownership arrangements, the returns earned by physician investors, and the effect of such arrangements on utilization, expenditures, and competition. n172

Whatever the ultimate fate of Rep. Stark's proposal, hospitals should expect stepped-up activity in this area from the Service and HHS. As mentioned above, expanded civil enforcement is likely to follow publication of HHS' final safe harbor regulations. For its part, the Service has begun alerting examining agents to the changing relationships between hospitals and physicians. Many of the arrangements considered herein have been the subject of continuing education for agents responsible for auditing exempt organizations. n173 The Exempt Organizations Examination Guidelines were revised last year to provide more detailed instructions for identifying excessive compensation in hospital settings. n174

Most important, the relationship between the Medicare and Medicaid fraud and abuse law and the tax laws has not escaped the officials charged with interpreting and enforcing them. In early 1989, representatives of the Assistant Commissioner (Employee Plans and Exempt Organizations) and the Office of the Assistant Chief Counsel (Employee Benefits and Exempt Organizations) met with representatives of HHS' Office of Inspector General to discuss the overlap between private inurement and fraud and abuse. Within the constraints of applicable disclosure laws, the two agencies are developing opportunities for coordination and information sharing. n175

V. CONCLUSION

The nature and magnitude of change in the nonprofit hospital sector of the economy demands flexibility in the administration of the tax laws. The community benefit standard under which most hospitals qualify for exemption allows sufficient flexibility to ensure that, despite these changes, hospitals continue to benefit all members of their community. Under that standard, attempts to avoid providing needed emergency care or to financially reward physicians for patient referrals may jeopardize a hospital's exempt status.

Hospitals will be able to fulfill a charitable mission only if they have the resources to do so. The Internal Revenue Code and regulations are designed to protect a hospital's charitable assets. Where these assets are in danger of being diverted for the benefit of private interests, even with hospital cooperation, the Code may be violated. Even in today's rapidly changing environment, hospital activities must be devoted to achieving exempt purposes. Competition -- even survival -- cannot justify activities which violate that rule.

The authors gratefully acknowledge the support and guidance of James J. McGovern, Assistant Chief Counsel (Employee Benefits and Exempt Organizations).

REFERENCE: 2. Only acute care general hospitals are reimbursed under PPS. Specialty and extended care hospitals still are reimbursed based on reasonable costs. At the end of fiscal year 1988, PPS, covered 5,626, or 84 percent of all hospitals. U.S. DEPT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMIN., 1989 HCFA STATISTICS.

1. The Social Security Amendments of 1983, Pub. L. No. 98-21, 97 Stat. 65, replaced the former retrospective cost-based reimbursement system with prospective payment for all short term general hospitals. Medicare provides an estimated 40 percent of an average hospital's revenues. Tokarski, Washington Report: Hospital Lobby, Government Debate Cost of Empty Beds, MOD. HEALTHCARE, Mar. 17, 1989, at 20.)

3. See Meyer, Managed Care Insurance Tops Fee For Service, AM. MED. NEWS, July 1, 1988, at 4.

4. The Secretary of Health and Human Services estimated in congressional testimony that occupancy rates currently average 60 percent at urban hospitals and 40 percent at rural hospitals. Tokarski, supra note 1, at 20.)

5. Burda, Opening News: Record 81 Hospitals Close, MOD. HEALTHCARE, Jan. 20, 1989, at 2.

6. Id. According to the article, 445 acute care hospitals have closed since 1980. The accuracy of these statistics has been questioned. See Burda & Greene, Opening News: AHA Closure List Questions, MOD. HEALTHCARE, Mar. 3, 1989, at 6.

7. OFFICE OF INSPECTOR GENERAL, U.S. DEPT OF HEALTH AND HUMAN SERVICES, HOSPITAL CLOSURE: 1987 May 1989).

8. For a grim prognosis regarding the coming shakeout, see Goldsmith, A Radical Prescription for Hospitals, 67 HARV. BUS. REV. 104 (1989).

9. Id.

10. Compare O'Brien v. Physician's Hosp. Ass'n, 96 Ohio St. 1, 9, 116 N.E. 975, 977 (1917) (the first concern of a public charitable hospital must be for those who are unable to pay), with Evangelical Lutheran Good Samaritan Soc'y v. County of Gage, 181 Neb. 831, 834, 151 N.W.2d 446, 449 (1967) (with the advent of present day social security and welfare programs, this type of charity is not often found because assistance is available to the poor under these programs). See Bromberg, The Charitable Hospital, 20 CATH. U.L. REV. 237, 242, 246 (1970).

11. See McGovern, Restructured Nonprofit Hospitals, 35 TAX NOTES 405 (1987).

12. These include "religious, charitable, scientific, testing for public safety, literary, or educational purposes, or to foster national or international amateur sports competition . . . , or for the prevention of cruelty to children or animals." I.R.C. § 501(c)(3) (1986). See infra notes 85-93 and accompanying text.

13. Id. see infra Section IV (discussion of inurement).

14. Treas. Reg. § 1.501(c)(3)-1(d)(1)(ii) (1976).

15. Mancino, Income Tax Exemption of The Contemporary Nonprofit Hospital, 32 ST. LOUIS U.L.J. 1015, 1016 (1988).

16. 1956-1 C.B. 202.

17. *Id.* at 203-04.
18. See Bromberg, *supra* note 10, at 242-43 (citing Note, Federal Income Tax Exemption for Private Hospitals, 36 *FORDHAM L. REV.* 747, 758 (1968)).
19. *Sound Health Ass'n v. Commissioner*, 71 T.C. 158, 180 (1978), acq., 1981-2 C.B. 2.
20. *Treas. Reg. § 1.501(c)(3)-1(d)(2)* (1976); T.D. 6391, 1959-2 C.B. 139-144.
21. *Id.*; see *Eastern Ky. Welfare Rights Org. v. Simon*, 370 F. Supp. 325 (D.D.C. 1973), rev'd, 506 F.2d 1278, 1287 (D.C. Cir. 1974), vacated on other grounds, 426 U.S. 26 (1976); *Sound Health*, 71 T.C. at 178.
22. See *Sound Health*, 71 T.C. at 180; Bromberg, *supra* note 10, at 243, 246.
23. Milligan, *Provision of Uncompensated Care in American Hospitals: The Role of the Federal Courts, Catholic Health Care Facilities, and Local Governments in Defining the Problem of Access for the Poor*, 31 *CATH. LAW.* 7, 14 (1988).
24. *Id.* at 24.
25. Mancino, *supra* note 15, at 1041.
26. 1969-2 C.B. 117.
27. See *Sound Health Ass'n v. Commissioner*, 71 T.C. 158, 180 (1978), acq., 1981-2 C.B.2. Bromberg, *supra* note 10, at 248; Mancino, *supra* note 15, at 1025-26.
28. 1969-2 C.B. at 118 (citing *RESTATEMENT (SECOND) OF TRUSTS §§ 368 and 372*, and *IV A. SCOTT, THE LAW OF TRUSTS §§ 368 and 372* (3d ed. 1967)).
29. 1969-2 C.B. at 119. Though largely supplanted, Rev. Rul. 56-185 has never been revoked. Its requirements regarding hospital organization, use of facilities, and inurement remain unchanged.
30. Bromberg, *supra* note 10, at 248-49 (citations omitted).
31. 1969-2 C.B. at 118.
32. *Id.* See also *Sonora Community Hosp. v. Commissioner*, 46 T.C. 519 (1966), aff'd, 397 F.2d 814 (9th Cir. 1968).
33. *Eastern Ky. Welfare Rights Org. v. Simon*, 370 F. Supp. 325 (D.D.C. 1973), rev'd, 506 F.2d 1278 (D.C. Cir. 1974), vacated on other grounds, 426 U.S. 26 (1976).
34. *Id.*; see *Eastern Ky. Welfare Rights v. Simon*, 506 F.2d 1278, 1281, 1286 (D.C. Cir. 1974), vacated on other grounds, 426 U.S. 26 (1976).
35. 506 F.2d at 1288.
36. *Id.*
37. *Eastern Kentucky and its progeny virtually eliminated any role litigation might play in seeking to change the result of Rev. Rul. 69-545.* See Milligan, *supra* note 23, at 18-21.
38. *Eastern Ky.*, 506 F.2d at 1289; Bromberg, *supra* note 10, at 249-50.

39. Rev. Rul. 83-157, 1983-2 C.B. 94.

40. Gen. Couns. Mem. 38,669 (Mar. 30, 1981) at 8. A general counsel memorandum (GCM) is a legal opinion of the Office of Chief Counsel that is based on the particular issues and facts of a specific case. GCMs are not intended for precedential use and do not represent the official agency position.

41. Eastern Ky., 506 F.2d at 1289; Bromberg, *supra* note 10, at 250; Milligan, *supra* note 23, at 14.

42. Mancino, *supra* note 15, at 1049.

43. There are an estimated 37.4 million uninsured persons in the United States, 29 million of them either unemployed individuals or their dependents. Mowll, *The Search For Solutions To The Indigent Care Crisis*, HEALTHCARE FIN. MGMT. (August 1989). See Note, *Preventing Patient Dumping: Sharpening the COBRA's Fangs*, 61 N.Y.U. L. REV. 1186, 1193-94 (1986).

44. See *Sound Health Ass'n v. Commissioner*, 71 T.C. 158, 172 (1978), acq., 1981-2 C.B. 2 (major factor in Tax Court finding that HMO provided sufficient community benefit was provision of emergency care to indigent nonmembers); Rev. Rul. 83-157, *supra* note 39 (major factor in determination in Rev. Rul. 69-545 that Hospital A is organized and operated for benefit of the community was operation of an open emergency room).

45. It appears that many of the other factors identified in Rev. Rul. 69-545 (e.g., open staff, community board) now are frequently found in for-profit hospitals as well.

46. Milligan, *supra* note 23, at 8. The author points out that the Service, by "weakening the charity care standards a hospital must meet to remain tax-exempt," deserves part of the blame for lessening the amount of uncompensated care provided by exempt hospitals. *Id.*

47. See Gen. Couns. Mem. 38,669 (March 30, 1981) at 8; J. SEAY & B. VLADECK, *IN SICKNESS AND IN HEALTH, THE MISSION OF VOLUNTARY HEALTH CARE INSTITUTIONS* 85 (1988). Rev. Rul. 83-157 offers no support for acute care general hospitals that wish to close their emergency rooms in the face of unmet need.

48. Bromberg, *supra* note 10, at 250. The same would be true where, e.g., the hospital requires all emergency patients to demonstrate an existing relationship with a staff physician.

49. See *infra* notes 75-80 and accompanying text.

50. See, e.g., Bromberg, *supra* note 10, at 251, 27-58. As a practical matter, most hospitals today find Medicare participation economically indispensable.

51. See Mancino, *supra* note 15, at 1049.

52. See, e.g., Clark, *Does the Nonprofit Form Fit the Hospital Industry?*, 93 HARV. L. REV. 1417 (1980); Horwitz, *Corporate Reorganization: The Last Gasp or Last Clear Chance for The Tax-Exempt, Nonprofit Hospital?*, 13 AM. J.L. & MED. 527 (1988).

53. I.R.C. § 501(m), Pub. L. No. 99-514, § 1012(a), 100 Stat. 2085, 2390 (Tax Reform Act of 1986).

54. Compare Herzlinger & Krasker, *Who Profits From Nonprofits*, 65 HARV. BUS. REV. 93 (1987) with Lewin, Eckels, & Miller, *Setting The Record Straight: The Provision of Uncompensated Care by Not-for-Profit Hospitals*, Lewin and Associates (1988). The latter offers a definition of uncompensated care that may make comparisons among facilities more meaningful, possibly removing one of the difficulties the Service experienced in administering Rev. Rul. 56-185.

55. Letter from Edward R. Roybal, Chairman, House Select Committee on Aging, to Charles A. Bowsher, Comptroller General, U.S. General Accounting Office (Feb. 2, 1987).

56. Milligan, *supra* note 23, at 26.

57. The American Health Lawyers Association has shown its awareness of the need to distinguish activities of exempt hospitals from those of for-profits by distributing a self-assessment guide intended to assist nonprofits in identifying and documenting characteristics that contribute directly to eligibility for exemption. Thus armed, hospitals will be better prepared to respond to challenges to their exempt status. AMERICAN HOSP. ASS'N, COMMUNITY BENEFIT AND TAX-EXEMPT STATUS, A SELF-ASSESSMENT GUIDE FOR HOSPITALS (1988). See also CATHOLIC HEALTH ASS'N OF THE U.S., SOCIAL ACCOUNTABILITY BUDGET (1989). These efforts may be more a response to state activities than federal. See *infra* note 61.

58. Hearings Before The Subcommittee On Oversight of the House Committee On Ways And Means, 100th Cong., 1st Sess. 768 (1987) (statement of Rep. Stark).

59. However, there may be support for such a position: of 647 responses to a Healthcare Financial Management reader survey, 68 percent agreed that the federal government should require hospitals to provide a minimum amount of charity care to be eligible for tax-exempt bonds. Mowll, *supra* note 43, at 20.

60. Rev. Rul. 75-384, 1975-2 C.B. 204 (citing IV A. SCOTT, THE LAW OF TRUSTS § 377 (3d ed. 1967)); RESTATEMENT (SECOND) OF TRUSTS § 377, comment c (1959).

61. State and local authorities have attempted to require exempt hospitals to provide uncompensated care, with varying results. As yet, no consensus has emerged in the courts as to whether this is proper. See *Hospital Utilization Project v. Commonwealth*, 461 A.2d 894 (Pa. Commw. Ct. 1983), *aff'd*, 487 A.2d 1306 (Pa. 1985); *West Allegheny Hosp. v. Board of Property Assessment, Appeals, and Review*, 455 A.2d 1170 (Pa. 1982); *Downtown Hosp. Ass'n v. Tennessee State Bd. of Equalization*, No. 87-1612-III (Ch. Ct., 20th Jud. Dist. Davidson County Tenn. Feb. 4, 1988); *Yorgason v. County Bd. of Equalization*, 714 P.2d 653 (Utah 1986); *Utah County v. Intermountain Health Care*, 709 P.2d 265 (Utah 1985); *Medical Center Hosp. of Vt. v. City of Burlington*, Chittendon County Super. Ct., No. S-658-87 CnC (Vt. Super. 1987), *aff'd*, No. 87-501 (1989 Vt. LEXIS 190) (Oct. 13, 1989).

62. Milligan, *supra* note 23, at 25; Note, *supra* note 43, at 1189-96.

63. A majority of states have enacted such laws. McClurg, *Your Money Or Your Life: Interpreting The Federal Act Against Patient Dumping*, 24 WAKE FOREST L. REV. 173, 190-97 (1989); see also Rothenberg, *Who Cares?: The Evolution of the Legal Duty to Provide Emergency Care*, 26 HOUS. L. REV. 21, 53-57 (1989); Note, *supra* note 43, at 1201-04. However, the discussion herein is limited to federal law.

64. Hospital Survey and Construction (Hill-Burton) Act, 42 U.S.C. § 291 (1982 & Supp. V 1987); 42 C.F.R. § 124 (1989); see McClurg, *supra* note 63; Rothenberg, *supra* note 63; Note, *supra* note 43.

65. 42 U.S.C. § 291 (Supp. 1988); 42 C.F.R. § 124 (1989).

66. 42 U.S.C. § 291c(e)(2); 42 C.F.R. §§ 124.501-.513. See Note, *supra* note 43, at 1198.

67. 42 U.S.C. § 291c(e)(1); 42 C.F.R. §§ 124.601-.607. See Note, *supra* note 43, at 1198.

68. 42 C.F.R. §§ 124.501-.512, .601-.607; see McClurg, *supra* note 63, at 198 n.107; Note, *supra* note 43, at 1198. The twenty-year limitation is not expressly part of the statute. *American Hosp. Ass'n v. Schweiker*, 721 F.2d 170, 181 (7th Cir. 1983), cert. denied, 466 U.S. 958 (1984).

69. 42 U.S.C. § 291c(e)(1); 42 C.F.R. §§ 124.601-.607; *American Hosp. Ass'n*, 721 F.2d at 178.

70. 42 C.F.R. § 124.603.
71. *Id.* § 124.603(b)(2).
72. McClurg, *supra* note 63, at 198 n.107.
73. Note, *supra* note 43, at 1200 n.100.
74. McClurg, *supra* note 63, at 198 n.107; Rothenberg, *supra* note 63, at 58-59; Note, *supra* note 43, at 1199-1201.
75. Pub. L. No. 99-272, § 9121(b), 100 Stat. 82, 164, as amended by Pub. L. No. 99-509, § 9307(c)(4), 100 Stat. 1874, 1996; Pub. L. No. 99-514, § 1895(b)(4), 100 Stat. 2085, 2933; Pub. L. No. 100-203, § 4009(a), 101 Stat. 1330, 1330-56; Pub. L. No. 100-360, § 411(b)(8), 102 Stat. 683, 771; Pub. L. No. 100-485, § 608(d)(18)(E), 102 Stat. 2343, 2419 (codified as amended at 42 U.S.C.A. § 1395dd (West Supp. 1989)). Proposed rules were issued June 16, 1988. 53 Fed. Reg. 22,513 (1988).
76. 42 U.S.C.A. § 1395dd (West Supp. 1989). See McClurg, *supra* note 63; Rothenberg, *supra* note 63; Note, *supra* note 43.
77. 42 U.S.C.A. § 1395dd. (West Supp. 1989).
78. *Id.*; see Note, *supra* note 43.
79. Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6018, 103 Stat. 2106, 2165.
80. Speech by James J. McGovern, Assistant Chief Counsel, Employee Benefits and Exempt Organizations, Internal Revenue Service, Sept. 14, 1989, reported in 44 TAX NOTES 1460 (1989).
81. Hall, Institutional Control of Physician Behavior: Legal Barriers to Health Care Cost Containment, 137 U. PA. L. REV. 431, 434 (1988).
82. See, e.g., Coddington, Strategies For Survival In The Hospital Industry, 63 HARV. BUS. REV. 129 (1985). Ironically, some of the most expensive new medical equipment now commonly provides a basis for hospital-physician joint ventures.
83. See OFFICE OF INSPECTOR GENERAL, U.S. DEPT OF HEALTH AND HUMAN SERVICES, FINANCIAL ARRANGEMENTS BETWEEN PHYSICIANS AND HEALTH CARE BUSINESSES (May 1989) at 2-6; Iglehart, The Debate Over Physician Ownership of Health Care Facilities, 321 NEW ENG. J. MED. 198 (1989).
84. To be exempt under § 501(c)(3), an entity must be both organized and operated exclusively for exempt purposes. If the entity fails either the organizational or operational test, it is not exempt. Treas. Reg. § 1.501(c)(3)-1 (1976).
85. Treas. Reg. § 1.501(c)(3)-1(c)(2) (1976). Thus, private inurement will cause an organization to fail the "operational test" under the regulations.
86. IRS EXEMPT ORGANIZATIONS HANDBOOK § 381.1.
87. The term "insider" does not appear in the Code or regulations, but is widely used in this context. See, e.g., HOPKINS, THE LAW OF TAX-EXEMPT ORGANIZATIONS § 12.2 (5th ed. 1987).
88. Treas. Reg. § 1.501(a)-1(c)(1982). Though the statute speaks of "a private shareholder or individual," that term has long been defined as any "persons having a personal and private interest in the activities of the organization." *Id.*

The word "private" is the antonym of "public" -- used merely to distinguish a private individual from the general public -- and is intended to limit those who personally benefit from the net earnings of a charitable organization to its intended beneficiaries. Gen. Couns. Mem. 38,322 (Mar. 24, 1980).

89. Gen. Couns. Mem. 38,459 (July 31, 1980).

90. Use of the term "control" in attempting to define insiders for purposes of inurement may be misleading. A better approach may be to focus on the ability to exert inside influence on the organization with respect to the transaction giving rise to the inurement or to distinguish between interested and disinterested individuals. See *American Campaign Academy v. Commissioner*, 92 T.C. 1053 (1989).

91. The Office of Chief Counsel made clear in Gen. Couns. Mem. 39,646 (June 30, 1987), that where funds of an exempt organization pass through another exempt organization and inure to the benefit of a private individual, both organizations will lose their exemptions.

92. *Northwestern Mun. Ass'n v. United States*, 99 F.2d 460, 463 (8th Cir. 1938).

93. *Spokane Motorcycle Club v. United States*, 222 F. Supp. 151 (E.D. Wash. 1963).

94. Treas. Reg. § 1.501(c)(3)-1(d)(1)(ii)(1976). The presence of a single substantial nonexempt purpose destroys the exemption regardless of the number or importance of the exempt purposes. *Better Business Bureau v. United States*, 326 U.S. 279, 283 (1945). When an organization operates more than incidentally for the benefit of private interests, it by definition does not operate exclusively for exempt purposes. § 1.501(c)(3)-1(d)(1)(ii)(1976).

95. Prohibited private benefits may include an "advantage; profit; fruit; privilege; gain; [or] interest." *Retired Teachers Legal Defense Fund v. Commissioner*, 78 T.C. 280, 286 (1982).

96. See, e.g., *Sonora Community Hosp. v. Commissioner*, 46 T.C. 519 (1966), *aff'd*, 397 F.2d 814 (9th Cir. 1968) (Tax Court balanced weak evidence of public benefit against strong evidence of private benefit in the context of a hospital dominated by its two founding physicians, who were the source of 90 percent of the facility's patients); Gen. Couns. Mem. 37,789 (Dec. 18, 1978) (balancing the public good accomplished by a below market lease against the private benefit conferred).

97. (Dec. 18, 1978).

98. *Id.* Gen. Couns. Mem. 39,598 (Dec. 8, 1986); Gen. Couns. Mem. 39,498 (Jan. 28, 1986).

99. Bromberg, *supra* note 10, at 252.

100. See, e.g., *Sonora Community Hosp.*, 46 T.C. at 519.

101. See, e.g., P. TREUSCH, *TAX-EXEMPT CHARITABLE ORGANIZATIONS* (3d ed. 1988).

102. See, e.g., R. DESIDERIO & S. TAYLOR, *PLANNING TAX-EXEMPT ORGANIZATIONS* § 12.02 (1988).

103. *American Campaign Academy v. Commissioner*, 92 T.C. 1053 (1989). The court observed that the presence of private inurement violates both prohibitions, but the absence of inurement does not mean the absence of private benefit.

104. Even these relationships are likely to be structured insofar as possible as independent contractor arrangements for economic, tax, or liability reasons.

105. Gen. Couns. Mem. 39,498 (Jan. 28, 1986); see also Gen. Couns. Mem. 39,598 (Dec. 8, 1986) (same result).

106. Gen. Couns. Mem. 39,670 (June 17, 1987).

107. Id.

108. See, e.g., Mancino, *supra* note 15, at 1062.

109. 1969-2 C.B. 231; see also Gen. Couns. Mem. 38,283 (Feb. 15, 1980).

110. We note that the radiologist served as the hospital's Chief of Radiology, though the revenue ruling expressly found that "he has no control over, or management authority with respect to, the hospital itself," and that the agreement was negotiated at arm's length. Rev. Rul. 69-383, 1969-2 C.B. 113. In today's environment, the Service looks very carefully for evidence of physician influence over a hospital. See INTERNAL REVENUE MANUAL § 7(10)69 (1989).

111. See Mancino, *supra* note 15, at 1053, stating that the primary source of a physician's influence over today's nonprofit hospital "is the physician's role as the primary source of patient admissions and the physician's power to change hospitals or to refer or admit patients at other hospitals."

112. See Gen. Couns. Mem. 39,498 (Jan. 28, 1986).

113. This article is concerned chiefly with federal law. For a detailed discussion of state laws regulating referral incentives, see OFFICE OF INSPECTOR GENERAL, U.S. DEPT OF HEALTH AND HUMAN SERVICES, FINANCIAL ARRANGEMENTS BETWEEN PHYSICIANS AND HEALTH CARE BUSINESSES: STATE LAWS AND REGULATIONS (April 1989).

114. Section 1128B of the Social Security Act, as amended, 42 U.S.C.A. § 1320a-7b (West Supp. 1989). The Medicare and Medicaid Antifraud and Abuse Provisions were enacted in 1972 and significantly strengthened in 1977 and 1987. While only tax exempt health care providers are subject to the inurement and private benefit restrictions, all participating providers are subject to the Medicare and Medicaid restrictions.

115. Section 1128B(b) of the Social Security Act makes it a felony to knowingly and willfully offer, pay, solicit, or receive any remuneration, in cash or in kind, to induce, or in return for referring an individual for, arranging for, or ordering items or services that will be paid for by Medicare or Medicaid. Violators risk fines of up to \$ 25,000, exclusion from Medicare and Medicaid, and up to five years in prison. The few narrow exceptions include (1) properly disclosed discounts, (2) amounts paid to bona fide employees, (3) group purchasing vendor rebates, and (4) practices specified in regulations to be issued by the Secretary of Health and Human Services. 42 U.S.C.A. § 1320a-7b(b)(West Supp. 1989).

116. 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). In Greber, a cardiologist paid other physicians who referred patients to him "interpretation fees," shown by the evidence to be payments intended in part for services and in part to induce referrals. Dr. Greber's conviction, upheld on appeal, demonstrates that the proper inquiry in analyzing economic arrangements involving referrals is not whether there is some legitimate purpose or explanation for a payment, but whether one purpose of the remuneration is to induce referrals. The Greber rationale recently was adopted in whole or in part by two additional courts of appeals. *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989)(adopted); *United States v. Bay State Ambulance and Hosp. Rental Serv.*, 874 F.2d 20 (1st Cir. 1989) (cited approvingly, exact reach of statute not decided, conviction upheld where based on payments made primarily as inducements).

117. Enforcement authority for the fraud and abuse laws has been delegated to the Department's Inspector General. 51 Fed. Reg. 34764 (1986); see also 42 U.S.C.A. § 139b(q) (West Supp. 1989) (providing for establishment of State Medicaid Fraud Control Units).

118. Pub. L. No. 100-93, 101 Stat. 680 (1987).

119. Hyman and Williamson, *Fraud And Abuse: Regulatory Alternatives in a "Competitive" Health Care Era*, 19 LOY. U. CHI. L.J. 1133, 1155 (1988).

120. 42 U.S.C.A. § 1320a-7(b)(7)(West Supp. 1989). In these cases, the Inspector General, not a prosecutor or grand jury, will determine whether a violation has occurred. Any individual or entity excluded is entitled to a pre-exclusion hearing, to Social Security Appeals Council review, and, ultimately, to judicial review of the Secretary's final decision. 42 U.S.C.A. § 1320a-7(f)(West Supp. 1989).

121. Publ. L. No. 100-93, § 14, 101 Stat. 680, 697 (1987); see 54 Fed. Reg. 3088 (1989); see generally Perigrine, *Expanded Enforcement Of The Fraud and Abuse Laws*, 23 J. HEALTH & HOSP. L. 10 (1990).

122. 54 Fed. Reg. 3088 (1989), Final regulations were required to be issued by August 18, 1989. Pub. L. No. 100-93, § 14, 101 Stat. 680, 697 (1987).

123. 54 Fed. Reg. 3088 (1989).

124. P. TREUSCH, *supra* note 101, at 248.

125. OFFICE OF INSPECTOR GENERAL, *supra* note 83, at 26.

126. *Harding Hosp., v. United States*, 505 F.2d 1068 (6th Cir. 1974); *Birmingham Business College v. Commissioner*, 276 F.2d 476 (5th Cir. 1960); *Mabee Petroleum Corp. v. United States*, 203 F.2d 872 (5th Cir. 1953).

127. Treas. Reg. § 1.162-7(b)(3)(1958); see Rev. Rul. 69-383, 1969-2 C.B. 113.

128. See 54 Fed. Reg. 3091 (1988).

129. See Rev. Rul. 76-91, 1976-1 C.B. 150; see also MacKelvie & McGuire, *Fraud, Abuse and Inurement: The Growing Impact on Provider-Physician Relations*, 23 J. HEALTH & HOSP. L. 1, 6 (1990).

130. See *BHW Anesthesia Found. v. Commissioner*, 72 T.C. 681 (1979).

131. See *Lowry Hosp. Ass'n v. Commissioner*, 66 T.C. 850 (1976) (loans from hospital to **nursing home** owned by physician who founded the hospital inured to physician's benefit); *Founding Church of Scientology v. United States*, 412 F.2d 1197 (Ct. Cl. 1969), cert. denied, 397 U.S. 1009 (1970) (inference drawn that loans to founder were disguised and unjustified distributions of earnings).

132. Rev. Rul. 73-313, 1973-2 C.B. 174.

133. *Id.*

134. Gen. Couns. Mem. 39,498 (Jan. 28, 1986).

135. These included payment of household and moving expenses, financial assistance in connection with home purchases, financing for office equipment, furniture, and remodeling, assistance in remodeling an office, and the provision of office and administrative services in connection with the physician's private medical practice.

136. The Service does not issue advance rulings on whether compensation is reasonable. Rev. Proc. 89-3, § 3.01(7). 1989-1 C.B. 810.

137. See, e.g., Gen. Couns. Mem. 35,865 (June 21, 1974), modified by Gen. Couns. Mem. 38,283 (Feb. 15, 1980), which held that establishing a profit sharing plan resulted in private inurement per se.

138. Gen. Couns. Mem. 39,670 (June 17, 1987); see also Gen. Couns. Mem. 39,674 (June 17, 1987); Gen. Couns.

Mem. 38,905 (June 11, 1982); Rev. Rul. 69-383, 1969-2 C.B. 113.

139. 1969-2 C.B. 113.

140. See *Birmingham Business College v. Commissioner*, 276 F.2d 476 (5th Cir. 1960); *Lorain Ave. Clinic v. Commissioner*, 31 T.C. 141 (1958).

141. See 42 U.S.C.A. § 1320a-7(a)(b) (West, Supp. 1989), enacted as part of the Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9313(c)(1), 100 Stat. 1874, 2003 (allowing the assessment of civil monetary penalties of up to \$ 2000 per affected patient against hospitals making payments to physicians as an inducement to reduce or limit services provided to Medicare and Medicaid beneficiaries under the physician's direct care).

142. Gen. Couns. Mem. 37,789 (Dec. 18, 1978); see also *Sonora Community Hosp. v. Commissioner*, 46 T.C. 519 (1966), *aff'd*, 397 F.2d 814 (9th Cir. 1968); Rev. Rul. 69-545, 1969-2 C.B. 117.

143. (Dec. 8, 1986); see also Gen. Couns. Mem. 39,646 (June 30, 1987).

144. See Gen. Couns. Mem. 39,646 (June 30, 1987).

145. 54 Fed. Reg. 3088, 3090 (1989).

146. See, e.g., *Patients for Sale?*, Wash. Post, Oct. 4, 1987, at C5; *Warm Bodies -- Hospitals That Need Patients Pay Bounties for Physicians' Referrals*, Wall St. J., Feb. 27, 1989, at 1.

147. See *Hancock Academy of Savannah v. Commissioner*, 69 T.C. 488 (1977) (private inurement found where exempt school paid too much for goodwill of for-profit predecessor); see also Brier, *Special Tax Problems of Health Care Providers*, 2 EXEMPT ORG. TAX REV. 380 (1989).

148. See, e.g., *Birmingham Business College v. Commissioner*, 276 F.2d 476 (5th Cir. 1960); *Lorain Ave. Clinic v. Commissioner*, 31 T.C. 141 (1958).

149. 54 Fed. Reg. 3088 (1989).

150. OFFICE OF INSPECTOR GENERAL, U.S. DEPT OF HEALTH AND HUMAN SERVICES, *Special Fraud Alert* (1989).

151. 54 Fed. Reg. 3088 (1989).

152. 74 T.C. 1324 (1980), *aff'd per curiam*, 675 F.2d 244 (9th Cir. 1982).

153. Rev. Proc. 84-46, 1984-1 C.B. 541; see M. PHELAN, *NONPROFIT ENTERPRISES* § 737 (1985).

154. Gen. Couns. Mem. 37,852 (Feb. 9, 1979); Gen. Couns. Mem. 39,005 (June 28, 1983); Gen. Couns. Mem. 39,546 (Aug. 14, 1986). See generally, McGovern, *Tax Exempt Organizations As Partners And Joint Venturers As Viewed By The Service* (N.Y.U. Fifteenth Conf. on Charitable Organizations, 1978).

155. Gen. Couns. Mem. 39,005 (June 28, 1983) (finding provision of low income housing to further exempt purposes); see also Gen. Couns. Mem. 39,732 (Nov. 4, 1987) (outpatient medical services); Gen. Couns. Mem. 39,444 (July 18, 1985) (office building for exempt affiliate).

156. Gen. Couns. Mem. 39,005 (June 28, 1983).

157. Gen. Couns. Mem. 39,444 (July 18, 1985).

158. See also I.R.C. § 704(b)(1982), which requires allocation of a partner's share of income, gain, loss, deduction, or credit to be determined in accordance with the partner's interest in the partnership if the allocations in the partnership agreement (which otherwise would control) lack substantial economic effect.

159. (Feb. 26, 1988). A private letter ruling is directed only to the taxpayer who requested it and applies only to the specific transaction described. Section 6110(j)(3) of the Code provides that private letter rulings may not be used or cited as precedent.

160. See OFFICE OF INSPECTOR GENERAL, *supra* note 150. The fraud alert highlighted these characteristics of joint ventures as indicators of potentially unlawful activity.

161. *Id.*

162. Speech by James J. McGovern, Assistant Chief Counsel, Employee Benefits and Exempt Organizations, Internal Revenue Service, May 2, 1989, reported in 43 TAX NOTES 644 (1989).

163. Admittedly, direct competition from physicians may be avoided.

164. Avoiding any linkage between the number of referrals and the amount of the economic benefit flowing to the referring individual is among the most basic recommendations a fraud and abuse lawyer makes.

165. A determination letter recognizing exemption may not be relied upon if there is a material change in operations that is inconsistent with the grounds for exemption. Treas. Reg. § 1.501(a)-1(a)(2)(1982). Many of the new arrangements discussed herein may constitute material changes.

166. 135 Cong. Rec. H240-243 (daily ed. Feb. 9, 1989).

167. *Id.*

168. Though an exception for physician ownership in ambulatory surgery centers would allow that incentive for referrals to continue. *Id.* at H241.

169. Pub. L. No. 101-239, § 6204, 103 Stat. 2106, 2236 (1989).

170. Both the General Accounting Office and the Inspector General had reported to Congress in 1989 that the best available evidence of abuse (principally higher utilization) related to physician ownership and self-referrals involved clinical laboratories. U.S. General Accounting Office, *Testimony on Referring Physicians; Ownership of Laboratories and Imaging Centers*, GAO/T-HRD-89-26 (1989); OFFICE OF INSPECTOR GENERAL, *supra* note 83.

171. Pub. L. No. 101-239, § 6204, 103 Stat. 2106, 2236 (1989).

172. Pub. L. No. 101-239, § 6204(e), 103 Stat. 2106, 2237 (1989).

173. See, e.g., INTERNAL REVENUE SERVICE, EXEMPT ORG. CONTINUING PROFESSIONAL EDUC. TECHNICAL INSTRUCTION PROGRAM FOR 1988 at 22 (Jan. 1988).

174. INTERNAL REVENUE MANUAL § 7(10)69 (1989).

175. See *supra* note 162, at 644; 1 MEDICARE COMPLIANCE ALERT at 1 (Oct. 16, 1989).

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LENGTH: 31368 words**TITLE:** Articles: Consumer Managed Care Appeals: Are the Available Procedural Protections Fundamentally Fair?**AUTHOR:** Ann H. Nevers *

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TEXT:

ABSTRACT: Managed care incentives to reduce costs have also resulted in incentives to deny care. Anecdotes concerning managed care denials of care have led to a consumer outcry for protection either through the use of procedural due process or by the establishment of patient rights that would include appeal and grievance protections. This Article reviews the procedural protections of constitutional due process, the Consumer Due Process Protocol, and the Patient Bill of Rights. The Article then extensively discusses the availability of these procedural protections in various public and private forums. The discussion of public forums includes proposals contained in recent national legislative initiatives. The author then reviews relevant federal and state law, as well as Uniform Law proposals. Next, the Article analyzes the protections provided by accreditation agencies, dispute resolution organizations, professional organizations, and health insurers. Finally, the author recommends criteria to be used to determine whether a procedure is fundamentally fair.

A young boy, who lost his arms and legs to gangrene after his health maintenance organization ("HMO") ordered his parents to drive to a distant emergency room for a high fever, sits in the Chamber of the House of Representatives during the patient protection debate of the 106th Congress. n1 A forty-year old woman diagnosed with breast cancer dies after her HMO refuses to pay for an autologous bone-marrow transplant. An \$ 89 million verdict for her survivors results from the HMO's denial. n2 Stories of managed care gone awry abound in the media and in the legislature. These stories all give rise to the cry: "It's not fair!" Are available procedural protections in public and private forums for consumer managed care appeals fundamentally fair? This Article will review procedural protection standards that have evolved to ensure fairness, current national healthcare reform legislation relating to consumer appeals and the availability of procedural protections currently available in public federal and state forums. The Article also examines private industry procedures of accreditation, dispute resolution organizations, professional organizations, and health plans to determine if those procedural protections are fair.

n1 David Espo, *House Approves HMO Bill*, ASSOCIATED PRESS ONLINE, Oct. 7, 1999, available in 1999 WL 28125878.

n2 Erik Eckholm, *\$ 89 Million Awarded Family Who Sued H.M.O.*, N.Y. TIMES, Dec. 30, 1993, at A2.

Disputes are inevitable in the healthcare context due to the complexity of the system. n3 Managed care has increased the complexity of healthcare appeals, creating an increased need for consumerism. n4 Managed care plans

have several characteristics that make appeals crucial. In the fee-for-service system, providers deliver healthcare before denial occurs; in managed care, denial of coverage or service occurs before the provider delivers the healthcare. In addition, the role of the physician differs. Managed care often requires physician gatekeepers to restrict services, while the fee-for-service physician may serve as an advocate for the consumer. n5 Finally, managed care creates an incentive to encourage patients needing expensive medical treatment to leave the plan. n6 As some have said, dissatisfaction with the a plan's process may be demonstrated when consumers "vote with their feet" and leave the plan.

n3 Disputes between consumers and payors "fall under four substantive areas: (1) eligibility for services; (2) the amount of payment for services; (3) coverage of services; and (4) poor quality of services resulting in medical injury." Eleanor D. Kinney, *Consumer Grievance and Appeal Procedures in Managed Care Plans*, 10 HEALTH LAW. 17, 19 (1998).

n4 Kathy L. Cerminara, *The Class Action Suit as a Method of Patient Empowerment in the Managed Care Setting*, 24 AM. J.L. & MED. 7, 18 (1998).

n5 Kinney, *supra* note 3, at 18.

n6 Jennifer E. Gladieux, *M + C Appeal Procedures: Reconciling Due Process Rights and Cost Containment*, 25 AM. J.L. & MED. 61, 71 (1999).

Typically, managed care denies services based on one or more of the following reasons: lack of medical necessity; unapproved or nonformulary drugs; referral requirements not being met; out of network services; contract interpretation; benefit exclusions; billing and coding discrepancies; and lack of coverage for durable medical equipment. n7 Denial usually occurs (1) prior to services when preauthorization or a gatekeeper referral are requested, (2) when a person is receiving inpatient hospital care that the utilization reviewer believes is no longer necessary or when the reviewer believes a lower level of care is appropriate, or (3) when payment is denied for services already received in an emergency setting or for out-of-network services. n8 The denial or adverse determination that precipitates an appeal often occurs when the claim is denied or a request for services is denied. n9 This adverse determination becomes the appealable event. n10 This appeal is distinguished from a grievance or complaint which involves investigation of quality concerns. n11

n7 Audio tape of Wood & Meyer, *Resolving Consumer Disputes in Managed Care*, SPIDR 27th Annual International Conference (Sept. 23-25, 1999) (on file with author) [hereinafter *SPIDR Managed Care*].

n8 See generally Eleanor D. Kinney, *Procedural Protections for Patients in Capitated Health Plans*, 22 AM. J.L. & MED. 301, 316 (1996). See also Susan J. Stayn, *Securing Access to Care in Health Maintenance Organizations: Toward a Uniform Model of Grievance and Appeal Procedures*, 94 COLUM. L. REV. 1674, 1691-1700 (1994).

n9 Stayn, *supra* note 8, at 1692-95.

n10 Kinney, *supra* note 3, at 19-20. See also Eleanor D. Kinney, *Resolving Consumer Grievances in a Managed Care Environment*, 6 HEALTH MATRIX 147, 159 (1996).

n11 1996 Medicare Managed Care Resource Information Directory (visited Apr. 10, 2000) <<http://www.hcfa.gov/medicare/mcpart1.htm>>, at 13-14.

Statistics on overall denial rates indicate that denials are infrequent. For example, a 1998 survey found that denials for eight categories of care were less than 6%, with the largest percentage of denials relating to mental healthcare. n12 Of those consumers who appeal, about half of all private disputes are resolved in favor of the consumer, while 31% of

Medicare appeals are resolved for the consumer. n13 The question that arises is whether the appeal levels are low because of lack of need to appeal, because of barriers to obtaining an appeal, because appeal statistics are not accurately reported, or for other reasons. Nevertheless, procedural protections in the appeal and grievance processes have emerged as a way to ensure fundamental fairness of the process in a way to protect and to empower the consumer.

n12 *Physician Survey Finds Widespread Use of Managed Care Techniques Along with Very Low Rates of Denial of Coverage for Services* (Mar. 1998) <<http://www.aahp.org/services/government&advocacy/policy/Highlights/Denialcv.htm>>.

n13 Karen Pollitz et al., *External Review of Health Plan Decisions: An Overview of Key Program Features in the States and Medicare*, at vii-viii (Kaiser Family Foundation Nov. 1998) [hereinafter *Kaiser Study*].

I. Procedural Protections

Certain procedural elements should be present in any managed care appeals process. These elements include: (1) "timely notice that appealable events have occurred and of the procedures for appeal"; (2) "prompt decisions by a knowledgeable, unbiased decision-maker"; (3) "discretion . . . to the decision-maker"; and (4) "methods for empowering patients in the grievance process." n14 A procedural audit should verify compliance and review the overall fairness of the system. n15 In looking at procedural protections, it is important to keep in mind the goals of fundamental fairness. The process should ensure a sense that justice has prevailed even when the desired outcome is not achieved. This happens when the entire process is fundamentally fair.

n14 Kinney, *supra* note 3, at 20-21.

n15 Margaret Gilhooley, *Broken Back: A Patient's Reflections on the Process of Medical Necessity Determinations*, 40 VILL. L. REV. 153, 156 (1995).

A. Due Process Protections

The due process clauses of the Fifth and Fourteenth Amendments create procedural protection in certain situations. n16 In 1970, *Goldberg v. Kelley* established that federal and state laws governing public assistance programs create a legal entitlement on behalf of any person who fits within the eligibility standards. n17 This case challenged the adequacy of the notice and hearing provisions of termination procedures of the federal program, Aid to Families with Dependent Children. In its ruling, the U.S. Supreme Court established a number of procedural protections for the process including: (1) written notice of a proposed adverse action including the reasons for the action; (2) the opportunity for the member to be heard in an informal hearing before an impartial administrative decisionmaker at a meaningful time and in a meaningful way; (3) opportunity for the member to appear personally and be represented by counsel; (4) opportunity for the member to present evidence and confront and cross-examine adverse witnesses at the hearing; and (5) a written final decision that includes reasons to support that decision. n18 Since *Goldberg*, courts have applied these requirements in situations in which coverage for medical treatment has been reduced or denied by the state. n19

n16 U.S. CONST. amend. V and XIV.

n17 397 U.S. 254, 261-62 (1970).

n18 *Id.* at 268-71.

n19 See *Caldwell v. Wallace*, 755 F.2d 870, 873 (11th Cir. 1985); *Phillips v. Noot*, 728 F.2d 1175, 1180 (8th Cir. 1984); *Eder v. Beal*, 609 F.2d 695, 699-700 (3d Cir. 1979).

The Supreme Court established an analysis for procedural due process requirements in *Mathews v. Eldridge*, a case involving an appeal of an adverse Social Security disability determination. n20 The Court used a balancing test to weigh the private interests affected by the action, the risk of an erroneous deprivation through the procedures used, and the government's interest in the administrative burdens imposed by the procedural requirements. n21 A state interest must exist before the Court will apply this balancing test. n22 Thus, procedural due process protections developed in *Eldridge* apply to government sponsored health plans such as Medicare and Medicaid. n23

n20 424 U.S. 319 (1976).

n21 *Id.* at 340-49. See also *Kinney*, *supra* note 8, at 326.

n22 *Blum v. Yaretsky*, 457 U.S. 991, 1003-06 (1982)

n23 *Kinney*, *supra* note 3, at 18.

In 1997, the California Supreme Court decided *Engalla v. Permanente Medical Group*, in which the plaintiff challenged the procedural process of a Kaiser arbitration proceeding involving a medical malpractice claim. n24 The demand for arbitration was filed on May 31, 1991, while the petitioner was terminally ill. n25 At the outset, the petitioner's attorney indicated that the petitioner had a terminal condition and that the process needed to be expedited. n26 However, the parties did not agree on the panel of three arbitrators until October 22, 1991. n27 In addition, the defense was aware of the fact that one of the chosen arbitrators was not available until after November. n28 The petitioner died the day after the panel was finally selected. n29

n24 938 P.2d 903, 908 (Cal. 1997).

n25 *Id.* at 909.

n26 *Id.* at 910.

n27 *Id.* at 912.

n28 *Id.* at 910.

n29 *Engalla*, 938 P.2d at 912.

The delay at issue in *Engalla* was far from rare. Statistics of Kaiser arbitrations held between 1984 and 1986 showed that such delays were common; indeed, the arbitrators were selected within the contractually stipulated sixty days in only one percent of the proceedings. In three percent of the cases, the arbitrators were selected by the end of 180 days. n30 The average time for selection of an arbitrator was 674 days and the average time to a hearing was an incredible 863 days. n31

n30 *Id.* at 912-13.

n31 *Id.* at 913. In 1992, a GAO study found that it took thirty-three months to resolve a medical malpractice claim in court, while the Kaiser system took nineteen months. See Rebecca A. Cerny, *Arbitration or Litigation: Efficacy and Fairness in Resolving Medical Malpractice Disputes through Arbitration Proceedings*, 27 J. HEALTH & HOSP. LAW 7, 193 (1994).

Relying in part upon these statistics, the *Engalla* plaintiff filed suit claiming that Kaiser's self-administered arbitration system was corrupt and biased, that there was fraudulent misrepresentation of the timeliness of the arbitration system, and that Kaiser's slow response to the arbitration request was grounds not to enforce the arbitration agreement. n32 The trial court agreed with the petitioner and denied the motion to compel arbitration. n33 The court of appeals reversed, n34 and the case went to the California Supreme Court. There, the court found that there were factual questions regarding whether the conduct was actually fraudulent, and whether the actions of Kaiser were sufficient to waive the right to compel arbitration. n35 While the court acknowledged the basic public policy favoring arbitration, it also indicated there were limits on enforcing arbitration agreements. n36 Following the decision, Kaiser established a blue ribbon panel to review the arbitration process and make recommendations. n37 The panel recommended that Kaiser establish an independent administrator to administer the arbitration program. n38 Kaiser has since contracted with a small law firm to administer the arbitration program. n39

n32 *Engalla*, 938 P.2d at 908, 914.

n33 *Id.* at 908.

n34 *Id.*

n35 *Id.*

n36 *Id.* Note, however, that other courts have continued to uphold arbitration clauses. See *Kaiser Found. Hosps. v. Superior Court*, 19 Cal. App. 4th 513, 515-18 (1993).

n37 *Kaiser Appoints Panel to Oversee Arbitration Program in California*, 6 HEALTH CARE POL'Y REP. (BNA), May 4, 1998, at 763.

n38 *California: Kaiser Should Create Independent Arbitration Administrator, Panel Says*, 7 HEALTH LAW REP. (BNA), Jan. 8, 1998, at 54.

n39 *Reynolds Holding, Arbitration Can Be Less Neutral Than You'd Think*, S.F. CHRON., Nov. 29, 1998, at 7Z3.

Similar issues were presented in *Grijalva v. Shalala*, a class action lawsuit n40 claiming that the Health Care Financing Administration ("HCFA") failed to monitor and sanction HMOs that did not implement effective appeals processes for service denials. n41 The plaintiffs brought action and requested enforcement of effective notice, hearing, and appeals procedures for Medicare HMO denials. n42 In its ruling, the district court established specific notice and hearing requirements. The ruling required that notice be given within five days after a written or oral request for a service and at least one day before reduction or termination of a course of treatment. n43 The court also required that the HMOs print the notice in twelve-point type and include in the notice (1) an explanation, in lay language, of the coverage rule upon which the adverse decision was based; (2) a description of regular and expedited appeal processes and the Peer Review Organization ("PRO"); (3) a description of additional evidence that would support the member's position and instructions on how to obtain and submit additional medical information in support of the member's position; and (4) an explanation of the procedures necessary for obtaining an informal hearing for reconsideration. n44 The court mandated that HCFA monitor compliance with these procedures. Noncompliance by an HMO could result in nonrenewal of a Medicare contract. n45 The district court also ordered a reconsideration process with certain protections, including in-person communication with the decisionmaker, an expedited process of no more than three

working days for urgent services, independent review upon denial of an expedited reconsideration, continuation of services until the appeal decision was complete, and procedures to facilitate the consumer in obtaining the records and letters necessary for an appeal. n46

n40 The class action lawsuit is one way consumers can assert power in the managed care setting. *See Cerminara, supra* note 4, at 8-9.

n41 946 F. Supp. 747, 749-50 (D. Ariz. 1996), No. CIV 93-711 TUC ACM, 1997 U.S. Dist. LEXIS 22861 (D. Ariz. Mar. 3, 1997) (order of procedures DHHS must follow), *aff'd*, 152 F.3d 1115 (9th Cir. 1998), *vacated*, 119 S. Ct. 1573 (1999).

n42 946 F. Supp. at 749.

n43 1997 U.S. Dist. LEXIS 22861 at *2. The five-day notice requirement could be extended up to sixty days if the HMO needed additional information and notified the member of this and gave the member steps to take to obtain the information along with time frames needed to complete the investigation. *Id.* at *3.

n44 *Id.* at *3-4. *See also* 152 F.3d at 1121-22.

n45 *Id.* at *4.

n46 *Id.* at *4-6. *See also* 152 F.3d at 1121-22.

The appellate court in *Grijalva* applied the three-pronged balancing test of *Eldridge*, and affirmed the district court order. n47 First, the court determined that there was a private interest based on the expense of medical costs and the resultant fact that adverse coverage decisions prevent access to medical care. n48 Second, the court found that the risk of an erroneous deprivation through the procedures used was high because most notices of denial failed to include the reasons for the denial, provide information to members of the right to present additional evidence, direct members to their physicians to obtain evidence of medical necessity, communicate procedures to contact the person reviewing the claim, or make any reference to the PRO appeals process. n49 Finally, the court considered the third prong, the governmental burden, and found that the administrative burden was minimal compared to the benefits of procedural protections. n50

n47 152 F.3d at 1121.

n48 *Id.* at 1121-22.

n49 *Id.* at 1122-23.

n50 *Id.* at 1123.

In May 1999, the Supreme Court vacated the appellate court's judgment and remanded the case to the Ninth Circuit. n51 The appellate court was directed to consider the impact of a 1999 Supreme Court decision, n52 the Balanced Budget Act of 1997 ("BBA"), n53 and Department of Health and Human Services ("DHHS") regulations. n54 Nevertheless, the *Grijalva* case prompted HCFA to revise the Medicare HMO appeal regulations. n55

n51 *Shalala v. Grijalva*, 119 S. Ct. 1573 (1999).

n52 American Mfrs. Mut. Ins. Co. v. Sullivan, 526 U.S. 40 (1999).

n53 Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251 (codified in scattered sections of 2, 8, 26, 38, 42, & 47 U.S.C.).

n54 42 C.F.R. § 422.568 (2000).

n55 Maria A. Morrison, *The Impact of Grijalva v. Shalala on the Medicare HMO Appeal Process and the Importance of Enforcing Appeal Process Regulations*, 103 DICK. L. REV. 735, 747-48 (1999).

B. Consumer Bill of Rights

As a result of concerns about denials of care and anecdotal information regarding bad outcomes, President Clinton established the Presidential Advisory Commission on Consumer Protection in the Health Care Industry. The Commission prepared a Consumer Bill of Rights and Responsibilities plan that it presented to the President in a November 1997 report. n56 The report includes a chapter describing provisions for complaints or appeals. n57 In that chapter, the Commission opined that "all consumers have the right to a fair and efficient process for resolving differences with their health plans, health care providers, and the institutions that serve them, including a rigorous system of internal review and an independent system of external review." n58

n56 ADVISORY COMMISSION ON CONSUMER PROTECTION AND QUALITY IN THE HEALTH CARE INDUSTRY, CONSUMER BILL OF RIGHTS AND RESPONSIBILITIES, REPORT TO THE PRESIDENT OF THE UNITED STATES (1997) [hereinafter BILL OF RIGHTS REPORT].

n57 *Id.* Ch. 7.

n58 *Id.* at 57.

More specifically, the Commission believed that consumer protection through internal appeals should include the following: (1) timely written notification of a decision to deny, reduce, or terminate services or deny payment for services, including an explanation of the reasons for the decisions and the procedures to appeal; (2) resolution of all appeals in a timely manner with expedited appeals occurring within seventy-two hours for emergency or urgent care consistent with Medicare; (3) claim review process conducted by healthcare professionals who are appropriately credentialed with respect to treatment reviewed and review of denials by those who were not involved in the initial decision; (4) written notification of the final determination by the plan of an internal appeal with the reason for the decision and method to appeal the decision to an external entity; and (5) reasonable processes for resolving complaints. n59

n59 *Id.*

External appeals systems include appeals that occur after the consumer has exhausted the internal processes, unless care is needed urgently. According to the Commission, these external appeals apply to any "decision to deny experimental or investigational treatment when the determination is based on lack of medical necessity," if the "amount in question exceeds a significant threshold, or if the patient's health or life is in jeopardy." n60 These appeals should be resolved in a timely manner with expedited decisions (within seventy-two hours) for emergent or urgent conditions. The external appeals process should rely on objective evidence. n61

n60 *Id.* at 57-58. External appeal would be conducted by a healthcare professional who is appropriately credentialed, has not been

involved in the initial decision, and does not have a conflict of interest. *Id.* at 58.

n61 *Id.*

C. Consumer Due Process Protocol

In 1997, the American Arbitration Association ("AAA"), the American Bar Association ("ABA"), and the American Medical Association ("AMA") joined forces to establish a "Commission on Health Care Dispute Resolution to develop due process standards and procedures for the fair and equitable resolution of health care disputes." n62 The Commission prepared a statement of fifteen principles entitled the "Consumer Due Process Protocol." n63

n62 *Nation's Leading Health, Legal, and Dispute Resolution Organizations to Develop Due Process Protocol for Health Care Disputes; American Arbitration Association, American Bar Association, and American Medical Association Form Commission to Ensure Fairness in Arbitration*, PR NEWSWIRE, Nov. 18, 1997, available in LEXIS.

n63 *Consumer Due Process Protocol: Statement of Principles of the National Consumer Disputes Advisory Committee* (Apr. 17, 1998) <http://www.adr.org/education/education/consumer_protocol.html> [hereinafter *Due Process Protocol*].

Principle 1 states that all parties are entitled to a fundamentally fair Alternative Dispute Resolution ("ADR") process. n64 Fundamental fairness requires that procedures protect the consumer who may not have other realistic alternatives to medical care. Minimum due process standards for fundamental fairness include:

informed consent; impartial and unbiased Neutrals; independent administration of ADR; qualified Neutrals; access to small claims court; reasonable costs . . . ; convenient hearing locations; reasonable time limits; adequate representation; fair hearing procedures; access to sufficient information; confidentiality; availability of court remedies; application of legal principle and precedent by arbitrators; and the option to receive a statement of reasons for arbitration awards. n65

n64 *Id.*

n65 *Id.*

Because these fairness procedures protect the consumer, a properly informed consumer may waive compliance with them. n66

n66 *Id.*

Principle 2 requires access to information regarding ADR programs. This information includes clear and adequate notice of contract provisions as well as information about the optional or mandatory nature of as to whether the dispute resolution process. is optional or mandatory. After the dispute has arisen, consumers should have access to all information necessary for effective participation in the dispute process. Practical examples of implementation include providing consumers with a written explanation for procedures to resolve a healthcare dispute one month before visiting the healthcare institution for services, providing an "ombudsperson" program to assist members in resolving their disputes, or making information available through the internet or other public places. n67

n67 *Id.*

Principle 3 recommends independent administration of the dispute resolution program and the use of an independent, impartial neutral. Independence and impartiality are important for both the neutral and the administrator of the program. This principle requires the neutral and the administrator to disclose any conflicts of interests, requires compliance by the neutral with appropriate ethical standards, and requires that the involved parties have the discretion to reject any neutral without cause. n68

n68 *Id.*

Principle 4 involves the quality and competence of the neutrals. Each program administrator can establish standards for competence of neutrals in the program. The less choice the consumer has over the selection of the neutral, the more important this component becomes. Competence requires adequate training and mentoring programs for neutrals. n69

n69 *Due Process Protocol, supra* note 63.

Principle 5 involves the right to seek relief in small claims court for disputes or claims within the scope of its jurisdiction. Small claims court provides an accessible and consumer-friendly forum for disputes that do not involve a large sum of money. n70

n70 *Id.*

Principle 6 is the right to dispute resolution at a reasonable cost based on the size of the dispute, the nature of the claim, and the consumer's ability to pay. A fundamental principle of fairness ensures that individuals have access to court regardless of their ability to pay. As a practical matter, in order to reach this goal, a managed care organization ("MCO") might have to subsidize costs. Alternatively, costs might be kept minimal through use of the internet, other electronic media, telephone, or written submissions of information in a dispute. n71

n71 *Id.*

Principle 7 requires a reasonably convenient location for both parties based on their ability to travel. This principle includes addressing issues of judicial forum selection, as well as selection of the location for a hearing. n72

n72 *Id.*

Principle 8 involves reasonable time limits. The dispute resolution proceedings should occur within a reasonable time, without unreasonable delay. In healthcare, this requirement is especially important because a delay in needed treatment or care can result in negative health outcomes or even death. Dispute resolution entities may want to develop "expedited procedures" or "fast track" reviews to resolve straight-forward claims or urgent claims that have a need for speedy review. n73

n73 *Id.*

Principle 9 involves the right to representation. The right to be counseled by an attorney or other representative is

an important part of dispute resolution. Any party seeking advice of counsel is responsible for those costs. n74

n74 *Id.*

Principles 10 and 11 focus on encouraging use of dispute resolution processes such as mediation and arbitration. n75 When arbitration is used in a contract, the MCO should provide notice of the arbitration agreement in such a way that the consumer can easily read and understand it. The Commission recommends that a specific notice of arbitration stand alone in the contract. Furthermore, this notice should indicate to the consumer that, by signing the agreement for binding arbitration, the consumer is giving up the right to go to court. The consumer should have access to the information concerning the arbitration agreement. n76

n75 *Due Process Protocol, supra* note 63. Mediation involves the use of a third party to facilitate discussion between the parties in a process whereby the parties themselves resolve the dispute. Arbitration involves a neutral third party making the decision for the parties. *Id.*

n76 *Id.*

Principle 12 requires a fundamentally fair hearing. Processes promoting fairness include providing adequate notice of the hearing and an opportunity to be heard and present relevant evidence. They also include guarantees of confidentiality during the process. It is presently unclear as to whether fairness should require a face-to-face hearing or whether the submission of information for decision is sufficient to ensure fairness. n77

n77 *Id.*

Principle 13 requires access to information material to the dispute, including processes to exchange information. In healthcare, access to information about health status, appeal processes and procedures, necessity of medical treatment, treatment options, and reasons and grounds for a denial are all necessary information for an appeal. n78

n78 *Id.*

Principle 14 provides for the empowerment of the arbitrator to grant whatever relief would be available in court. Most neutral decisionmakers have this power. n79 However, in healthcare, the decisionmaker may be affiliated with the organization denying the initial review. Thus, the decisionmaker must have the autonomy to make a new, neutral, and equitable decision.

n79 *Id.*

Principle 15 focuses on arbitration awards. Generally, review of arbitration awards is very limited under arbitration statutes, exemplified by the fact that some statutes do not require the arbitrator to provide a written explanation or reason for the award. On the other hand, some arbitration rules require at least a statement of the rationale for the award. A written decision provides written documentation of the award and the rationale for the decision, and thus accords both parties with the information necessary for a review of the decision and for any possible appeal. n80

n80 *Id.*

D. ABA Interdisciplinary Roundtable

In April 1997, the ABA Commission of Legal Problems for the Elderly hosted an interdisciplinary roundtable that focused on the resolution of consumer disputes in managed care. n81 Work groups made exploratory recommendations regarding these issues. n82 The work group on grievance and appeals systems recommended eight general principles that grievance and appeal systems should meet. These principles provide for the following: (1) fair, simple, efficient, and uniform processes, (2) closure of individual disputes, (3) procedures that support consumer rights and choice, including availability of decision criteria and decisions, (4) identification of problem areas for continuous quality improvement, (5) ongoing evaluation of the grievance and appeal system, (6) time frames relevant for healthcare needs, (7) independent and qualified decisionmakers and review entities, and (8) member protection from retaliation. n83 The workgroup also recommended further study to determine the role of ADR. n84

n81 RESOLUTION OF CONSUMER DISPUTES IN MANAGED CARE: INSIGHTS FROM AN INTERDISCIPLINARY ROUNDTABLE (Naomi Karp and Erica Wood eds., Sept. 1997) [hereinafter INTERDISCIPLINARY ROUNDTABLE].

n82 Note, however, that the exploratory recommendations as a whole were not endorsed by the plenary Roundtable nor do they represent the policy of the ABA. *Id.* at 2.

n83 *Id.* at 2-3.

n84 *Id.* at 4.

The ADR workgroup also made exploratory recommendations that focused on early, informal, and nonbinding dispute resolution processes. The group recognized the power imbalance between health plans and consumers, which enhances the need for procedural protections. n85 The group suggested that ADR options would be facilitated by a corporate cultural commitment to encourage the general development of ADR options to resolve consumer concerns and encourage offering a variety of methods to resolve concerns. n86 In addition, consumers should find any system easy to use. To achieve this goal, a consumer assistant could be on staff to help the consumer understand and navigate the system. n87 The corporation should encourage early resolution of disputes through appropriate ADR techniques, such as mediation or neutral fact finding. n88 Any informal ADR processes should not delay formal resolution or appeal processes. n89 Finally, corporations should share information on the best practices and pilot projects in order to continue to improve the way ADR works within the system. n90

n85 *Id.* at 11.

n86 INTERDISCIPLINARY ROUNDTABLE, *supra* note 81, at 11-12.

n87 *Id.* at 13.

n88 *Id.* at 14.

n89 *Id.* at 15.

n90 *Id.* at 16.

E. Procedural Protections and Fundamental Fairness

A variety of procedural protections are available or proposed through due process rights, the Consumer Bill of Rights, the Consumer Due Process Protocols, and the exploratory recommendations of the ABA interdisciplinary roundtable. These protocols provide procedural protections for managed care appeals in four major categories, (1) timeliness, n91 (2) decisionmaker neutrality, n92 (3) the appeal process, n93 and (4) communication and empowerment. n94

n91 *See Engalla v. Permanente Med. Group*, 938 P.2d 903, 920-21 (Cal. 1997). *See also* BILL OF RIGHTS REPORT, *supra* note 56, at 58.

n92 *Due Process Protocol*, *supra* note 63, at 12-15.

n93 *See Engalla*, 938 P.2d 903. *See also Grijalva v. Shalala*, 946 F. Supp. at 761.

n94 Kinney, *supra* note 3, at 21-22.

Procedural protections dealing with timeliness would require corporations to establish time frames for completion of the appeals process and for expedited appeals based on the urgency of the consumer's medical condition. n95 These timeliness protections are especially important in light of the fact that in the managed care arena, the decision to deny care usually means that the consumer will not receive services until the denial is overturned. Thus, the timing of such a decision can be a matter of life or death for the consumer. n96

n95 BILL OF RIGHTS REPORT, *supra* note 56, at 58.

n96 *See Engalla*, 938 P.2d at 912.

The second procedural protection considers the need for decisionmaker neutrality. The decisionmaker should be independent, empowered to make an autonomous decision, and, if necessary, should possess pertinent expertise. External appeals are one popular method of ensuring neutrality of the decision-maker. n97

n97 BILL OF RIGHTS REPORT, *supra* note 56, at 58.

The third procedural protection is the appeal process itself. In order for the appeal process to protect the consumer, it should include easy access to an appeal, n98 use ADR methods to resolve the dispute, n99 and provide incentives for resolving the dispute early in the process. n100 As appeals become more protracted, the timeliness of the decision making becomes an issue.

n98 INTERDISCIPLINARY ROUNDTABLE, *supra* note 81, at 13.

n99 *Due Process Protocol*, *supra* note 63, at 27-28.

n100 INTERDISCIPLINARY ROUNDTABLE, *supra* note 81, at 15.

Finally, effective communication and empowerment are important procedural protections. MCOs need to inform consumers of their healthcare benefits and their appeal rights in a comprehensible manner--before the consumer ever

uses the benefits. n101 Rather than hiding contract exclusions in the fine print of a contract, MCOs should effectively inform the consumer about the true benefits of their contract. Furthermore, MCOs should communicate to consumers their appeal rights at the time of any denial of care. MCOs should also communicate to their consumers, in a timely manner, the information necessary for an appeal.

n101 *Due Process Protocol*, *supra* note 63, at 11.

Nonetheless, even with the recommended *procedural* protections in place, the question remains: are appeal processes *fundamentally* fair? Fairness involves more than specific procedures or protections--it invokes matters of substance. Synonyms of "fairness" include equitableness, impartiality, fair dealing, honest, and uprightness, n102 all of which mean free from bias in judgment. Therefore, even if sufficient procedural protections are generally available, similarly situated people must not be treated differently because of the forum in which they participate. In other words, fundamental fairness criteria go beyond specific procedural protections and include the broad context of the appeal system.

n102 V THE OXFORD ENGLISH DICTIONARY 675 (2d ed. 1998).

The following standards can be used to determine whether an appeals system is *fundamentally* fair. First, a fair appeals process should establish minimum standards based on procedural protections. The parties should reach an agreement about what are acceptable minimum procedural protections that should be available for all consumers. Second, fairness requires that processes treat all people equally, rather than applying different standards for different health plans. Currently, health plans can "forum shop" to find the forum that protects their corporate interest, but this may occur at the expense of fairness to the consumer. Third, a fair process requires that there be procedural protections for contract exclusions and medical necessity denials, so that there is less disparity of impact from these processes or at least notice that services are excluded from a contract before the consumer needs those services. Fourth, fairness requires a focus on the balance of power at all stages of the process, from contracting through appeals. Whether this balance occurs through an ombudsman, consumer advocate, adequate communication, or otherwise, consumers need empowerment in the appeal process in order for the appeal process to be fundamentally fair for them. n103 Fifth, ease of use of the appeal system is a measure of fundamental fairness. If the system is so difficult for the consumer to navigate that appeals do not occur, then the system is not fairly balanced. n104 Finally, a fair system should include health plan accountability through system-wide checks and balances to prevent health plan abuses. Whether the checks and balances occur through public reporting of appeals, public or private oversight, or consumer advocacy watchdogs, the health plan must be held accountable for fairly measuring, administering, and reporting appeals. n105

n103 Kinney, *supra* note 8, at 325-26; Kinney, *supra* note 10, at 162.

n104 INTERDISCIPLINARY ROUNDTABLE, *supra* note 81, at 13.

n105 *Engalla v. Permanente Med. Group*, 938 P.2d 903 (Cal. 1997).

II. National Public Forums

A. National Legislative Activity

In 1992, President Clinton campaigned for the presidency with an emphasis on a sweeping reform of healthcare. Managed competition was adopted as a strategy for the proposed Health Security Act of 1993. n106 In this proposal, claims for payment or provisions of services, or requests for preauthorization of services were appealable events. n107

The Health Security Act would have placed the states in a primary role to resolve disputes by establishing complaint review offices that would hold de novo hearings of claim denials. n108 Consumers would have been given the option of proceeding to court or following an expedited review hearing with an early resolution program. n109 The early resolution program also would have given the consumer the option to elect mediation. n110 Finally, appeals from expedited review hearings would have gone to a "Federal Health Plan Review Board." n111 Upon the defeat of this sweeping legislation, its procedural protections were, at a minimum, postponed.

n106 Health Security Act of 1993, H.R. 3600, 103d Cong. (1993).

n107 Kinney, *supra* note 10, at 161.

n108 Stayn, *supra* note 8, at 1710.

n109 *Id.*

n110 Timothy S. Jost, *Administrative Adjudication Under Health Care Reform*, 47 ADMIN. L. REV. 425, 436 (1995).

n111 Stayn, *supra* note 8, at 1710.

It was not long, however, before analogous protections were again at the forefront of public debate. In early 1999, the House of Representatives first considered the "Patient Bill of Rights Act." n112 One of the reasons given for introducing the bill was to provide a mechanism to "hold managed care plans responsible for denial of care with real, reliable, and enforceable appeals and remedies." n113 This bill provided for appeals and grievance processes n114 and for a health insurance ombudsman in each state. n115 The appeals process included internal appeals of adverse determinations to a physician or health professional who was not involved in the initial decision. n116 The bill established time frames for internal review of thirty days, except for expedited appeals which were to be completed in seventy-two hours. n117

n112 Patient Bill of Rights of 1999, H.R. 358, 106th Cong. (1999) [hereinafter *House Rights Bill*].

n113 145 CONG. REC. H5355 (July 12, 1999) (statement of Mr. Pallone).

n114 *House Rights Bill*, *supra* note 112, § 131.

n115 *Id.* § 123.

n116 *Id.* § 132(2)(A).

n117 *Id.* § 132(3)(A).

The bill also provided that if the health plan failed to comply with the internal appeal time frames, the consumer had the right to proceed directly to external appeal. n118 The external appeals process required a contract with a qualified external appeal entity. n119 Procedural protections in the external appeal process included the following: (1) the right to a fair, de novo determination; (2) determination of whether the decision is an externally appealable decision; (3) the opportunity to submit evidence, have representation, and make oral presentation; (4) provision of information

regarding the matter on appeal and provisions of the health plan; (5) timely decisions within sixty days or seventy-two hours for expedited appeals; and (6) notice of the basis of the determination and the right to further review by the courts at the conclusion of the appeal. n120 The Patient Bill of Rights' provisions were also applicable to plans organized under the Employee Retirement Income Security Act ("ERISA") because the bill provided that ERISA preemption would not apply and that a plan member could sue for damages from personal injury or wrongful death. n121 Patient protections that were not included in this bill include reasonable cost and location provisions, use of ADR processes, and the necessity of following legal principle and precedent. n122

n118 *Id.* § 132(3)(B).

n119 *Id.* § 133(b)(1).

n120 *Id.* § 133(b)(C)(2).

n121 *Id.* § 301.

n122 *See Due Process Protocol, supra* note 63; BILL OF RIGHTS REPORT, *supra* note 56.

The "Patient Protection Act of 1999" n123 differed from the Patient Bill of Rights in that it incorporated ADR as an optional process and included more provisions for healthcare provider involvement in the review. n124 This proposal included provisions for access to information, n125 access to a neutral medical decisionmaker, n126 time limits for internal review, n127 optional external review by an independent medical expert, n128 expedited review for urgent and emergent care, n129 the use of ADR, n130 and the right to reasons for the decision. n131 It did not include provisions of cost or location of the appeals processes, fair hearing and the right to representation, or the need to follow legal principle or precedent. n132

n123 Patient Protection Act of 1999, H.R. 448, 106th Cong. (Feb. 2, 1999).

n124 *Id.* § 4013. It also provided for a physician to review all initial decisions. *Id.* § 1201(b)(3).

n125 *Id.* § 1101.

n126 *Id.* § 1201(b)(3).

n127 Appeal protections include establishment of internal review by a "fiduciary" within thirty days unless it was an urgent situation that would need to be decided in ten days or an emergent decision that needs to be decided in seventy-two hours. It also provides for specialty review in seventy-two hours and reconsideration time periods of twenty-five days. *Id.* § 1201(b)(A-B).

n128 *Id.* § 1201(b)(4).

n129 *Id.* § 1201(b)(B).

n130 Any use of dispute resolution to resolve the healthcare liability action or claim must contain provisions relating to the "statute of limitations, noneconomic damages, joint and several liability, punitive damages, collateral source rule, and periodic payments." *Id.* § 4013.

n131 *Id.* § 1201(b)(A).

n132 *See Due Process Protocol, supra* note 63; BILL OF RIGHTS, *supra* note 56.

The Bipartisan Consensus Managed Care Act, was passed by the House in October, 1999, n133 after other legislation stalled during the summer of 1999. n134 This bill includes provisions to improve managed care through the improvement of utilization review process requirements, n135 the provision of grievance and appeals processes, n136 improved access to care, n137 and protection of the doctor-patient relationship. n138 The managed care appeal provisions focus on internal appeal notice and time requirements, n139 external appeal availability, n140 and expedited review within seventy-two hours. n141 It is noteworthy that the external review provision does not apply to specific contract exclusions from coverage or decisions about whether a person is a plan participant. n142 The bill requires ERISA plans to comply with appeal and grievance requirements; however, the bill does not address fair hearing procedures, the right of representation, or any consumer assistance programs. The bill also does not address the use of ADR.

n133 The Bipartisan Consensus Managed Care Act was sponsored by representatives Charlie Norwood and John Dingell. It was a bill to amend Title I of ERISA, Title XXVII of the Public Health Service Act, and the Internal Revenue Code of 1986 to protect consumers in managed care plans and other health coverage. Bipartisan Consensus Managed Care Improvement Act of 1999, H.R. 2723, 106th Cong. (1999) [hereinafter *Bipartisan Bill*].

n134 The Quality Care for the Uninsured Act, H.R. 2990, passed the House in early October. It was seen by some as a "poison pill" to kill other managed care bills. It did not include the same substantive provisions for appeals. Quality Care for the Uninsured Act of 1999, H.R. 2990, 106th Cong. (1999).

n135 *Bipartisan Bill, supra* note 133, § 101.

n136 *Id.* §§ 101-104.

n137 *Id.* §§ 111-119.

n138 *Id.* §§ 131-135.

n139 *Id.* § 102. The internal appeals procedures includes a right of review with notice in writing of the denial with reasons for the denial and rights to further appeal. The consumer then has 180 days to request and full review. Internal appeal processes require reviews to be conducted by the plan or insurer and by a person who did not make the initial denial. The time frames for internal review are fourteen days unless additional information is needed, in which case notice of needed information must be provided in five days. Once the additional information is received, a decision must be made within fourteen days, or within twenty-eight days from the receipt of the request for internal review. *Id.*

n140 *Id.* § 103. The act requires external appeal procedures after denial of a claim for benefits that is based on a determination that it is "not medically necessary," that the requested treatment is "investigatory" or experimental, or any other decision based on medical judgment. A fair, de novo review by a qualified external appeal entity is required. The entity would also make determinations of external appealability. Appeal decisions must be made within twenty-one days, except for expedited reviews that are expected to be completed within seventy-two hours. The appeal decision must include the basis for the decision and further appeal rights. *Id.*

n141 *Id.* § 102(c). Expedited review procedures apply when the normal time frame for making a decision would seriously jeopardize the life or health of the participant, beneficiary or enrollee or the ongoing care would otherwise be terminated. *Id.*

n142 *Id.* § 103(a)(2)(C).

One of the two bills that did not pass was the Health Care Quality and Choice Act of 1999. n143 This bill was very similar to the "Bipartisan Consensus Managed Care Improvement Act of 1999," which the House did pass. The Health Care Quality and Choice Act differed from the Bipartisan Bill in that the Health Care Quality and Choice Act required expedited appeals to be made in forty-eight hours n144 and allowed for binding arbitration to resolve disputes as long as the arbitration provided for a fair de novo review. n145 The other bill that did not pass was the Group Health Plan Review Standards Act of 1999, the Boehner Bill, which would have amended ERISA and provided for grievance procedures. n146 The Boehner Bill provided for time limits for benefit determinations, n147 medical professional involvement in internal denial decisions, n148 external review processes, n149 and the use of dispute resolution processes through collective bargaining. n150

n143 This bill was sponsored by representatives Coburn and Shadegg. *See* Health Care Quality and Choice Act of 1999, H.R. 2824, 106th Cong. (1999).

n144 *Id.* § 101.

n145 *Id.* § 303.

n146 Group Health Plan Review Standards Act of 1999, H.R. 2089, 106th Cong. (1999) [hereinafter *Boehner Bill*].

n147 *Id.* § 2(b)(10)(K). These time frames include thirty days to make an initial decision, thirty days to conduct internal review, twenty-five days to make a reconsideration, and five days for an accelerated need decision. *Id.* § 2(b)(10)(I)(L)

n148 *Id.* § 2(b)(3). The Boehner Bill provides for internal review of denials, with medical professionals to make initial coverage decisions involving medical necessity or investigational items or experimental technology. *Id.*

n149 *Id.* § 2(b)(4)(D)(ii). External review by an independent medical expert is optional. If used, the expert must be selected by an intermediary. External review can be waived in advance if the plan agrees to abide by the final decision of an independent medical expert and the consumer waives the right to review of a final decision. *Id.* § 2(b)(5).

n150 *Id.* § 2(b)(5)(B). The collective bargaining agreements incorporate time limits outlined in the statute, provide for review by a physician, and allow each party to present scientific and medical evidence to support its position. *Id.*

In the summer of 1999, the Senate introduced and passed its own version of the "Patients' Bill of Rights Act." n151 Like the other bills, the Senate bill provides for clinical involvement with internal appeal processes, n152 external appeals, n153 and expedited appeals. n154 The Senate bill also provides for the creation of a health insurance ombudsman in each state to assist consumers in choosing health plans and to help with grievances and appeals. n155

n151 Patients' Bill of Rights Plus Act, S. 1344, 106th Cong. (1999) [hereinafter *Senate Rights Bill*].

n152 *Id.* § 503(d). The review process includes participation of one or more clinical peers who were not involved in the initial decision. The decision must be made within thirty days of provision of information for review, with the option of a thirty-day extension for circumstances beyond the control of the health insurer. *Id.* § 503(b).

n153 *Id.* § 503(e). External appeals of adverse determinations require that a decision can be made by an external body if the amount involved exceeds a significant threshold or the patient's life or health is jeopardized, but does not include denials based on exclusion from coverage by contract. An external appeal also arises from the exhaustion of the internal appeals process. External appeals are decided by a qualified external appeal entity that has been approved by the state. *Id.*

n154 *Id.* § 403 (b). The appeal must be decided within seventy-two hours if a decision within the normal time frame would seriously jeopardize the life or health of the participant. *Id.*

n155 *Id.* § 123.

In February 2000, Senate Majority Whip Don Nickles was appointed to Chair the Managed Care Reform Conference Committee tasked with negotiating differences in the Senate and House versions of the bills. Meanwhile, the House passed a nonbinding motion instructing the committee to meet as soon as possible and to accept the House managed care bill. n156 Key differences to be discussed include the number of people covered by the bill, who determines whether care is medically necessary, the kind of available appeals, and "how to hold health plans accountable." n157 While the Senate bill was limited in scope to protect "the 48 million people in 'self-insured' employer-sponsored group health plans subject to ERISA," the House bill was passed with broad inclusion of approximately 161 million people in all group health plans, including both ERISA and non-ERISA plans. n158 A subgroup of the Conference Committee has been meeting to resolve differences of opinion regarding appeal processes. Proponents of the House bill were urging appeal decisions that were not based on the MCO definition of medical necessity. n159 Other discussion have focused on claims criteria for external review. n160

n156 *Plan Regulation: Nickles to Chair Managed Care Panel; Lott Hints Again of Limited Right to Sue*, HEALTH CARE DAILY REP. (BNA), Feb. 2, 2000, at d7.

n157 David Nather, *Managed Care Conferees Reach Consensus on Three Protections; Tough Issues Remain*, 8 HEALTH CARE POLICY REP. (BNA), Mar. 31, 2000, at 395.

n158 Phyllis C. Borzi and Sara Rosenbaum, *Pending Patient Protection Legislation: A Comparative Analysis of Key Provisions of the House and Senate Versions of H.R. 2990*, prepared for the Kaiser Family Foundation (Mar. 2000), at 2-3 <<http://www.kff.org>> (located in Health Reform directory).

n159 Jennifer Combs, *Plan Regulation: Group of Conferees convene to Consider How to Move Forward on External Appeals*, HEALTH CARE DAILY REP. (BNA), Mar. 31, 2000, at d11.

n160 Liz White, *Plan Regulation: Conferees Leave Sub-Group Meeting with No Deal on External Appeal Process*, HEALTH CARE DAILY REP. (BNA), Apr. 13, 2000, at d9.

On April 13, 2000, the Conference Committee subgroup reached an agreement on the elements of an external appeal process. The group agreed that "patients who have exhausted their health plan's internal review process may appeal to an external reviewer, which would be chosen by an independent review entity that contracts with the plan." n161 Regulations would be established to prevent conflicts of interest in choosing a reviewer so that the reviewer could remain independent and unbiased. External review would be available if the cost of treatment exceeds a "significant financial threshold" or when the life or health of the member is in danger. Three conditions would trigger external review: (1) plan determination of lack of medical necessity or appropriateness, (2) plan determination that the treatment is experimental or investigational, or (3) plan denial of a claim considered to not be covered by the plan. Patients would be required to pay a \$ 50 filing fee for the appeal, which could be waived for low-income persons and refunded if the claimant prevails. n162 The external review process would provide for the medical reviewer to make a "new, independent determination based on the medical condition of the patient and consistent with the valid, relevant scientific and clinical evidence." n163 Legislative language still must be drafted based on the broad agreements reached regarding the external review process. n164 The public supports an effective resolution of this situation. In a Kaiser opinion poll conducted in April 1999, 83% of those polled favored independent review, although the number dropped to 57% if the independent review requirements were to result in increased premiums. In February 2000, 48% of the public felt that a law is more urgently needed than when the debate began two years ago. n165

n161 *Plan Regulation: Small Conferee Group Reaches Accord on Broad Principles of External Appeals*, HEALTH CARE DAILY REP. (BNA), Apr. 14, 2000, at d9.

n162 *Id.*

n163 *Id.* (quoting "an aide").

n164 *Id.*

n165 Kaiser Public Opinion Update, Feb. 2000 <<http://www.kff.org>> (*located in Health Insurance Coverage directory*).

B. Medicare

The Social Security Act of 1965 created Medicare as a federal health insurance program for those over sixty-five years of age and for those with certain specified needs. n166 DHHS, through HCFA, establishes requirements to protect Medicare beneficiaries, including appeal requirements. n167 HCFA has modified Medicare appeal requirements as a result of the *Grijalva* decision. These modified requirements apply to Medicare carriers that receive fee-based reimbursement. The stages of the Medicare appeal process include an initial claim determination, reconsideration, fair hearing, a hearing in front of an Administrative Law Judge ("ALJ"), and court review. n168 Medicare also gives the Medicare carrier the right to reopen claims at the carrier's discretion, based on good cause. n169 Medicare also requires hospitals to provide notice of Medicare appeal rights when a Medicare beneficiary is discharged from the hospital and provides for PRO review of the discharge. n170 In Medicare, the appealable adverse determination is the "initial determination" that denies services. n171

n166 Medicare Part A provides reimbursement for inpatient hospital and skilled nursing facility services. Medicare Part B reimburses physicians and outpatient providers. *See* 42 U.S.C. § 1395(d).

n167 42 C.F.R. § 417.124(g) (2000).

n168 *See* Department of Health & Human Services, Office of Inspector General, *Medicare Administrative Appeals, ALJ Hearing Process* (Sept. 1999) <<http://www.dhhs.gov/progorg/oei/reports/a408.pdf>> [hereinafter *ALJ Hearing Process*].

n169 The reopening, unlike an appeal, is not a matter of course. A claim may be reopened within a one or four year period for good cause. Good cause for reopening typically includes presentation of new and material evidence that was not readily available at the time of the determination, where there is an error on the face of the evidence, or there is a clerical error in the claim file. *See Reopening and Revision of Claims Determinations and Decisions*, MEDICARE CARRIERS MANUAL Part 3, Chapter XII, 12100, 12100.8 (visited Apr. 6, 2000) <http://www.hcfa.gov/pubforms/14_car/3b12024.htm>. *See also* 42 C.F.R. § 405.841 (2000).

n170 *See* Department of Health & Human Services, Health Care Financing Administration, *The Notice of Discharge and Medicare Appeal Rights (NODMAR)* (Feb. 11, 1999) <<http://www.hcfa.gov/medicare/op1082.htm>>. The discharge must include (1) the reason why inpatient care is no longer needed; (2) the effective date of the enrollee's risk of financial liability; and (3) the enrollee's appeal rights. Additionally, these notices must be approved by the HCFA regional office. Immediate review by the PRO is available within one full working day after it receives the patient's request, medical records, and other information necessary to make a decision. *Id.*

n171 Kinney, *supra* note 3, at 20.

Medicare also requires expedited appeals within seventy-two hours. n172 Expedited review is mandatory when

there is a physician written statement to support the need for urgent services. n173 Expedited review is not required in the following: situations involving review of a hospital discharge by PRO, physician concerns about situations concerning the denial of payment, n174 or in situations in which the decision is to deny an expedited appeal. n175 If the carrier refuses a request for expedited review, the appeal is handled in the normal sixty-day time frame. n176

n172 Medicare expedited appeals must take place within seventy-two hours when the enrollee's "health, life, or ability to regain maximum function may be jeopardized by the standard sixty-day organization determination process." Health plans were given notice of this requirement on July 22, 1997, and were given until August 28, 1997, to comply. Information about appeal rights was required to be in the member handbook, or other plan documents by December 31, 1997. See Department of Health & Human Services, Health Care Financing Administration, *Program Memorandum: All Medicare Contracting Health Maintenance Organizations (HMOs), Competitive Medical Plans (CMPs), and Health Care Prepayment Plans (HCPPs). Subject: Implementation of the Expedited Appeal Regulation* (July 22, 1997) <<http://www.hcfa.gov/medicare/xappeals.htm>> [hereinafter *Medicare Program Memorandum*].

n173 *Id.*

n174 *Id.*

n175 *Id.* The expedited review can be extended ten days if additional information is needed to make a decision. *Id.*

n176 *Id.*

A Medicare reconsideration request must be filed within sixty days of the initial decision or denial. n177 Parties can present information to the health plan. n178 When the HMO reconsideration grants the member's request, then the HMO can issue the decision. n179 However, when the reconsideration decision denies the member's request, then the HMO must forward the case to HCFA with a written explanation. n180 HCFA then contracts with Center for Health Dispute Resolution ("CHDR") to make a reconsideration decision. n181 This process of providing for an independent review without specific consumer request is unique to Medicare. Even though independent review is available, few consumers use it. In 1997, less than one percent of all Medicare claims were appealed through external review. n182 Less than 5% of all Medicare beneficiaries have ever filed an appeal. n183 Medicare also provides for a fair hearing process in which the health plan hearing officer holds an appeal hearing in which the parties have the opportunity to attend with representation, present witnesses, and receive an independent decision. n184

n177 42 C.F.R. § 417.616 (2000).

n178 *Id.* § 417.618.

n179 *Id.* § 417.620.

n180 *Id.*

n181 *External Reviews of Health Plan Decisions*, Testimony of David A. Richardson, President of the Center for Health Dispute Resolution, available in 1999 WL 16947269.

n182 *Insurance Regulation: Outside Reviews of Health Plan Decisions Helpful but Rarely Used, House Panel Told*, 6 Health Care Pol'y Rep. (BNA), Apr. 27, 1998, at 695.

n183 *Id.*

n184 Department of Health & Human Services, Health Care Financing Administration, *Appeals Process*, MED. CARRIER MANUAL 12027, 12028 (visited Apr. 6, 2000) <http://www.hcfa.gov/pubforms/14_car/3b12024.htm> [hereinafter *Appeals Process*].

The next level is to appeal to an ALJ, in a nonadversarial hearing. n185 To qualify for an ALJ hearing, the amount in controversy must be \$ 100 or more for a service provided by Part A, or \$ 500 or more for a service provided by Part B. n186 To obtain an ALJ hearing, the claimant must file a written request within sixty days of the date of the hearing officer decision. n187 Once the carrier receives an ALJ decision, the carrier must implement the ALJ decision within fifteen days of receipt of the decision from the regional office. n188

n185 *See ALJ Hearing Process, supra* note 168, at 5-7.

n186 *Id.* at 4.

n187 *Appeals Process, supra* note 184, at 12027.

n188 *Id.* at 12028.

This ALJ process is now under review. n189 Some of the issues under review are the lengthy time for appeals, n190 limited ALJ experience with Medicare appeals, n191 high reversal rates on behalf of the appellant, n192 increased numbers of appeals, n193 high appeal rates by providers in a system designed to protect the consumer, n194 and the nonadversarial nature of the hearing process. n195 Other concerns with the process include the fact that ALJ decisions do not set precedent, n196 and that there are not any HCFA regulations regarding conduct of the hearings. n197 In an attempt to pre-empt these concerns, one carrier improved the process by establishing regular meetings between itself and the ALJs. The carrier learned more about the ALJ process and the ALJs learned more about the carrier decisionmaking process. After communication was instituted, ALJ reversal on claim decisions decreased from 50% in fiscal year 1994 to 31% in fiscal year 1997. n198

n189 *Id.* The 1999 OIG report on Medicare Administrative Appeals focused on the ALJ Hearing process. *See ALJ Hearing Process, supra* note 168.

n190 In 1999 it was reported that the average ALJ process for Part A (Hospital) claims took 301 days and Part B (Physician) claims took 524 days. *Medicare Coverage Policy Determinations and Appeals, Before the Subcomm. on Health House Committee Ways & Means* (Apr. 22, 1999) (statement of Michael Hash, Deputy Administrator Health Care Financing Administration) <<http://www.hcfa.gov/testmony/1999/medcov1.htm>>.

n191 The ALJs had more expertise in Social Security rules than Medicare regulations since their appeal caseload typically involved social security appeals. *See ALJ Hearing Process, supra* note 168.

n192 A large percentage of appeals reaching the ALJs are reversed, which creates incentives to appeal. Further, a reversal has a negative impact on the carrier. In many cases, Medicare contractors and ALJs use differing criteria in ruling on issues. This different analysis could account for the high number of reversals. Typically Medicare contractors rely on Medicare law, HCFA regulations, HCFA rulings, and national coverage determination in making a decision. The ALJs also use Medicare law, HCFA regulations and rulings, and national coverage determinations. However, they rarely use contractor manuals and local medical review policy because, unlike the contractors, they are not bound by these standards. *See ALJ Hearing Process, supra* note 168, at 6, 9.

n193 Statistics showed an overall increase in ALJ appeals from 1996 to 1998. The total increase for both Part A & B claims was 73%. *Id.* at 8.

n194 The appeal process is nonadversarial, which means that appellants can present their appeals without the presence or opposition of the opposing party. The process was established to allow beneficiaries to appeal. However, the study found that the appeal process was primarily used by providers. *Id.* at 8-9.

n195 Medicare is not able to defend itself in the ALJ hearing. Providers may represent themselves with an attorney or with expert testimony, but Medicare is represented at the hearing only via the written record. *Id.* at 10.

n196 This lack of precedent setting authority contributes to inconsistent rulings by the ALJs. *See ALJ Hearing Process, supra* note 168, at 11.

n197 Because there are no HCFA regulations for conducting the hearings, ALJs rely on Social Security Administration disability regulations. *Id.* at 10.

n198 *Id.* at 12.

The following are recommendations to improve the ALJ process: separating the administrative appeals process for beneficiaries and providers, establishing an adversarial ALJ hearing for provider appeals, developing parallel training programs for Medicare contractors and ALJs, developing and requiring both Medicare contracts and ALJs to apply the same standards, developing regulations for conducting Medicare ALJ appeals, establishing a case precedent system for DHHS Departmental Appeal Board ("DAB") rulings, and creating formal communication and information networks that span the entire appeals environment. n199

n199 *Id.* at 16-17.

Providers and beneficiaries can also appeal to the DHHS DAB. This board provides for the notice of appeal, a discovery period, a conference or evidentiary hearing, reconsideration, and other resolution options, such as those of ADR. Board decisions are subject to judicial review. Even though an evidentiary hearing is an option, there is no "right" to a hearing or a conference. n200

n200 Department of Health & Human Services, Department Appeals Board, *Practice Manual* (last revised Sept. 17, 1999) <<http://www.hhs.gov/progorg/dab>>.

Reports on the effectiveness of the appeals process indicate that the number of appeals is low in relation to the number of people enrolled in Medicare. The statistics for Fiscal Year 1997 show that appeals from fee-for-service claims denials were 0.72% of all claims filed. n201 There are several reasons for the low numbers of appeals, including: (1) consumers are unaware of their rights to appeal; (2) Medicare recipients may not be able to appeal for themselves because of age, illness, or financial limitations; (3) consumers may prefer to disenroll rather than to appeal; n202 or (4) Medicare recipients may have no one to help with the appeal. n203 Another report by the DHHS Office of Inspector General ("OIG") on Medicare HMO Appeal and Grievance Processes indicated that HMOs did not fully comply with the HCFA directives for processing appeals because many of them incorrectly categorized appeals as grievances. In addition, HMOs' marketing and enrollment materials and operating procedures contained incorrect information on appeal and grievance rights, HMOs did not maintain statistical information on grievances or appeals, and some HMO staff did not have the HCFA HMO/CMP Manual created for HMOs to use as a guide for these processes. n204

n201 *See Medicare Appeals Processes Before the Subcomm. on Health House Committee Ways & Means* (Apr. 23, 1998) (statement of Michael Hash, Deputy Administrator Health Care Financing Administration) <http://www.hcfa.gov/testimony/1998/98_0423.htm>.

n202 Stayn, *supra* note 8, at 1700-01.

n203 Erica Wood, *Will Older Grievants Get Heard: Accessibility of Dispute Resolution in Managed Care*, in INTERDISCIPLINARY ROUNDTABLE, *supra* note 81, at 73, 84.

n204 Department of Health and Human Services, Office of Inspector General, *Medicare HMO Appeal and Grievance Processes: Overview* (Dec. 1996) <<http://www.dhhs.gov/progorg/oei/reports/a201.pdf>>.

Because communication between the HMO and the consumer regarding denied services or payment was not always effective, consumers often did not understand how to use the appeals processes. n205 A survey of beneficiaries found that 86% of the beneficiaries knew that they had a general right to appeal, but few were given a notice of denial and few filed a formal appeal. n206 In a review of cases at ten carrier locations, the OIG found similar inconsistencies. n207 In August 1997, the Medicare Rights Center ("MRC") established a national HMO appeals hotline that facilitates Medicare appeals. n208 During the first six months, MRC received 179 cases. n209 The reasons for appeals included: consumer confusion regarding Medicare rights and benefits (40%), HMO noncompliance with Medicare laws, regulations or appeal processes (49%), and other reasons (11%). n210

n205 *Managed Care: Four Reports Detail Problems with Medicare HMO Appeals and Grievances*, 8 Medicare Rep. (BNA), Jan. 24, 1996, at 4.

n206 Department of Health & Human Services, Office of Inspector General, *Medicare HMO Appeal and Grievance Processes: Beneficiaries' Understanding*, at i (Dec. 1996) <<http://www.dhhs.gov/progorg/oei/reports/a202.pdf>>.

n207 Department of Health & Human Services, Office of Inspector General, *Medicare HMO Appeal and Grievance Processes: Review of Cases*, at 4 (Dec. 1996) <<http://www.dhhs.gov/progorg/oei/reports/a204.pdf>> [hereinafter *Medicare HMO Appeals*]. Additionally, beneficiaries were not always advised of their appeal rights at the time of services or payment denial, the HMOs did not distinguish appeals and grievances, and they did not fully comply with HCFA directives for processing appeals and grievances. Several of the HMOs had cases in which the beneficiaries appealed several times before initiating the appeals process. Several of the HMOs did not issue an initial determination within sixty days, and nine of the ten plans did not make the reconsideration determination within sixty days or inform the beneficiary in a timely manner. Documentation of initial claims determinations, dates of reconsideration, and notification of decision were haphazard. *Id.* at 6-11.

n208 Beth Demel, *Case Studies from the Medicare Rights Center HMO Hotline* in GUIDE TO MANAGED CARE STRATEGIES 2,000: AN ANNUAL REPORT ON THE LATEST PRACTICES AND POLICIES IN THE NEW MANAGED CARE ENVIRONMENT 349 (Joseph Burns & Paula Bruggeman eds. 1999).

n209 *Id.*

n210 *Id.* at 349-50.

C. Medicare + Choice

In 1997, the BBA created the Medicare + Choice ("M + C") program, which has the goal of providing multiple health plan models to Medicare beneficiaries enrolled in risk contracting plans. n211 This program provides for appeals protections, including external review through an independent quality review and improvement organization. n212 Appeal requirements include notice provisions and a limited fourteen-day time frame for review. n213 HCFA also provides for expedited review in a manner similar to other expedited review programs. n214

n211 This new Medicare plan provides for Medicare models as a coordinated care plan, private fee-for-service plan, and Medical

Savings Account with a high deductible as a demonstration project. 42 U.S.C. § 1395w-21 (1999).

n212 42 U.S.C. § 1395w-22. External reviews are not required for private fee-for-service plans or nonnetwork MSA plans that do not use utilization review. *Id.*

n213 The time frame for making a nonexpedited decision was reduced from 60 days to 14 days. *See Morrison, supra* note 55, at 754.

n214 Expedited review may be made when the normal time frame would "seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function." 42 U.S.C. § 1395w-22 (1999). When a physician requests an expedited appeal, it must be honored. HCFA may contract with an independent review organization to resolve the appeal in a timely manner. *Id.*

Under this Act, the first level of appeal is reconsideration. Reconsideration must occur within sixty days of the receipt of the request for reconsideration. Only a physician who is not involved in the initial decision and who has appropriate expertise in the field of medicine that necessitates the treatment can review a determination to deny coverage due to lack of medical necessity. n215 At the reconsideration level, HCFA is required to contract with an outside entity to make the decision. HCFA has contracted with CHDR to do this. n216 CHDR has thirty days to make a decision, with the possibility of an extension of up to fourteen days, if warranted. n217 CHDR must complete expedited appeals within seventy-two hours. All appeals from health plans are automatically sent to an independent appeal administrator for independent review with no monetary thresholds or other barriers. Of the independent contractor cases reviewed, CDHR decided 22% of the cases in favor of the beneficiary.

n215 *Id.*

n216 *External Reviews of Health Plan Decisions*, Testimony of David A. Richardson, President of the Center for Health Dispute Resolution, available in 1999 WL 16947269.

n217 42 C.F.R. § 422.590 (2000).

A plan is deemed to meet the requirements for external appeals if the health plan is accredited by a private organization which enforces standards that are not less stringent than the provisions under the Balanced Budget Act. n218 Coordination of these standards takes place through HCFA's Quality Improvement System for Managed Care ("QISMC"). QISMC considered but did not adopt the National Committee for Quality Assurance ("NCQA") standards. Instead, QISMC adopted its own standards for review. n219

n218 42 U.S.C. § 1395w-22.

n219 Department of Health & Human Services, Health Care Financing Administration, *Interim QISMC Standards* (Sept. 28, 1998) <http://www.hcfa.gov/quality/qlty_3.htm>. *See also* Department of Health & Human Services, Health Care Financing Administration, *Guidelines for Implementing and Monitoring Compliance with Interim QISMC Standards, Domain 2: Enrollee Rights* (Sept. 28, 1998) <http://www.hcfa.gov/quality/qlty_3.htm>.

Nevertheless, the M + C standards are not as broad as the *Grijalva* requirements in several ways. First, the *Grijalva* definition of determinations includes denials, terminations, and reductions of services. n220 In contrast, M + C focuses on determinations that involve denials and terminations of services, but not reductions of services. n221 Second, *Grijalva* requires notice of a coverage determination within five days of a request or one day before treatment is reduced or terminated. n222 M + C provides that beneficiaries will receive notice within fourteen days and allows for an extension. n223 Third, the M + C notice requirements are not as comprehensive as *Grijalva*. n224 While *Grijalva* requires that the provision of denied services continue until a final decision has been made, HCFA does not require

health plans to pay expenses pending appeal. n225 This difference may reflect a balancing by HCFA of the need to provide appeal process protections, while managing program costs. n226

n220 Morrison, *supra* note 55, at 754.

n221 *Id.*

n222 *Id.* at 756-57.

n223 *Id.* at 757.

n224 *Id.*

n225 *Id.*

n226 *Id.* at 754.

D. Employee Retirement Income Security Act

ERISA was enacted in 1973. It provides for federal pre-emption of state law for employee benefit plans ("EBPs") that are employer sponsored. n227 The intent of ERISA is to allow multistate health plans to operate free from the hindrance of a hodgepodge of individual state requirements.

n227 29 U.S.C. § 1003 (1999)

ERISA also requires employee benefit plans to give participants and beneficiaries notice n228 and information n229 about the plans and their rights. An administrative hearing process must be established for appeals, but there is no requirement that the hearing be timely or independent. n230 When ERISA plans purchase coverage through federally qualified HMOs, they are considered compliant with ERISA claims procedures. n231 A beneficiary or participant can bring a civil action in federal district court against a plan fiduciary. There is no right to sue the Secretary of Treasury, Secretary of Labor, or the corporation providing the benefit. n232

n228 29 U.S.C. §§ 1029-1031 (1999). A Summary Plan Description that includes rights under the plan must be provided. ERISA also requires notice to the participant when a claim has been denied and an opportunity to review of the denial. *See id.* §§ 1029-1031, 1133.

n229 A written explanation of reasons for denials must be given and an administrative hearing process must be established for appeals. *Id.* § 1133.

n230 29 U.S.C. §§ 1021-1031 (1999). *See also* 29 C.F.R. § 2560.503-1 (2000).

n231 29 C.F.R. § 2560.503-1(j).

n232 29 U.S.C. § 1451 (1999).

By statute, ERISA pre-empts state regulation of EBPs and courts have interpreted this pre-emption broadly. n233

Recently, however, courts have begun to rein in ERISA pre-emption and to allow state court lawsuits in certain instances. n234 Recent ERISA cases have established the idea that state laws regarding quality of care are not "related to" the administration of the employee benefit plan and, therefore, are not pre-empted by ERISA. n235 However, courts have held that state laws regarding utilization management decisions "relate to" the employee benefit plan and are pre-empted by ERISA. n236 In *Corcoran v. United Healthcare*, the court found that the utilization management program of clinical decisionmaking constituted a benefit determination. n237 Similarly, in *Jass v. Prudential Health Care Plan*, the court considered the utilization review dispute to involve medical benefits and, therefore, to be pre-empted by ERISA. n238

n233 See *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41 (1987).

n234 See David L. Trueman, *Managed Care Liability Today: Laws, Cases, Theories, and Current Issues*, 33 J. HEALTH L. 191 (2000).

n235 See *Pacificare of Oklahoma v. Burrage*, 59 F.3d 151 (10th Cir 1995); *Dukes v. U.S. Healthcare Inc.*, 57 F.3d 350 (3d Cir. 1995).

n236 *Corcoran v. United Healthcare, Inc.*, 965 F.2d 1321 (5th Cir. 1992).

n237 *Id.* at 1331.

n238 88 F.3d 1482, 1495 (7th Cir. 1996).

The Department of Labor final regulations for ERISA appeals require that a plan provide a written statement of the reasons for the denial within ninety days. n239 On appeal a "full and fair" review is required with a written decision within sixty days. n240 If the appeal goes to court, the court will generally conduct a de novo review. n241 The Health Insurance Portability and Accountability Act ("HIPAA") also requires sixty days' notice. n242 A claimant cannot recover for harm caused by the denial of the claim and cannot receive punitive damages. n243

n239 29 C.F.R. § 2560.503(1)(e) (2000).

n240 *Id.* § 2560.503(1)(g) & (h).

n241 While the court will generally conduct a "de novo" review, if the employee benefit plan gives the administrator or fiduciary discretionary authority, then an "arbitrary and capricious" standard of review will be used. See *Whately v. CNA Ins. Co.*, 189 F.3d 1310, 1313 (11th Cir. 1999)

n242 42 U.S.C. § 1395w-22(g)(2)(A) (1999).

n243 *Id.*

In September 1998, the Department of Labor issued proposed ERISA regulations governing other aspects of beneficiary rights. These proposed regulations require that the health plan establish and maintain "reasonable claims procedures" for "appeal of adverse benefit determinations." n244 According to these regulations, EBPs must include a description of these procedures and their time limits in their summary plan descriptions. n245 The process cannot include arbitration nor require more than one appeal prior to bringing a civil action. n246 The claimant may have a representative act on his behalf. n247 The plan must make benefit determinations within fifteen days n248 unless they

involve an urgent care request, in which the case the plan must make the decision within seventy-two hours. n249 The notice of benefit determination must include the reasons for the decision, reference to plan provisions on which the determination is based, a description of any additional information needed, a description of plan review procedure, and time limits including the right to appeal and the right to an expedited review process for urgent claims. n250 Every appeal must include a "full and fair review" unless certain procedures ensuring fairness are otherwise followed. n251 Group health plans have additional requirements for medical decisionmaking, which mandate that an independent healthcare professional review medical necessity and that expedited appeals be provided for urgent care. n252 Some critics have faulted the proposed regulations' definition of urgent care, the exclusion of arbitration from the initial process, and the failure to include external review in the process. n253

n244 *Department of Labor Proposed Regulations*, 63 Fed. Reg. 48,390 (Sept. 9, 1998).

n245 *Id.*

n246 *Id.*

n247 *Id.*

n248 *Id.*

n249 *Id.* An urgent situation arises when reliance upon the normal time periods could "seriously jeopardize the life or health of the claimant or the ability of the claimant to regain maximum function, or . . . subject the claimant to severe pain that cannot be adequately managed." *Id.*

n250 *Id.*

n251 *Id.* The procedures required for fairness are to provide a reasonable time to appeal, provide an opportunity to submit written information, provide claimant access to records considered in making the decision, and provide for a review that does not defer to the initial decisionmaker, takes into account all information, and which is decided by someone other than the initial decisionmaker or one of his subordinates. *Id.*

n252 *Id.*

n253 Brian Briles & David Sandman, *Ensuring Equal Access to Care*, in *REGULATING MANAGED CARE: THEORY, PRACTICE, AND FUTURE OPTIONS* 135 (Stuart H. Altman et al. eds., 1999).

E. Administrative Dispute Resolution Act

The Administrative Dispute Resolution Act of 1996 ("Act") was enacted to encourage the use of dispute resolution within federal agencies. n254 While each agency has wide latitude regarding adoption of an ADR policy, the Act provides some parameters for procedural protections. Agencies are encouraged to explore alternative means of resolving disputes in connection with various agency activities.

n254 Under the Act, agencies were encouraged to examine ADR in connection with formal and informal adjudications, rulemakings, enforcement actions, issuing and revoking licenses or permits, contract administration, litigation brought by or against the agency, and other agency actions. *See* 5 U.S.C. § 571 (1999).

The Act provides for appointment of neutrals, who may be members of the agency or of other agencies. However, the neutral must be someone without any conflict of interest. The Act also mandates that dispute resolution proceedings stay confidential, unless: the parties and the neutral consent in writing; the communication has already been made public; the statute requires public communication; or if a court determines that disclosure is necessary to prevent a material injustice, establish a violation of the law, or prevent harm to public health or safety of such magnitude as to outweigh the need for confidentiality. The parties to the dispute shall not voluntarily disclose any dispute resolution communication unless at least one of these specific exceptions is met. n255

n255 *Id.* § 574.

Parties can consent to arbitration either before or after a dispute arises. However, the agency may not require any person to consent to arbitration as a condition of entering into a contract or obtaining a benefit. n256 Arbitration awards become binding and final within thirty days of being served on the parties unless, within this time period, a party requests an extension. Judicial review is available to persons adversely affected by the award. n257

n256 *Id.* § 575.

n257 *Id.* §§ 580, 581.

F. Other

HMOs are regulated by the Health Maintenance Organization Act of 1973, which sets standards affecting key aspects of plan design and operation. n258 Designation as a "federally qualified" HMO is voluntary and can be viewed as a federal seal of approval; moreover, the designation provides protection from state laws that conflict with the requirements of the federal act. "Federally qualified" HMOs are those that meet the requirements set forth in the HMO Act. Status as a "federally qualified" HMO is one way to qualify as a Medicare contractor. The requirements for such qualification include maintaining meaningful procedures for resolving grievances, providing information about grievance procedures with enrollment in applications, and disclosing of the procedures to enrollees. These procedures must ensure that grievances are transmitted promptly to decisionmakers who have the authority to take corrective action and perform a full investigation. n259

n258 Health Maintenance Organization Act, 42 U.S.C. § 300e-e17 (1999).

n259 A Report from the American Association of Health Plans, *The Regulation of Health Plans* 4, 32 (Feb. 3, 1998) <<http://www.aahp.org/menus/index.cfm>>.

The Older Americans Act was amended in 1992 to provide for a **nursing home** ombudsman. The role of the ombudsman is to investigate complaints and facilitate resolution of complaints in a neutral, nonregulatory role. n260 Some commentators suggest that the ombudsman program model could be used to address concerns of managed care. n261 Consumers continue to have a difficult time negotiating the complexities of the system required to file an effective managed care appeal. n262 A trained ombudsman could facilitate communication of appeal rights, resolve disputes between the health plan and the member, and provide useful information to enable the consumer to better negotiate the system. A consumer assistance program could provide specific services, such as the following: helping consumers make informed choices about health plans; helping those enrolled in health plans to understand their rights and responsibilities under the plan; providing a toll free phone number for questions and problems; assisting with internal and external appeal processes; making referrals to health plans, employers, and regulators as needed to resolve disputes; and keeping accurate records. n263 Such a system would help consumers negotiate the fragmented health system, empower

consumers to make effective healthcare choices, and resolve concerns at an earlier, less formal stage in the proceedings.
n264

n260 42 U.S.C. § 3058h-f (1999).

n261 See William F. Benson, *The Long-Term Care Ombudsman Program: A Model for Health Care Consumers*, in REGULATING MANAGED CARE: THEORY, PRACTICE & FUTURE OPTIONS 119-22 (Stuart H. Altman et al. eds., 1999).

n262 *SPIDR Managed Care*, *supra* note 3.

n263 Ron Pollack, *Regulation from a Consumer's Perspective*, in REGULATING MANAGED CARE: THEORY, PRACTICE & FUTURE OPTIONS 263, 272 (Stuart H. Altman et al. eds., 1999).

n264 *Id.*

G. Procedural Protections and Fundamental Fairness

Procedural protections in national public forums vary from forum to forum. The first procedural protection is the timeliness of the decision. The legislative proposals include time frames for appeals; however, depending on the legislation, the time frames vary from thirty to sixty days for regular appeals and from forty-eight to seventy-two hours for expedited appeals. n265 Medicare, M + C, and the ERISA proposed regulations all require plans to make expedited appeals decisions within seventy-two hours. n266 M + C and ERISA proposed regulations require regular appeals to be handled in fourteen and fifteen days respectively.

n265 *House Rights Bill*, *supra* note 112.

n266 *Medicare Program Memorandum*, *supra* note 172, at 9. See also 42 U.S.C. § 1395w-22(g)(3)(B)(i)-(iii) (M + C); 29 C.F.R. § 2560.503-1(7)(d)(2)(i) (ERISA).

The next procedural protection, decisionmaker neutrality, is included with requirements for external review under some of the legislative proposals, Medicare, and M + C. External review provisions still contain "loopholes" however. For example, the Quality Care for the Uninsured Act, passed in October 1999, does not require external review of specific contract exclusions from coverage or decisions about whether a person is a plan participant. n267 The proposed ERISA standards require a "full and fair review," but have been criticized for not including external review provisions.

n267 *Quality of Care for the Uninsured Act*, *supra* note 134.

The appeals process is the next procedural protection included in the various national forums. Of the federal public forums, Medicare and M + C provide the most consumer protections in the appeals process. Any denial at the reconsideration level is automatically forwarded to HCFA for review by an independent review agency. The consumer does not need to request that the plan forward the appeal. A denial by the health plan is sufficient to move the appeal to independent external review. n268

n268 42 C.F.R. § 422.590.

The final procedural protections of communication and empowerment can occur in a variety of ways. The Senate bill provides for the creation of a health insurance ombudsman in each state to assist consumers in choosing health plans and negotiating the appeals process. n269 Medicare and M + C require communication of appeals rights upon denial of care or discharge from the hospital, yet the number of appeals remains low. n270 More discussion may be needed to determine the most effective method to communicate with consumers so that they have necessary information to make appropriate choices.

n269 *Senate Rights Bill*, *supra* note 151.

n270 *Medicare HMO Appeals*, *supra* note 207, at 3.

Fundamental fairness criteria have not all been met in federal public forums. While Medicare and M + C establish widespread standards, they have not been incorporated in other forums as minimum standards for procedural protections. Moreover, there remains a large discrepancy between the way people are treated in federal government programs n271 and ERISA plans. n272 Furthermore, there are no specific procedural protections for contract exclusions or medical necessity decisions. In attempting to balance power by providing for nonadversarial ALJ hearings, Medicare has inadvertently empowered physicians who use the process with counsel, disempowered Medicare, and left the majority of consumers outside of existing appeals processes. n273 Ease of use by the consumer and implementation of more checks and balances need to be integrated into federal public forums.

n271 *MEDICARE CARRIERS MANUAL*, *supra* note 169, at 12100.

n272 ERISA, 29 U.S.C. §§ 1101-1114 (1999).

n273 *Medicare HMO Appeals*, *supra* note 207.

III. State Public Forums

A. State Legislation

In 1998, Kaiser conducted a study of the availability of external appeals of health plan decisions denying care. Thirteen states had already implemented external appeals, and in 1998 seven more states enacted external review legislation. In 1978, Michigan was the first state to implement external review, when legislation requiring independent medical experts to participate in disputes about medical necessity and appropriateness of care was enacted. n274 The scope of external review varies from medical necessity determinations, n275 to any consumer disputes, n276 to experimental and investigational therapies, n277 to emergency care. n278 External reviews are either provided by Independent Review Organizations ("IROs") n279 or by a state review body. n280 Either the state or the health plan covers the cost of the appeal. n281 Most states provide that external review decisions are binding. n282 For example, Arizona established a three-tiered appeal procedure that includes an informal and formal appeal within the health plan, followed by an independent external review. n283 Minnesota allows consumers to choose arbitration following internal appeal. n284 In New York, the state can impose financial penalties on MCOs for failure to comply with managed care requirements. n285

n274 *Kaiser Study*, *supra* note 13, at 1-2.

n275 States requiring external review of some or all medical necessity determinations are Arizona, Connecticut, Missouri, New Jersey,

New Mexico, Texas, and Vermont (mental health and substance abuse only), Maryland, New York, Tennessee, and Pennsylvania. *Id.* at 8-11, 53-55.

n276 States requiring external review of any consumer grievance are Florida, Michigan, Pennsylvania, Hawaii, and Minnesota. *Id.*

n277 States requiring external review of investigational therapy are California, Ohio (focus on therapies for terminally ill patients), and New York. *Id.*

n278 Rhode Island requires external review for prospective and retrospective emergency cases and prospective nonemergency medical necessity determinations. *Id.*

n279 States that use an IRO are Arizona, California, Connecticut, Missouri, New Jersey, New Mexico, Ohio, Rhode Island, Texas, Maryland, New York, Pennsylvania, Tennessee, and Vermont. *Id.*

n280 State review bodies include: Florida state employee panel advised by outside physicians; Michigan Health Department Task Force; and Vermont provider panel appointed by the Insurance Department. Hawaii uses a three person panel with a health plan representative, medical doctor, and insurance commissioner. Minnesota does not specify the review entity. *Kaiser Study, supra* note 13, at 8-11, 53-55.

n281 The health plan pays for the review in Arizona, California, New Jersey, Ohio, Rhode Island (health plan and consumer each pay half), Texas, Maryland, and New York. The state pays for review in Connecticut, Florida, Michigan, Missouri, and New Mexico. *Id.* at 45, 52-53.

n282 External reviews are binding in each of the thirteen states, with the exception of New Jersey and Pennsylvania. Maryland and Minnesota, however, did not specifically address this issue in their respective statutes. *Id.*

n283 ARIZ. REV. STAT. § 20-2536 (1999).

n284 MINN. STAT. § 62D.11 (1999).

n285 *Organizations Fined for Noncompliance with Bill of Rights Law*, Health Care Daily Rep. (BNA), May 29, 1998, at d3.

Most states require consumers to exhaust internal review procedures before using external review, n286 although exceptions do exist for emergencies and life threatening situations. n287 The time to appeal in the states ranges from thirty days to no limitation. n288 Most states either do not charge consumers fees for appeals, or waive the nominal appeals fee in hardship situations. n289 All states except Florida, which holds an informal hearing, conduct a review based on the file documentation. n290 Time limits for completion of review range from ten to sixty days, except for Florida, which allows 120 days. n291 However, actual times for reviews generally exceed the specified time limits. n292 All states with external appeal requirements, except Arizona, provide for expedited review, with time frames ranging from twenty-four hours to eight days. n293

n286 Missouri does not require consumers to exhaust all internal procedures, and the Minnesota statute does not specifically address this issue. *See Kaiser Study, supra* note 13, at 23. *See also* MINN. STAT. § 62D.11.

n287 Florida provides an exception for emergencies, Michigan for expedited review, New Mexico allows the state to waive, and Texas provides an exception for life threatening conditions. *Kaiser Study, supra* note 13, at 23.

n288 Consumers have fifteen days to appeal in Pennsylvania; thirty days to appeal in Arizona, Connecticut, New Mexico, Hawaii, and Maryland; forty-five days to appeal in New York; and sixty days to appeal in New Jersey, Rhode Island, and Tennessee. Florida allows

consumers one year to appeal and Michigan allows two years. There are no filing deadlines specified in the statutes of California, Missouri, Ohio, Pennsylvania, Texas, Vermont, and Minnesota. *Id.*

n289 Rhode Island requires the consumer to pay half the review cost. Connecticut and New Jersey charge the consumer \$ 25 to appeal, a fee that may be waived in the presence of financial hardship. Some other states with charges include Pennsylvania and Vermont, each of which charge the consumer \$ 25, and Tennessee, which charges the consumer \$ 100. *Id.* at 35.

n290 *Id.*

n291 *Id.*

n292 *Id.*

n293 Florida and Maryland have a time limit of twenty-four hours for life threatening cases and forty-five days for other expedited reviews. Expedited review must be completed in forty-eight hours in New Mexico, Pennsylvania, Rhode Island, and Vermont. They must be completed in seventy-two hours in Michigan. They must be completed in seven days in California, Tennessee, and Ohio. Finally, they must be completed in five to eight days in Texas. *Id.* at 39.

In general, the external appeals procedures are infrequently invoked. The thirteen states surveyed by Kaiser reported low numbers of appeals. For example, the 1997 Pennsylvania review rate was 0.04 cases per 1,000 enrollees, compared to a Medicare review rate of 1.650 per 1,000 enrollees in the same year. n294 Other states also have low appeal rates. n295 Health plans claim that low rates are due to consumer satisfaction, while state regulators attribute the low rates to lack of consumer awareness of the right to an appeal and the difficulty of appealing during an illness. n296

n294 *Id.* at 8-11, 52.

n295 In New Jersey there were eighty-two external appeals during the first sixteen months of the program, Connecticut had eighteen appeals in the first seven months, Rhode Island had fifty appeals in eighteen months, and Texas reported a total of 196 appeals. *See Health Department Issues First Report on External Appeals of HMO Coverage Decisions*, 7 HEALTH L. REP. (BNA), Sept. 17, 1998, at 37. In Maryland there were 69 appeals in the first few months. *See HMO Appeals: Maryland Process is Little Used*, 6 AM. POL. NETWORK, AM. HEALTH LINE, June 1, 1999, at 11.

n296 *Kaiser Study*, *supra* note 13, at 18.

Cases that go to external review are as likely to be decided for the consumer as for the health plan. n297 This result is consistent with the results of litigated coverage disputes. A recent quantitative analysis of cases from 1960 to 1994 found that courts ordered treatment in 57% of coverage cases. n298 This rate appears to be lower in ERISA cases. n299 More recently, courts have upheld contractual limits on coverage. n300 Courts are beginning to look at procedural protections to ensure that managed care processes are "fairly developed, disclosed, and implemented." n301

n297 *Id.* at 8-11.

n298 M.A. Hall et al., *Judicial Protection of Managed Care Consumers: An Empirical Study of Insurance Coverage Disputes*, 26 SETON HALL L. REV. 1055, 1062 (1996). *See also* G. Anderson et al., *When Courts Review Medical Appropriateness*, 36 MED. CARE 8, 1295-1302 (1998).

n299 *See* Anderson et al., *supra* note 298, at 1298 (having case decided in the federal appellate decreases the chance that "coverage would be found" to be present in the language of the contract).

n300 E. H. Moreim, *Medicine Meets Resource Limits: Restructuring the Legal Standard of Care*, 59 U. PITT. L. REV. 1, 46 (1997).

n301 Peter D. Jacobson, *Legal Challenges to Managed Care Cost Containment Programs: An Initial Assessment; Are the Courts Willing to Hold Health Plans Accountable for the Delay or Denial of Care?*, 18 HEALTH AFFAIRS 69, 82 (July/Aug. 1999).

The Kaiser study also found that regulators regard external review as a valuable and fair process. n302 The study showed that external reviews are useful for difficult cases, such as those involving requests for experimental treatment. n303 In addition, the review process has a sentinel effect, because feedback from external review can result in health plan changes. n304 As of September 30, 1999, there were twenty-eight states with independent external review procedures in place. n305

n302 *Kaiser Study*, *supra* note 13, at 6.

n303 *Insurance Regulation: Outside Reviews of Health Plan Decisions Helpful but Rarely Used, House Panel Told*, 6 Health Care Pol'y Rep. (BNA), Apr. 27, 1998, at 695.

n304 *Id.*

n305 States with external review procedures as of September 30, 1999, are: California, Colorado, Connecticut, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Louisiana, Maryland, Michigan, Minnesota, Missouri, Montana, New Jersey, New Mexico, New York, Ohio, Oklahoma, Pennsylvania, Rhode Island, Tennessee, Texas, Vermont, Virginia, and the District of Columbia. *See State Managed Care Patient Protections* (Oct. 1999) <<http://www.Familiesusa.org/hitmisup.htm>>.

A number of states have established ombudsman or consumer assistance programs. n306 As of September 30, 1999, there were ten states with these types of programs. n307 For example, Connecticut passed a Managed Care Accountability Act in 1999 that established an Office of Managed Care Ombudsman. n308 The role of the Connecticut ombudsman is to (1) assist consumers with health plan selection, (2) explain rights and responsibilities to consumers, (3) provide information regarding problems and concerns and make recommendations, (4) assist with complaints and appeals, (5) analyze laws and policies about healthcare consumers and make recommendations, (6) facilitate public comment on laws and policies, (7) ensure consumers have timely access to services, (8) review consumer records, (9) prepare notices about services to be posted in the workplace, (10) establish a toll-free number for consumer access, (11) pursue administrative remedies, (12) adopt regulations, and (13) perform other actions in accordance with the role. n309 Managed Care Ombudsman programs are intended to improve the efficiency of up-front grievance systems and reduce the confusion experienced by healthcare consumers. n310 Some states have implemented ombudsman programs for general healthcare consumers, while other states have implemented ombudsman programs for the Medicaid population. n311

n306 *Id.*

n307 States with an ombudsman or consumer assistant program include: California, Connecticut, Florida, Georgia, Illinois, Kentucky, Maine, Rhode Island, Vermont, and Virginia. *Id.*

n308 1999 CONN. LEGIS. SERV. 99-284 (West).

n309 *Id.*

n310 Ronald F. Pollack, *Ombudsman Programs* (visited Apr. 7, 2000) <<http://www.Familiesusa.org/omron.htm>>.

n311 States with ombudsman programs for Medicaid include California, Michigan, Minnesota, Oregon, Tennessee, Texas, and Wisconsin. *Id.*

B. Medicaid

The national government provides money for states to provide healthcare services to those who do not have sufficient income to pay for medical health services. States typically determine qualification for assistance by using a percentage of the national poverty level. In order to receive national funds, the state Medicaid plans must provide "an opportunity for a fair hearing before the State agency to any individual whose claim for medical assistance under the plan is denied or not acted upon with reasonable promptness." n312 Medicaid must inform the member of the right to the hearing and the hearing procedures. The hearing is required when a claim has been denied. n313 The BBA also requires Medicaid MCOs to establish internal grievance procedures by which members may challenge denials of coverage. n314

n312 42 U.S.C. § 1396(a)(3) (1999).

n313 42 C.F.R. §§ 431.210, 431.220.

n314 42 U.S.C. § 1396u-2(b)(2)(c)(4).

National Surveys have identified problems with the implementation of Medicaid grievance procedures. These problems include:

(1) Consumers are unaware of grievance procedures and are not informed of them when a service is denied at a plan/provider level; (2) Grievance procedures exist only on paper--managed care organizations are unaware of their notice and hearing obligations; (3) In-plan procedures, when they do exist are lengthy and confusing; (4) Complaints get buried at the plan level and when members try to complain to the state, they are simply referred back to the plan; (5) State Medicaid agencies lack ongoing mechanisms to monitor complaints and grievances and include them in their accountability loops; and (6) Managed care organizations that have not historically served the Medicaid population do not understand the constitutional and other fair hearing requirements that attach to the Medicaid program. n315

n315 Gordon Bonnyman & Michele M. Johnson, *Unseen Peril: Inadequate Enrollee Grievance Protections in Public Managed Care Programs*, 65 TENN. L. REV. 359, 374-75 (1998).

Medicaid appeals have been criticized as having broad and vague procedures. Recent proposed regulations provide for external quality review of Medicaid MCOs by external review organizations to assess compliance with provisions of the Balanced Budget Act. n316

n316 *Medicaid Program; External Quality Review of Medicaid Managed Care Organizations*, Proposed Rule, 64 Fed. Reg. 67, 223 (Dec. 1, 1999).

C. Uniform Laws

The National Association of Insurance Commissioner ("NAIC") has developed a number of model acts dealing with managed care. While the model acts are not binding, they do provide a uniform basis from which individual states may establish and enact statutes. NAIC has developed several model acts that serve as a basis for managed care appeal

legislation. These model acts include the Health Maintenance Organization Act, n317 the Utilization Review Model Act, n318 the Health Carrier Grievance Procedure Model Act, n319 and the Health Carrier External Review Draft Model Act. n320

n317 N.A.I.C. HEALTH MAINTENANCE ORGANIZATION MODEL ACT (1999).

n318 N.A.I.C. UTILIZATION REVIEW MODEL ACT (1999).

n319 N.A.I.C. HEALTH CARRIER GRIEVANCE PROCEDURE MODEL ACT (1999).

n320 N.A.I.C. HEALTH CARRIER EXTERNAL REVIEW MODEL ACT (Draft 1999). This Model Act was recently revised. *See* N.A.I.C. HEALTH CARRIER EXTERNAL REVIEW MODEL ACT (Draft Mar. 6, 2000).

The Health Maintenance Organization Act provides generally for grievance procedures. It requires every HMO to establish and maintain a grievance procedure to provide for the resolution of grievances. The Act requires HMOs to maintain records regarding grievances received and requires state oversight of grievance procedures. n321 Legislation similar to the HMO Model Act has been adopted in thirty states, n322 and related legislation has been adopted in twenty-three. n323 All state HMO statutes require HMOs to have some form of grievance mechanism. n324

n321 N.A.I.C. HEALTH MAINTENANCE ORGANIZATION MODEL ACT (11)(A).

n322 Alabama, Alaska, Arkansas, Colorado, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Louisiana, Maine, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, Rhode Island, South Carolina, Tennessee, Texas, Vermont, Virginia, West Virginia, and Wyoming. *See* ASPEN HEALTH LAW CENTER, MANAGED CARE STATE REGULATION 28-34 (1998).

n323 Arizona, California, Connecticut, Delaware, Florida, Idaho, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Hampshire, New York, North Carolina (POS), Oklahoma, Oregon, Pennsylvania, South Dakota, Utah, Washington, and Wisconsin. *Id.*

n324 *Id.* at 46-52.

The Utilization Review Model Act applies to health carriers who conduct utilization review procedures. n325 Appeal provisions of the Act provide that the carrier will notify the provider of an adverse determination within twenty-four hours. n326 The written notification of the adverse determination shall include the principal reasons for the determination, instructions for making an appeal, and instructions for requesting a written statement of the clinical rationale for the decision. n327 Requests for reconsideration go to the reviewer who made the initial adverse determination or to a clinical peer, if the reviewer is unavailable, for a decision within one working day of receipt of the request. n328 The health plan should establish standard appeals procedures that include provisions for evaluation by an appropriate clinical peer not involved in the initial adverse determination, decisionmaking within twenty days of the request for appeal, and a written appeal decision with pertinent information. n329 The Model Act also provides for expedited appeals to occur within seventy-two hours, n330 conducted by a clinical peer who was not involved in the original determination. n331

n325 The Act holds the health carrier responsible for compliance with its provisions whether the carrier implements those standards directly or delegates the responsibility by contract. This Model Act confuses the terms grievance and appeals by instructing the member to file a grievance (appeal) for a claims denial. For purposes of this discussion, however, the word appeal will be used to mean a request for

review of an adverse decision even though the word "grievance" is used to mean the same thing in the act. *See* N.A.I.C. UTILIZATION REVIEW MODEL ACT (4).

n326 The Act also provides that if a carrier notifies a beneficiary of a decision by telephone, the carrier will provide written or electronic notification to the covered person within one working day of the telephone notification.

n327 This rationale shall be provided to any party who requests it through appropriate procedures. *See id.* at (11)(A).

n328 *Id.* at (10).

n329 Information that should be included includes the name, title, and qualifying credentials of the person evaluating the appeal, the reviewer's understanding of the reason for the request, the reviewer's decision in clear terms, including the medical rationale, evidence, or documentation used to arrive at the decision (including clinical review criteria), and the procedure for initiating an appeal. *Id.* at (11)(A).

n330 Expedited appeals are required when the standard time frame would "seriously jeopardize the life or health of a covered person or would jeopardize the covered person's ability to regain maximum function." This appeal also includes clinical peer evaluation for all requests concerning an admission, availability of care, continued stay, or health services for emergency care. *Id.* at (11)(B).

n331 The health carrier must provide access within one day to the clinical peer who performed the review. *Id.* at (11)(B)(6). The plan should send a confirmation of the expedited decision within two days of the decision. The Act also requires confidentiality. *Id.* at (13).

The Health Carrier Grievance Procedure Model Act discusses appeals provisions. n332 The Act requires the health carrier to maintain registers that document the dates of appeals, the dates of the review or hearing, resolution at each level, the date of resolution, and the name of the person for whom the grievance was filed. Appeal provisions cover first and second level reviews. Carriers should make first level reviews of adverse determinations within twenty working days. n333 There is no right to attend a review, but appellees can submit written materials n334 containing pertinent information. n335 Second level grievance review provides for the right to have notice and to appear in person before a representative of the health carrier for determination by a review panel. n336 The carrier should hold the panel review meeting, at a reasonably accessible location, within forty-five days of receipt of the request. n337 Specifically, the consumer can attend the second level review, present her case to the panel, submit supporting material before and after the review meeting, ask questions of any representative of the health carrier, and be assisted or represented by a person of her choice. n338 The carrier should send a written decision within five days of the review meeting. n339 The Model Act also provides for expedited reviews to occur within seventy-two hours, for reasons similar to other external review provisions. n340

n332 Again the Act's definition of "grievance" to mean a request for a new decision to reverse and initial adverse determination confuses the words grievance and appeal. For purposes of this discussion, "appeal" will be used to denote a request for a new decision overturning an initial adverse determination. *See* HEALTH CARRIER GRIEVANCE PROCEDURE MODEL ACT.

n333 The initial review period can be extended an additional ten days if the health carrier provides written notice to the covered person of the need for the extension and the reason for the delay. *See id.* at (7)(B)(1).

n334 Information about who is coordinating the appeal must be provided to a person requesting it within three days. *Id.* at (7)(B)(2).

n335 Pertinent information includes the names and credentials of those participating in the process, the reviewers' understanding of the grievance, the reviewers' decision in clear terms, the evidence used in making the decision, instructions for clinical rationale or review criteria, and a statement about how to obtain a second level review. *Id.* at (7)(C).

n336 The majority of the panel shall be comprised of individuals not previously involved in the determination. A previously involved

person, however, may be a member of the panel or appear before the panel to present information. Furthermore, the majority of persons on the panel should be healthcare professionals who have appropriate expertise. HEALTH CARRIER GRIEVANCE PROCEDURE MODEL ACT (8).

n337 In cases in which a face to face meeting is not possible, the carrier must offer the person the opportunity to communicate through conference call, video conferencing, or other technology at the Carrier's expense. *Id.* at (8)(C).

n338 If the health carrier decides to have an attorney present, it must give the consumer fifteen days notice of this fact. *Id.*

n339 The decision shall include the names and titles of members of the panel, a statement of the nature of the grievance, rationale for the panel's decision, evidence considered in making the decision, instructions for obtaining a written statement of rationale, and notice of the right to contact the insurance commissioner if dissatisfied. *Id.*

n340 Expedited reviews can occur when normal review time frames would "seriously jeopardize the life or health of a covered person or would jeopardize the covered person's ability to regain maximum function." Expedited reviews should be evaluated by a clinical peer. Expedited reviews are required for all requests concerning an admission, availability of care, continued stay, or health services for a covered person who has received emergency services but has not been discharged from a facility. Expedited review of *retrospective* adverse determinations is not permitted. *Id.* at (10).

NAIC also published the Health Carrier External Review Model Act in draft form. n341 It provides for an external review upon written request and upon exhaustion of the internal grievance processes. Consumers shall request standard external review within sixty days after receipt of a notice of adverse determination. The review should take place within five days of receipt of the request for review by the individual. n342 However, carriers must conduct external review within seventy-two hours if the consumer's medical condition or circumstance requires it. n343

n341 N.A.I.C. HEALTH CARRIER EXTERNAL REVIEW MODEL ACT (Draft 1999).

n342 *Id.* at (8).

n343 *Id.* at (9).

A March 2000 revision of the Draft External Review Model Act includes expanded language regarding the medical or scientific evidence that is required to make a medical necessity determination or decision about whether a service or treatment is experimental. n344 It also includes expanded language regarding experimental or investigational treatment, which provides for external appeal for these denials by the person or their representative when the physician certifies in writing that the requested services would be less effective if not promptly initiated. n345

n344 NAIC HEALTH CARRIER EXTERNAL REVIEW MODEL ACT (Draft Mar. 6, 2000).

n345 *Id.*

This Draft Model Act generally provides for three different alternatives for states to implement external review for experimental or investigational treatment decisions. The first alternative requires a request for external review to go through the Insurance Commissioner, who screens it for eligibility, then forwards it to an IRO that makes a recommendation back to the Insurance Commissioner. The Commissioner then reviews the recommendation in light of the person's health coverage provisions, before notifying the person of the decision. The second option is to request external review with the Insurance Commissioner who screens the request and forwards it to the IRO for review. The third option requires the request for external review to go to the health carrier, who then assigns an IRO to review the

case. n346

n346 *Id.*

D. Procedural Protections and Fundamental Fairness

Time frames for managed care appeals vary from state to state. Furthermore, many states require that consumers exhaust any and all internal reviews prior to external review. This internal process may take months or years before the consumer ever reaches a truly neutral forum. The model acts establish time frames for reviews and appeals, yet states may alter these times. External appeal processes adopted in a number of states encourage decisionmaker neutrality. The Acts encourage decisionmaker neutrality through the use of external appeal in a number of states. Appeal processes in some states have established managed care ombudsman or consumer advocates to assist the consumer with the appeal process. Formal use of ADR processes still remains limited and at the discretion of the parties. There also are no real incentives to encourage early resolution of denial of care disputes, because most consumers must exhaust layers of internal appeals before reaching an outside appeal entity. n347

n347 *Kaiser Study, supra* note 13, at 23.

Fundamental fairness in state public forums is still evolving. While a trend toward adopting external appeal requirements is emerging, there is no consensus on minimal procedural protections, nor are people treated equally. State by state differences in approaches may further accentuate differences in handling appeals, because people may now "forum shop" by moving to a state with more procedural protections. States' responses to contract exclusions or medical necessity denials take the form of mandated benefit laws. These laws and their protections vary by state. State approaches to balancing power on appeal and making the system easy to use have varied, but remain more focused on specific responses to abuses than to widespread reformation of systemic inadequacies. Finally, health plan accountability varies from state to state depending upon state reporting and oversight laws for health plans. n348

n348 *Id.*

IV. Private Industry Accreditation

MCO accreditation is a voluntary process. Industry competition often drives the need for accreditation because many large employers will only contract with accredited plans. n349 Other incentives for accreditation arise because accredited government contractors are considered "deemed" to have met the government regulatory requirements. This accreditation results in less government oversight. An M + C plan is deemed to have met government regulatory requirements if it is accredited and if the accrediting body adopts the standards of M + C. n350

n349 National Committee for Quality Assurance, *Overview* (visited Apr. 8, 2000) <<http://www.ncqa.org/pages/main/overview3.htm>> [hereinafter "NCQA *Overview*"].

n350 QISMC develops standards that are similar to NCQA accreditation standards. If an entity is NCQA accredited, it must still meet QISMC standards in order to qualify for Medicare + Choice. *See Gladieux, supra* note 6, at 111-12.

A. National Committee for Quality Assurance

NCQA is a private, nonprofit organization dedicated to assessing and reporting the quality of MCOs. It does this by

establishing standards for accreditation, conducting accreditation reviews, and publishing results of accreditation reviews. n351 As of the end of 1999, forty of the five hundred plans NCQA had reviewed for their HMO/POS products were categorized as excellent. n352 In March 1999, NCQA announced that independent external appeals would be integrated into the year 2000 accreditation standards. n353 Other revised or new standards for the year 2000 include requiring an appeal to an IRO after internal appeal processes are complete. n354 MCOs are also required to involve practicing medical specialists in the appeals review process. n355

n351 NCQA *Overview*, *supra* note 349.

n352 NCQA *Recognizes Nations' Best Health Plans with Introduction of New 'Excellent' Accreditation Status* (Oct. 18, 1999) <<http://www.ncqa.org/pages/communications/news/excellentrel.htm>>.

n353 NCQA *to Require Health Plans to Offer Independent Appeals; Accreditation 2000 Draft Focuses on Consumer Issues* (Mar. 16, 1999) <<http://www.ncqa.org/pages/communications/news/a2krel.html>>.

n354 NCQA, STANDARDS FOR THE ACCREDITATION OF MCOS 2, Standard Rights Responsibilities ("RR") 3.6 (1999) (effective July 1, 2000 to June 30, 2001) [hereinafter NCQA ACCREDITATION STANDARDS].

n355 *Id.* at 3, Standard RR 3.5.

NCQA has established standards for utilization management timeliness for precertification decisions, n356 concurrent review, n357 and retrospective review. n358 The rationale for these time frames is to minimize disruption of healthcare. n359 The member or the physician can initiate expedited appeals for acute or urgent conditions. n360 The plan must make expedited appeals decisions no later than three calendar days after the review commences, with written confirmation in two working days. n361 When a plan sends a denial notice at any level, it should include the reason for the denial, including utilization management criteria or benefit provisions, n362 and notice of further appeal rights. n363 A physician reviewer must also be available to physicians by phone to discuss the decision. n364

n356 NCQA precertification decisions for nonurgent care must be made within two working days of obtaining all the necessary information and those involving urgent care within one calendar day. Written or electronic confirmation of the decision must be provided within two working days of the decision. If the decision is to deny services, notice of appeal rights (including expedited appeals) should be included with the decision. *Id.* at 54, Standard Utilization Management ("UM") 4.1.1-4.1.6.

n357 NCQA concurrent review decisions for inpatient, outpatient, and residential behavioral care should be made within one working day of making the decision. Ambulatory care decisions should be made within ten working days of obtaining all information. Notice of decision should be given within one working day of the decision. The denial notice should include information about appeals, including expedited appeals. *Id.* at 54-55, Standard UM 4.1.7-4.1.10.

n358 NCQA retrospective review decisions should be made within thirty working days of obtaining all the necessary information and written notice of the decision should be sent within five working days of making the decision. *Id.* at 55, Standard UM 4.1.11-4.1.12.

n359 *Id.*

n360 *Id.*, Standard UM 4.2.1.

n361 *Id.*, Standard UM 4.2.

n362 NCQA ACCREDITATION STANDARDS, *supra* note 354, at 56, Standard UM 6.2.

n363 *Id.*, Standard UM 6.3.

n364 *Id.*, Standard UM 6.1.

Appeal processes required by NCQA include internal first and second level appeals and external appeals. n365 First level appeals require plans to send notice of the appeal process within five working days of receiving a request for the appeal, documentation of the substance of the appeal, and full investigation of the substance of the appeal. n366 The plan must make the appeal decision within thirty working days, n367 arrange for the appeal to be decided by someone not involved in the initial decision, n368 and provide notice of the decision and further rights to appeal. n369 The second level of appeal also requires full investigation and documentation. n370 A panel comprised of individuals not involved in the previous proceedings makes this decision. n371 The member has the right to appear before the panel or communicate by conference call or other technology. n372 The member has the right to be represented by a practitioner or another member at the hearing. n373 The panel must make a decision within thirty working days of receiving the request, and send a written notice of the decision within five working days of completing the review. n374

n365 *Id.* at 81-88, Standards RR 3.1 to RR 4.3.

n366 *Id.* at 82-3, Standards RR3.2.1 to RR 3.2.3.

n367 NCQA ACCREDITATION STANDARDS, *supra* note 354, at 83, Standard RR 3.2.4.2.

n368 *Id.*, Standard RR 3.2.4.1.

n369 *Id.*, Standard RR 3.2.5.

n370 *Id.*, Standards RR 3.3.1 & 3.3.2.

n371 *Id.*, Standard RR 3.3.3.1.

n372 NCQA ACCREDITATION STANDARDS, *supra* note 354, at 83-84, Standards RR 3.3.3.2 & RR 3.3.3.4.

n373 *Id.* at 84, Standard RR 3.4.

n374 *Id.* at 83-84, Standard RR 3.3.3.3 & 3.3.4.

NCQA requires that external review be available when the member is appealing a decision based on medical necessity, n375 after two levels of internal review have resulted in denial, when the internal review time limits have been exceeded without good cause, or when the MCO has elected to bypass one or both levels of internal review. n376 The IRO will conduct a thorough and independent review and make a decision that is binding on the MCO. n377 The members can have a representative act on their behalf and are not required to pay costs or fees of the review. n378 The MCO is required to use the information from the external reviews to review its medical necessity decisionmaking process. n379

n375 *Id.* at 84, Standard RR 3.6.1.1.

n376 *Id.*, Standard RR 3.6.12.

n377 NCQA ACCREDITATION STANDARDS, *supra* note 354, at 85-86, Standards RR 3.6.3.1, 3.6.3.1.2 & 3.6.3.5.

n378 *Id.* at 86, Standard RR 3.6.3.3 & RR 3.6.3.4.

n379 *Id.*, Standard RR 3.6.3.6.

B. Joint Commission on Accreditation of Healthcare Organizations

The Joint Commission on Accreditation of Healthcare Organizations ("JCAHO") has accredited hospitals for a number of years. It has also established accreditation standards for healthcare networks and does some accreditation in this area. n380 These standards are intended for managed care plans, integrated delivery networks, provider-sponsored organizations ("PSOs"), preferred provider organizations ("PPOs"), specialty networks, provider-hospital organizations ("PHOs"), and other networks. n381 The member rights and responsibilities standards provide for member protections when disagreements concerning care or treatment decisions arise. n382 Networks accredited by JCAHO are required to employ the following methods in resolving disagreements about care or treatment decisions:

- . describe the treatment authorization process;
- . identify treatment decisionmakers;
- . obtain information about investigation procedures provided by the network;
- . provide timely notice of treatment authorization denials;
- . list basis and reasons for adverse determinations;
- . explain how to appeal;
- . define time frames for appeal; and
- . establish appeal time frames related to urgency, and inform members of steps available to resolve a disagreement, such as internal grievance procedures, arbitration and legal proceedings. n383

n380 JCAHO, COMPREHENSIVE ACCREDITATION MANUAL FOR HEALTH CARE NETWORKS, MANAGED CARE PLANS, INTEGRATED DELIVERY NETWORKS, AND PROVIDER SPONSORED ORGANIZATIONS (JCAHO 1998-2000) [hereinafter JCAHO STANDARDS].

n381 *Id.* at 2.

n382 *Id.* at 5.

n383 *Id.* at 96, Standard RI.2

The network must also provide for the receipt and resolution of member complaints and grievances in a timely manner, including an appeal process. n384

n384 The network must establish procedures for complaints and grievances, respond in a timely manner and review aggregate reports. *Id.* at 104-05, Standard RI.5.

C. Utilization Review Accreditation Committee

The Utilization Review Accreditation Committee ("URAC") is an accrediting organization that was instituted to "promote accountability of health care organizations." URAC accreditation programs are developed by expert committees with representation from various healthcare parties, including employers, consumers, providers, regulators, and healthcare organizations. URAC accreditation programs include Case Management Organization Standards, Health Plan Accreditation Standards, Health Network Standards, and Health Utilization Management Standards. Each accreditation program includes grievances and appeals as a category of accreditation review. n385

n385 The seven accreditation categories include: Scope of Services, Personnel, Operations/Process, Quality Improvement, Delegation of Responsibilities, Confidentiality, and Grievances & Complaints. *See Overview of URAC Accreditation Programs and Standards*, (visited Apr. 8, 2000) <<http://www.urac.org/summaries.htm>> [hereinafter *URAC Standards*].

The Case Management Organization Standards require entities to have policies and procedures that refer complaints outside the scope of case management responsibilities to the appropriate entity. These policies and procedures must include the rights and responsibilities of all parties, the time frames for action, and a description of how notification of the complaint process will take place. n386

n386 *Id.*

Health Plan Accreditation Standards apply to integrated networks, such as HMOs and risk-bearing PPOs. These standards require that the plan offer complaint and grievance processes to both patients and providers. The grievance process must include two levels of review. Plans must offer external review for utilization management decisions that they do not resolve by internal grievance and appeal procedures. n387

n387 *Id.*

Health Network Standards apply to PPOs and specialty networks. The URAC standards are the most commonly used benchmark to assess PPO quality. The network standards require the network to maintain a complaint and grievance process for patients and providers, which includes implementing a resolution process for complaints and grievances. n388

n388 *Id.*

The Health Utilization Management Standards apply to utilization review activities. The standards require the organization to establish a three-step process for determination of medical necessity. First, licensed healthcare professionals must perform the initial clinical review. Second, review by a physician or provider, similar to the one requesting services, provides peer clinical review and renders a clinical opinion regarding professional services. The reviewer must be available to discuss the review determination with the treating provider within one business day of the determination. Appeals consideration is the third step. A clinical peer who is board-certified and is in the same specialty as the provider requesting review must consider the appeal. Either the patient or provider may appeal. The organization

must provide for expedited appeals for cases involving ongoing or imminent medical care. The Utilization Management Organization must follow clinical review criteria based on sound clinical principles during all phases of the review. If the member requests them, the organization must provide the criteria upon which the denial is based. n389

n389 *Id.*

D. Procedural Protections and Fundamental Fairness

One procedural protection that is available through all private accreditation processes is specific time frames for review. Another procedural protection is the provision for expedited time frames for urgent appeals when the life or health of the consumer will be impacted by a delayed decision. Decisionmaker neutrality is encouraged through identification of the decisionmaker and by provisions requiring notice of the basis and reasons for decisions. The accrediting agencies require that peer review of medical necessity decisions be based on sound clinical principles and consider clinical peer involvement an important aspect of the process. Accreditation appeal processes focus on provisions of notice to the consumer of the appeal processes themselves, but do not directly focus on ways to make the appeals processes more accessible, the use of alternative dispute resolution techniques, or incentives for resolving the dispute earlier in the process. n390

n390 NCQA ACCREDITATION STANDARDS, *supra* note 354; JCAHO STANDARDS, *supra* note 380; URAC Standards, *supra* note 385.

Application of fundamental fairness criteria to private accreditation processes demonstrates that further evolution is needed for the processes to be fundamentally fair. While there are similarities between the accreditation standards, there is no generally accepted minimum procedural protection. Nonetheless, the review of the health plan process by an external body may create incentives to appropriately and fairly administer the appeals process.

V. Private Forums

Dispute resolution organizations are private organizations that promote dispute resolution through processes that differ from those of a court. ADR is a form of privatized justice. The need for informal processes must be balanced against procedural protections to ensure that the interests of the parties are adequately served in the private forum. n391 Dispute resolution typically takes several forms, including mediation, arbitration, Early Neutral Evaluation ("ENE"), and Summary Jury Trials. There are also variations, including minitrials in which both sides present oral arguments for their positions and "med-arb," in which mediation is tried first, followed by arbitration if a solution cannot be reached. n392 When compared with litigants, ADR participants are often more satisfied with the process because they maintain a sense of control over the dispute resolution process. n393 ADR can be useful in managed care because it promotes early in-person communication with the decisionmaker, provides the consumer the opportunity to express needs and concerns, empowers the consumer, provides for multiple options, provides an additional forum for problem solving, and more quickly resolves disputes. n394 Some of the disadvantages of ADR in managed care include loss of procedural due process rights available in court, delay of the appeal process, compromised decisions, failure to enhance power imbalances, and it enables the industry to delay needed reforms to the system. n395

n391 Jack M. Sabatino, *ADR as "Litigation Lite": Procedural and Evidentiary Norms Embedded within Alternative Dispute Resolution*, 47 EMORY L. J. 1289, 1294-96 (1998).

n392 *Id.* at 1296, 1299.

n393 *Id.* at 1344.

n394 INTERDISCIPLINARY ROUNDTABLE, *supra* note 81, at 121.

n395 *Id.* at 120.

There are a number of private dispute resolution organizations that facilitate dispute resolution. These include the American Arbitration Association, Center for Health Dispute Resolution, Center for Public Resources, Institute for Dispute Resolution, Society of Professionals in Dispute Resolution, and JAMS. n396 Some of the procedural protections that these private organizations provide include: (1) notice of the dispute and the process to resolve the dispute; (2) exchange of information about the dispute; (3) opportunity to present information to the neutral; (4) attendance at the hearing or conference and the sharing of information; and (5) other protections similar to court procedures. n397

n396 Sabatino, *supra* note 391, at 1301.

n397 *Id.* at 1303.

A. American Arbitration Association

The AAA is nonprofit corporation founded in 1926. It specializes in business-related arbitration. In 1992, the AAA established Health Care Claims Settlement Procedures. n398 Participation in the program, which provides for arbitration or mediation, is voluntary. The parties have the right to be represented by an attorney or other person at any time.

n398 See Josef Rohlik, *Arbitration as a Model for Resolution of Health Care Disputes between Health Care Professionals and Health Care Organizations*, 41 ST. LOUIS U. L.J. 1005, 1009 (1997).

Mediation rules provide that the party requesting the mediation give a brief statement regarding the nature of the dispute and provide this statement to the other party and to the AAA. The parties choose a mediator from the AAA panel. If the parties cannot agree, AAA will appoint a qualified mediator. The session is scheduled for a date, time, and place agreeable to the parties and the mediator. Ten days before the mediation session, the parties provide the mediator with statements of their positions. The mediator does not have authority to impose settlement, but helps the parties reach a satisfactory resolution of the dispute. The mediation sessions are private and confidential, and no stenographic record is made of the mediation. Parties share the cost of the mediator. n399

n399 American Arbitration Association, *Health Care Claims Settlement Procedures, A Program of the American Arbitration Association* (effective July 1, 1992) <http://www.adr.org/rules/commercial/health_care_sp.html> [hereinafter *AAA Health Procedures*].

AAA arbitration rules for healthcare claims provide for a panel of professionals to serve as arbitrators. The party requesting the arbitration completes a request for arbitration form and pays the filing fee. The opposing party has ten days from receipt of the notice by AAA to file an answering statement. Either party must make any new or different claim in writing and file it with AAA, with notice to the other party before the arbitrator is appointed or, subsequently, with the arbitrator's consent. The opposing party has ten days to respond to a new claim. The AAA provides the parties with a list of names of arbitrators from which to choose. Parties have ten days to select an arbitrator from the list and return it to AAA. If the parties fail to agree on an arbitrator, AAA will select one. The arbitrator must disclose any conflict of interest. At the request of any party or AAA, an administrative conference will be scheduled within ninety

days of the filing of the claim. The parties exchange information at this preliminary hearing and establish the breadth of discovery. The AAA sends notice of hearing ten days prior to the hearing, and the parties have the right to representation or the presence of an interpreter. The arbitrator has the discretion to allow or exclude the testimony of any witness at the hearing. At the hearing, both parties have the opportunity to present testimony, witnesses, and exhibits. There is no direct communication between the parties and arbitrator other than at the oral hearing. The arbitrator judges the materiality of information presented. Based on the arbitrator's initiative or for good cause, the arbitrator may reopen the hearing. The arbitrator may grant any remedy or relief deemed just and equitable within the scope of the agreement of the parties. The AAA delivers this award in writing to the parties. n400 As of 1997, there had been approximately three hundred arbitration cases administered under the AAA Health Care rules. n401

n400 *Id.*

n401 Rohlik, *supra* note 398, at 1013.

B. Center for Health Dispute Resolution

CHDR is the private entity that contracts with HCFA for reconsideration of appeals in Medicare Managed Care and M + C. It is an independent agency that involves legal and medical professionals as part of its decisionmaking. n402 CHDR provides impartial "on-the-record" or "in-person" administrative review. The processes used include mediation and arbitration. Communication of the decision includes a written decision that includes the medical rationale, contract interpretation, and regulatory analysis in language the health plan member can understand. n403 Since contracting with Medicare in 1989, CHDR has handled 55,000 cases arising from every state and from hundreds of health plans. n404 It also conducts state external reviews for Arizona, Connecticut, and Rhode Island. n405

n402 The Center for Health Dispute Resolution (visited Apr. 8, 2000) <<http://www.healthappeal.com>>.

n403 The Center for Health Dispute Resolution, *Commercial External Review* (visited Apr. 8, 2000) <<http://www.healthappeal.com/commercial.htm>>.

n404 *Plan Regulation: External Appeals Should Be Available For All Coverage Disputes, Reviewer Says*, Health Care Daily Rep. (BNA), Apr. 19, 1999, at d7.

n405 *Id.*

CHDR facilitates four features of the Medicare Managed Care Appeal model: (1) all claim denials are subject to appeal, including medical necessity denials and other benefit based denials; (2) the appeals process is linked to Medicare coverage policy; (3) Medicare appeal rights are widely publicized; and (4) the Medicare appeal model provides for automatic independent review by a team that includes physicians. n406

n406 *Hearing on Patient Appeals in Health Care Before the Subcomm. on Health of the House Committee on Ways and Means*, 105th Cong. (Apr. 23, 1998) (statement of David A. Richardson, Jr., President, The Center for Health Dispute Resolution), *available at* <<http://www.waysandmeans.house.gov/health/105cong/4-23-98/4-23rich.htm>>.

For Medicare and M + C appeals, CHDR makes reconsideration decisions in conformance with HCFA policies, regulations, and manuals. CHDR assigns a review coordinator to coordinate the review with the health plan and HCFA as needed. CHDR also provides information to carriers through a summary of difficult and frequently occurring cases that arise due to confusion about the rules regarding care. n407 The process for reopening of reconsiderations is similar

to Medicare and based on the discretion of CHDR. n408 The CHDR Medicare Managed Care Reconsideration Process Manual provides for expedited considerations within seventy-two hours. n409 Once a decision has been made by CHDR, the health plan has sixty days within which to implement the decision. The health plan must mail a statement of compliance to CHDR within this time frame. CHDR does not conduct or provide administrative hearings as part of the determinations, but can provide information to the ALJ or appeal council hearings upon request. n410

n407 Center for Health Dispute Resolution, Reconsideration Notes, Vols. 1-3, (visited Apr. 8, 2000) <<http://www.healthappeal.com/news.htm#reconnotes1>>.

n408 Reopening is at the discretion of CHDR and only for "sufficient cause," which can include errors of evidence, clerical errors, receipt of information not known at the time the reconsideration was processed, or when fraud is suspected. *Id.*

n409 An expedited appeal must be decided within seventy-two hours. The health plan has twenty-four hours to submit the appeal to CHDR. Center for Health Dispute Resolution, *CHDR Medicare Managed Care Reconsideration Process Manual* (visited Apr. 8, 2000) <<http://www.healthappeal.com/medicare.htm#M+CManuals>>.

n410 *Id.*; Center for Health Dispute Resolution, *Instructions for Preparation and Submission of HCFA Level Reconsiderations* (visited Apr. 8, 2000) <<http://www.healthappeal.com/medicare.htm#M+CManuals>>.

CHDR's M + C process became effective January 1, 1999, and includes additional procedural safeguards including a seventy-two hour time limit for expedited reconsideration. n411 Other time frames for review are, ten working days for standard service reconsideration, and fifteen working days for standard claims reconsideration. CHDR notification of a decision includes an explanation of the right to appeal the decision, the reasons for the decision, coverage basis for the determination, and other relevant information in language the consumer can understand. Once a decision has been made, health plans have sixty days to file a statement of compliance with CHDR. n412

n411 CHDR may request any additional information needed to make a decision. Health plans have specific time frames within which to comply with information requests. *Id.*

n412 *CHDR Medicare Managed Care Reconsideration Process Manual*, *supra* note 409; *Instructions for Preparation and Submission of HCFA Level Reconsiderations*, *supra* note 410.

C. Center for Public Resources Institute for Dispute Resolution

The Center for Public Resources ("CPR") Institute for Dispute Resolution is a nonprofit organization comprised of major corporations and law firms that promote alternatives to litigation, such as industry-specific programs to resolve disputes through mediation and arbitration. CPR rules of procedure are similar to the Federal Rules of Civil Procedure. n413 In 1995, CPR in conjunction with the American Hospital Association ("AHA"), prepared Model Procedures that included procedures for resolving subscriber-payor disputes. n414 The goal of the proposed procedure was to "create a forum that is credible, informative and offers subscribers a day in court, while avoiding the high costs of litigation." n415 For cases involving amounts under \$ 10,000, or disputes in which care has already been rendered but reimbursement was denied, CPR recommends mandatory mediation-arbitration agreed to in advance by contract. n416 This process can be binding or nonbinding.

n413 Sabatino, *supra* note 391, at 1303.

n414 AMERICAN HOSPITAL ASSOCIATION & CPR INSTITUTE FOR DISPUTE RESOLUTION, MANAGING CONFLICT IN

HEALTH CARE ORGANIZATIONS: A HANDBOOK 53-55 (1995) [hereinafter CPR HANDBOOK].

n415 *Id.* at 53.

n416 *Id.*

For matters over \$ 10,000, CPR recommends the following Conflict Resolution Management ("CRM") Model. n417 The process begins with written notice to invoke the CRM process. n418 The process only begins after the "payer's administrative review procedures" are exhausted. n419 The parties select one to three neutrals, depending on the size of the claim, within thirty days of receiving notice of the intent to arbitrate. n420 Mediation must be held within fifteen days of selection of the neutral. n421 The mediation is confidential n422 and the consumer has the right to be represented by an attorney, physician, or other person. n423 CPR Mediation Model Rules provide for the submission of a written statement summarizing the case prior to mediation. n424 As part of the mediation, parties are expected to initiate settlement offers. n425 If the parties are unable to agree on settlement terms, the mediator may submit a settlement proposal that is fair for both parties and give the parties an assessment of the likely outcome of the case if it were to go to trial. n426 If the parties still cannot reach an agreement, the mediator will discuss arbitration options, but will not serve as the arbitrator unless all parties agree. n427

n417 *Id.*

n418 *Id.* at 54.

n419 CPR HANDBOOK, *supra* note 414, at 54.

n420 *Id.*

n421 *Id.*

n422 *Id.* at D-10.

n423 *Id.* at 54.

n424 CPR HANDBOOK, *supra* note 414, at D-12.

n425 *Id.* at D-11.

n426 *Id.*

n427 *Id.* at D-12.

By agreement, in the initial contract or after the dispute has arisen, the parties can proceed to binding arbitration. n428 The CPR "Non-Administered Arbitration Rules" provide for notice of arbitration by the party initiating the proceeding, which must indicate the nature of the dispute, the arbitration provision on which the notice is based, the general nature of the claim, and the relief requested. n429 The respondent has twenty days to file a notice of defense. n430 The arbitrator is selected from the CPR Panel by the parties or may be appointed by CPR. n431 A new neutral, an originally selected neutral who observed but did not participate in the mediation, or a neutral who conducted the

mediation can conduct the arbitration. n432 The parties will then proceed with a preliminary hearing, discovery, and an arbitration hearing similar to other arbitration proceedings. n433 By agreement of the parties, the award can be binding.

n428 *Id.*

n429 CPR HANDBOOK, *supra* note 414, at E-7.

n430 *Id.*

n431 When three arbitrators are chosen, each party appoints one and then those two arbitrator choose the third arbitrator, who chairs the panel. There are also provisions to challenge and replace arbitrators. *Id.* at E-8 to E-12.

n432 *Id.* at 54-55.

n433 *Id.*

D. American Health Lawyers Association

The American Health Lawyers Association ("Health Lawyers") provides dispute resolution services for healthcare industry disputes, including disputes between providers and community members. It has established Rules of Procedure for Arbitration and Mediation. Parties may request mediation, arbitration, or med-arb. n434

n434 AMERICAN HEALTH LAWYERS ASSOCIATION ALTERNATIVE DISPUTE RESOLUTION SERVICE, RULES OF PROCEDURE FOR MEDIATION & RULES FOR ARBITRATION (rev. 1999), *available at* <<http://www.healthlawyers.org/adr.htm>> [hereinafter HEALTH LAWYERS PROCEDURES].

The rules provide arbitration procedures, which govern any arbitration unless otherwise agreed to by the parties. The Health Lawyers rules provide that the parties will select an arbitrator from an arbitration panel. One arbitrator decides the case unless the parties agree otherwise. When there is more than one arbitrator and they are not all in agreement, the majority decision prevails. n435 Unless otherwise specified by contract, the parties will request and receive a list of seven arbitrators from which to choose. If a potential arbitrator fails to respond within the specified time, the next name on the list will be used. n436 The arbitrator is required to disclose any conflicts of interest that would affect impartiality at the outset. n437

n435 *Id.* Rule 1.05.

n436 *Id.* Rules 2.02 & 2.03.

n437 *Id.* Rule 2.05.

Once the selection process is complete, the arbitrator or one of the parties, by request, may schedule a preliminary hearing or preliminary teleconference to consider any matters that will expedite the process. These matters might include the schedule for the production of documents, the identity of witnesses to be called, and the schedule for other discovery. The arbitrator can allow discovery as necessary to ensure a full and fair presentation of the issues. The parties then agree on a location for the arbitration hearing. If they cannot agree, it will be held at the location indicated on the request for ADR form, or be determined by the arbitrator. n438 The arbitrator will provide notice of the hearing time,

date, and place. Parties may be represented by counsel or other authorized representative. If either party desires a stenographic record of the hearing, he shall make arrangements and bear the costs of the stenography and give notice to all other parties. The arbitrator can determine the propriety of the attendance of any person at the hearing. The hearing will include oral or written statements of the parties to clarify information. The parties can present witnesses. The arbitration can proceed even if a party who has received notice fails to appear. The arbitrator has discretion regarding evidence to be admitted during the proceeding. Once the hearing is completed, the arbitrator has thirty days to render an award. n439

n438 *Id.* Rules 4.01, 4.02, & 4.03.

n439 HEALTH LAWYERS PROCEDURES, *supra* note 434, Rules 4.04-4.07, 4.10-4.11 & 6.04.

The Health Lawyers rules also provide for expedited procedures. The expedited procedures provide for telephone notice and communication. The arbitrator will give notice of the hearing seven days in advance by telephone and the hearing will be held within thirty days from the selection of the arbitrator. There is no provision for discovery under the expedited procedure. The hearing must be completed within one or two consecutive days. The decision should be complete within twenty days of the hearing. n440

n440 *Id.* Rules 5.01-5.03 & 6.04.

Arbitration awards should be in writing. The arbitrator may grant relief deemed equitable within the scope of the arbitration agreement. The parties may agree that the arbitrator may not award consequential, exemplary, incidental, punitive, or special damages arising from a tort unrelated to employment or the termination of employment--unless the arbitrator determines that there is clear and convincing evidence that the party is guilty of intentional conduct, acted with reckless disregard for the rights of the other party, or if there was fraud. The arbitrator may award any liquidated damages to which the parties have agreed. The decision of the arbitrator is binding upon the parties. n441

n441 *Id.* Rule 6.06.

E. Other Dispute Resolution Organizations

The Society of Professionals in Dispute Resolution ("SPIDR") was organized in 1972 as an international organization intended to serve three functions. First, SPIDR guards the standards and ethics in the field of dispute resolution. Second, it develops intellectual and professional roots in the field and educates the public about dispute resolution. Finally, it supports its members in a wide array of dispute resolution fields. As a professional membership organization, it promotes the professionalism of its member conflict resolvers. SPIDR does not have specific standards of arbitration or mediation, but through conferences and member activities, it provides a forum for the exchange of information regarding developments in the field, including healthcare. A recent conference in the autumn of 1999 included presentations on the role of dispute resolution in Managed Care. n442

n442 Society of Professionals in Dispute Resolutions, *What is SPIDR?* (visited Apr. 8, 2000) <<http://www.spidr.org/abt.htm>>.

JAMS is a for-profit business formed in 1994 when three national ADR groups merged. More recently, some of the neutrals have purchased the **company** and simplified the name from JAMS-Endispute to JAMS. JAMS is focused on providing leadership in a variety of dispute resolution areas. JAMS arbitration procedures require the initiating party to provide written proof that the other party has been given notice. n443 JAMS ADR includes both mediation and

arbitration. n444

n443 Sabatino, *supra* note 391, at 1302, 1309.

n444 *Id.* at 1302.

F. Professional Organizations

The ABA has encouraged use of ADR techniques through its support of the development of uniform guidelines and laws. In 1997, the ABA participated in the development of the Consumer Due Process Protocols and hosted an interdisciplinary roundtable to discuss consumer disputes in managed care. n445 More recently, the ABA worked with the National Conference of Commissioners on Uniform State Laws to develop model mediation laws. n446 The ABA also supported recent legislative provisions that foster internal review and independent external appeals and provisions that hold ERISA plans accountable through court provisions. n447 The ABA has also encouraged use of ADR in resolving disputes. n448

n445 INTERDISCIPLINARY ROUNDTABLE, *supra* note 81.

n446 *ABA Announces Collaboration with the National Conference of Commissioners on Uniform State Laws on a Model Mediation Law* (Mar. 25, 1998) <<http://www.abanet.org/media/mar98/nccusldr.html>>.

n447 *Letters to the 106th Congress* (July 7, 1999) <<http://www.abanet.org/legadv/congletters/106th/patients7799.html>>.

n448 *Letters to the 106th Congress* (Mar. 18, 1999) <<http://www.abanet.org/legadv/congletter/106th/health31899.html>>.

The AMA also has taken a political role in the development of healthcare policy. It was involved in the development of the consumer due process protocols. It lobbied for the passage of the Quality of Care for the Uninsured Bill. n449 More recently, it has outlined several principles for making healthcare coverage a reality for all Americans. n450

n449 *News Releases: AMA Celebrates "Colossal Victory" for Patients* (Oct. 7, 1999) <<http://www.ama-assn.org/ad-com/releases/1999/991007.htm>>.

n450 *News Releases: Top Medical, Consumer & Business Leaders Outline Principles for Making Health Care Coverage a Reality for All Americans* (Nov. 17, 1999) <<http://www.ama-assn.org/ad-com/releases/1999/991177.htm>>.

Finally, the American Association of Health Plans ("AAHP") represents more than one thousand HMOs and managed care plans across the country. n451 AAHP plans cover about 140 million people. n452 In 1996, AAHP sent a statement of appeal principles to HHS after the *Grijalva* district court decision. The Association encouraged health plans to provide "accessible, fair, and timely grievance and appeals procedures." n453 This process includes timely notice of coverage determination in comprehensible language, n454 expedited review processes, and streamlined appeals processes with time limits on each phase of the appeal. n455 In 1997, AAHP adopted policies to expedite appeals to provide reasonable coverage for emergency room care. n456 In 1999, AAHP encouraged its members to voluntarily offer external appeals. n457

n451 *Legislation and Other Developments: Managed Care*, 7 MED. REP. (BNA), Nov. 8, 1996, at 44 [hereinafter *Managed Care Legislation*].

n452 *Health Plan Association Adopts Policies on Emergency Care Appeals*, 5 HEALTH CARE POL. REP. (BNA), Feb. 3, 1997, at 5.

n453 *Managed Care Legislation*, *supra* note 451.

n454 American Association of Health Plans, *AAHP Policy Statements, Patient Appeals* (visited Apr. 8, 2000) <<http://www.aahp.org>> (located in Services, Policy Statements directory).

n455 *Id.*

n456 *Health Plans Association Adopts Policies on Emergency Care*, HEALTH CARE DAILY REP. (BNA), Jan. 31, 1997, at d2.

n457 *AAHP Board Endorses External Appeals, Urges Member Plans to Offer Voluntarily*, HEALTH CARE DAILY REP. (BNA), Feb. 24, 1999, at d3.

G. Health Plans

A recent SPIDR conference included a report of preliminary findings of a recent joint study of fifty health plans. The study looked at internal appeal processes and found that eighty to ninety percent of disputes were resolved by customer service representatives. Appeals then went through several levels. Many of the health plans followed NCQA criteria. Some plans had an appeal specialist whose role was to act as a consumer advocate, while others had appeal specialists who served in more of a mediator role. Some of the appeal processes included a review committee. Statistics of reversals of denial decisions varied widely. Some health plans allowed the member to attend a hearing at the second or third level of review. The survey also found discrepancies between the plans' perception that they had provided adequate notice of appeal to the consumer and the actual level of member knowledge as to the availability of appeals. It was also noted that many consumers use a "back door approach" to appeals, by asking someone they knew at the health plan to help them resolve the issue. n458

n458 *SPIDR Managed Care*, *supra* note 7.

A 1998 GAO study of HMOs and indemnity plans looked at whether the plans included key features needed for an effective complaint and appeals system. n459 The study reviewed procedural protections including: timeliness through an explicit time period for appeal or expedited review, integrity of decisionmaking through use of medical professionals in decisionmaking, appeal decisions made by individuals who were not involved in the initial decision, effective communication in providing information about how to appeal, acceptance of oral complaints and appeals, and the provision of notice of appeal rights with the initial denial or denial of the appeal. n460 The studies found that HMOs included more of the process protections than indemnity plans. n461 The procedure many HMOs did not follow was to require decisions to be made by individuals not involved in the original denial. n462

n459 UNITED STATES GENERAL ACCOUNTING OFFICE, *INDEMNITY HEALTH PLANS: KEY FEATURES OF CONSUMER COMPLAINT & APPEALS SYSTEMS*, GAO/HEHS-98-189 (June 1998) [hereinafter *GAO INDEMNITY PLANS*].

n460 *Id.* at 4-5.

n461 *Id.* at 5-6.

n462 *Complaint, Appeals Policies Have More Gaps in Indemnity Plans than HMOs*, HEALTH CARE DAILY REP. (BNA), Aug. 4, 1998, at d5.

The Office of Personnel Management ("OPM") contracts with private health plans to administer the Federal Employees Health Benefits Program ("FEHBP"). Less than 1% of all claims in this system are appealed, and the majority of these are filed against indemnity plans, not MCOs. n463 FEHBP endorses the provisions of the Patient Bill of Rights, including complaint and appeal processes. FEHBP has had an external review process in place for twenty years. n464 FEHBP members are encouraged to use internal appeal processes with the health plan for initial reconsiderations. n465 If the claim is still denied, the member can appeal to OPM. OPM will acknowledge receipt of the appeal within five days, contact the member for additional information within fourteen days, and send a final decision within sixty days. n466

n463 *Outside Reviews of Health Plan Decisions Helpful But Rarely Used, House Panel Told*, 6 HEALTH CARE POL'Y REP. (BNA), Apr. 27, 1998, at 695.

n464 OPM, *Patients' Bill of Rights and the Federal Employees Health Benefits Program*, (modified Nov. 3, 1999) <<http://www.opm.gov/hr/insure/html/billrights.html>>.

n465 OPM, *Filing Disputed Claims* (modified Aug. 2, 1999) <<http://www.opm.gov/hr/insure/html/dispute.html>>.

n466 *Id.*

Health plans have been slow to implement procedural protections on their own. On January 12, 1999, Aetna announced that it would become the first national managed care organization to voluntarily provide external review of coverage decisions. n467 This review process involves the right to appeal coverage denials to a neutral, independent physician reviewer. n468 This review process allows all members to request external reviews after the first and second level internal appeals processes have been completed. Aetna uses four independent organizations to complete the external reviews. n469 These organizations will decide external reviews within sixty days. Expedited external reviews will also be "available when a member's life, health or ability to regain maximum function would be in jeopardy if a decision were not rendered before the 60 day period elapses." n470 Aetna covers the cost of the independent review except in states where there is a legislated filing fee. The independent reviewer's decision will be binding on both the plan and the member only in jurisdictions that allow such a result. n471

n467 *NCQA Adds External Review Requirement to Managed Care Accreditation Standards*, Health Care Daily Rep. (BNA), Mar. 16, 1999, at d3.

n468 Aetna, *Press Releases: Aetna U.S. HealthCare to Institute First Voluntary External Review Policy for Managed Care* (Jan. 12, 1999) <<http://www.aetna.com/news>> [hereinafter *Aetna External Review*].

n469 The four independent review organizations that will be used by Aetna include HAYES Plus Inc, CHDR, Island Peer Review Organization, and CORE, Inc. See *Aetna: Announces Independent Review Process*, AM. POL. NETWORK AM. HEALTH LINE (Aug. 16, 1999).

n470 *Aetna External Review*, *supra* note 468.

n471 *Id.*

Recently, Aetna settled with the Texas Attorney General in a class action lawsuit which claimed that health plans

used "financial incentives to reward doctors who stayed within budget guidelines in patient care and punish those doctors who did not." n472 In the settlement, Aetna agreed to (1) stop using positive or negative financial incentives with doctors to limit patient care; (2) use an ombudsman to handle complaints and appeals for Texas consumers; n473 (3) expand external review to include appeals for "emergency care coverage, specialists' visits, and experimental treatments"; n474 and (4) base medical necessity determinations on current medical standards and to disclose those standards. n475 Many of these provisions restate current practices at Aetna and reflect an effort to better inform the public of existing policies, as well as to create new initiatives to benefit consumers. n476

n472 *Texas, Aetna announce HMO Settlement*, United Press International (Apr. 11, 2000) [hereinafter *Texas/Aetna*].

n473 The ombudsman would be subject to state attorney general oversight. See Mary Deibel, *Texas-Aetna Deal Could Set National Standard for Patient Care*, Scripps Howard News Service (Apr. 11, 2000).

n474 *Id.*

n475 *Id.*

n476 *Texas/Aetna*, *supra* note 472.

In contrast, the Blue Cross Blue Shield Association continues to oppose national legislation that expands plan liability and increases costs. n477 In June 1999, Blue Cross Blue Shield of Massachusetts became the first locally based Blues plan to offer external review. n478 Its external appeals are available after the **company** internal appeal process is complete for disputes regarding the medical necessity of care. n479 The plan will pay for two-thirds of the three hundred dollar cost to appeal. n480

n477 Rodd Zolkos, *Industry Monitoring Health Care Legislation: Organizations Representing Insurers, Agents Lobbying Congress for Favorable Outcomes*, BUS. INS. (Aug. 16, 1999), available in 1999 WL 8769121.

n478 *Massachusetts Blues First Local Plan to Launch External Appeals Program*, 7 HEALTH CARE POL'Y REP. (BNA), June 7, 1999, at 939.

n479 *Id.*

n480 *Id.* This fee can be waived for hardship and will be refunded if the plan's decision is overturned. *Id.*

A 1995 Rand survey of physicians, hospitals, and health plans in California found that seventy-one percent of HMOs used arbitration agreements. In contrast, none of the surveyed PPOs used arbitration agreements. n481 The HMO arbitration agreements were primarily used to resolve coverage disputes, but the number of disputes was small. The California Association of Health Maintenance Organizations reported only four coverage disputes per one million enrollees in its survey response. n482 In 1998, twenty-two plans affiliated with the California Association of Health Plans announced that they would voluntarily establish independent panels of doctors to review patient appeals. n483

n481 Elizabeth Rolph et al., *Medical Malpractice: External Influences and Controls: Arbitration Agreements in Health Care: Myths and Reality*, 60 L. & CONTEMP. PROBS. 153, 173 (1997).

n482 *Id.* at 180.

n483 *HMOs Voluntarily Institute Outside Reviews*, AM. POL. NETWORK, AM. HEALTH LINE (Dec. 3, 1998).

H. Procedural Protections and Fundamental Fairness

Procedural protections in private forums focus on the time frame for decisionmaking after the appeal has reached an external review body. These time frames do not consider how long it takes the consumer to exhaust internal procedures. n484 The private forums are strong in **protecting** the neutrality of the external decisionmaker and allowing for empowerment of appropriate decisionmaking through external appeal. The appeal process focuses on one stage of the appeal, which often uses dispute resolution techniques such as arbitration or mediation to make a decision. However, these external processes are often implemented late in the appeals process, after internal appeals are exhausted. n485 While the private forums create a strong independent method of reviewing appeals, the focus of how they impact the overall appeal processes varies in scope. These private forums often impact a limited segment of the appeal process at a relatively late stage in the process.

n484 *SPIDR Managed Care*, *supra* note 7.

n485 *Id.*

Fundamental fairness in private forums varies from forum to forum, although there is a general similarity in procedural protections regarding timeliness and neutrality of the decisionmaker. The entity that administers the external segment of the appeal may well determine the specific procedures used. There is really no focus on contract exclusion or medical necessity protections in these forums. Balance of power and ease of consumer use are not especially protected in this forum. The private forums enhance health plan accountability and may provide balance by reviewing prior health plan decisions and by providing new unbiased decisions regarding the matters under appeal. n486

n486 *See, e.g., AAA Health Procedures*, *supra* note 399; *CHDR Medicare Managed Care Reconsideration Process Manual*, *supra* note 409; *CPR HANDBOOK*, *supra* note 414; *AHILA PROCEDURES*, *supra* note 434.

VI. Procedural Protections and Fundamental Fairness

Procedural protections available in public and private forums for consumer managed care appeals create patchwork protections that disregard fundamental fairness. There are a variety of reasons why fundamental fairness is difficult to implement in the existing managed care arena. The reasons for the unfairness, recommendations to promote fairness, and the issues of implementation are discussed below.

First, there are no minimum standards for procedural protections that apply across the industry. n487 Recommendations include establishing uniform procedural protections that apply to all managed care appeals. These protections could be accomplished through uniform legislation that applies to all plans, or through private sector accreditation with similar minimum guidelines for all plans. This type of uniformity would be difficult to implement in the highly regulated managed care arena, in which both state and federal regulations impact managed care appeals. Private sector accreditation can provide uniform guidelines nationally, but it continues to be a voluntary process for health plans to choose accreditation status. As long as there are individual consumers and small employer groups that base health plan choice decisions solely on price, health plans will continue to compete in the marketplace without accreditation status. While government contracts may include standards similar to those found through voluntary accreditation, unless the different standards are aligned, there will continue to be a variety of demands on health plans in terms of how to structure the appeals. n488

n487 *Cf.* Medicare Carriers Manual at 12100; 29 C.F.R. § 2560.503(1)(e) (2000); 42 C.F.R. § 431.210; *id.* § 431.220; NCQA ACCREDITATION STANDARDS, *supra* note 354.

n488 Kinney, *supra* note 3, at 18.

Second, different procedural protections are applicable to people depending on the health plan they enroll in. The groups who are protected may overlap, but protections are not consistent across the board. n489 Recommendations include moving away from patchwork legislation based on anecdotal concerns to integrated system-wide standards that apply equally to all managed care appeals. This approach is also difficult to implement. Unfortunately, legislation that promotes fairness for one group of people or that corrects a previous process that was inherently biased, may result in an unfair impact on other groups of people. Another difficulty is coming up with procedural protections that everyone can agree upon. Differences of opinion about how things should take place are often the basis of differing proposals and differing requirements among the states. n490

n489 *See, e.g.*, GAO INDEMNITY PLANS, *supra* note 459.

n490 *See, e.g.*, Kaiser Study, *supra* note 13.

Third, reasons for denial may be based upon contract exclusion provisions that were negotiated between the health plan and the employer. These provisions are often negotiated without protection of the specific interest of the consumer. Later, when medical care is denied based on contract exclusions, consumers respond with surprise and anger. n491

n491 Kinney, *supra* note 3, at 19.

Recommendations include better communication of benefit coverage and exclusions with the consumer at an earlier time, through both written and verbal explanations of benefits before services are needed. This approach would establish realistic expectations for actual benefit coverage under the contract and could be accomplished through informal ombudsman programs or consumer advocates who provide health plan training meetings for new members, or follow-up benefit phone calls to new health plan enrollees. Written materials to members should explain exclusions so that consumers can understand them. Follow-up written and verbal contact concerning benefits and benefit changes should occur at regular intervals. Difficulties in implementation include concerns that the mandating of such consumer communications would impose an additional financial burden on health plans; moreover, it is likely health plans will resist communications that would result in an increased volume of appeals. It is also unlikely that health plans will agree to a consumer advocate as part of contract negotiations, because employers are deemed to represent their employees in the contract discussions. n492

n492 *See generally* Kinney, *supra* note 3.

Fourth, denials based on medical necessity are based on a subjective standard that can be interpreted differently by different individuals. Furthermore, because medical necessity is always evolving, this becomes a "moving target" to decide what is currently medically necessary. Recommendations include establishing objective standards for evaluation of medical necessity decisionmaking that are established and communicated prior to the time the decision is made. Appropriate standards would include medical professional standards, national utilization management criteria, or other private guidelines that meet general industry approval. The difficulty is that the rapid change in medical technology

regularly creates new medically necessary procedures and treatment. n493 Thus, consumers are often left not knowing whether the desired health services will be covered by the plan.

n493 *Id.*

Fifth, fairness implies a balance of cost and benefit. However, cost and benefit balancing are separated in the managed care setting, in which payors are responsible for medical care costs, employers are responsible for certain premium costs, and consumers have nominal out-of-pocket expenses. It is easy for the consumer to perceive fairness as the best medical care available without regard to the costs. It is also easy for consumers to perceive fairness as a return to good health. n494 Recommendations include continuing member cost sharing of medical service costs, providing more information to consumers about actual costs of care, allowing consumers to "buy up" benefits by paying a higher premium for services that are expensive, but which the consumer desires, and providing incentives for consumers to make responsible decisions regarding appropriate healthcare needs.

n494 *Id.*

Sixth, fairness implies a balance of power between the parties involved, so that neither party is favored. In managed care appeals, there is a large imbalance of power in that the health plan establishes the process for appeal; employs the individuals making the appeal determination; has access to the contract, guidelines, and medical records needed to make a determination; and controls the timing of when the appeal will be heard and decided. n495 Recommendations include use of an external, neutral decisionmaker to make a fair determination. One less formal way to balance the power yet resolve the dispute is to establish a consumer ombudsman or advocate to assist the consumer. Further, mediation is a tool with which the health plan and consumer could informally resolve the dispute, but only if the health plan participates in good faith. Health plans may find that the willingness to "talk around the table" provides large dividends in terms of goodwill. n496

n495 See GAO INDEMNITY PLANS, *supra* note 459.

n496 See INTERDISCIPLINARY ROUNDTABLE, *supra* note 81.

There are a number of issues presented by the implementation of a consumer assistance or ombudsman program. An informal ombudsman program can only work if the ombudsman is familiar with the process of appeal available to the consumer, has access to adequate decisionmaking information to communicate the reasons for appeal, and has access to key health plan officials who would be involved in the next level of decisionmaking. There are some advantages to having a plan employee as the ombudsman, in that such a person would be knowledgeable about the plan appeal requirements, understands the system, and can facilitate communication within the plan. On the other hand, such an ombudsman may be more subject to biased decisionmaking, may have a difficult time serving as a true member advocate, and may be perceived by consumers as an "insider" with biased motives.

Seventh, if "knowledge is power" and the health plan has all of the information, there is an imbalance between the parties. n497 Recommendations include making information regarding the appeal process, appeal rights, right to representation, right to a hearing, and reasons for the initial decision available to the consumer in a timely manner. This could be implemented through a formal educational program for consumers, a formal ombudsman program, or more understandable written and verbal communication with the consumer during appeal. Implementation concerns include administrative burdens, concerns about increasing numbers of appeals, and finding ways to make the information "user friendly" and comprehensible. n498

n497 Kinney, *supra* note 3, at 21.

n498 *See generally* INTERDISCIPLINARY ROUNDTABLE, *supra* note 81.

Eighth, the timing of the decisionmaking creates unfairness. Healthcare appeals typically take place when the consumer is already sick or in a weakened health condition. Further, the timing of the decisionmaking is crucial to the patient, whose health may be failing rapidly without the desired medical care. n499 The recommendation is to use expedited appeals. Although expedited appeals and emergency room access laws address this concern, they need to apply to all consumers. Provision of a representative to facilitate the appeal on behalf of the consumer is also useful. This could be a private attorney, a consumer ombudsman, or advocate who represents the interests of the consumer. n500

n499 *See, e.g.*, Engalla v. Permanente Med. Group, 938 P.2d 903 (Cal. 1997).

n500 *Due Process Protocol*, *supra* note 63.

Ninth, the complex nature of the healthcare system and appeal processes makes it difficult for the consumer to negotiate the system. The fact that very few claims are appealed may be more a result of the "hassle factor," than of claim satisfaction. n501 The recommendations are to provide more consumer-friendly literature, train customer service representatives to provide more accurate information, and implement ombudsman programs to help the consumer negotiate the system. The consumer should be informed of benefit and appeal rights through multiple processes and at multiple times. n502 The appeal process should be easy to use.

n501 *See* GAO INDEMNITY PLANS, *supra* note 459.

n502 NCQA ACCREDITATION STANDARDS, *supra* note 354.

Tenth, appealed claims often continue through multiple layers of review well into the review process before they are resolved. Even if the consumer does receive a decision in her favor, the decision may occur too late for effective treatment. Cost and combativeness of the parties rise as the duration of the dispute increases. n503 The recommendations are: training customer service representatives who are on the front line with customers to have stronger dispute resolution skills in order to facilitate problem resolution at an earlier level; empowering appeal decisionmakers to review earlier decisions with the ability to make a new, impartial decision; incorporating the use of ADR earlier in the process through mediation or arbitration; and making the decision at the lowest level possible in order to shorten the time and cost of lengthy appeals. The implementation concerns include the administrative time and costs of training in the fast-paced managed care setting. n504

n503 INTERDISCIPLINARY ROUNDTABLE, *supra* note 81.

n504 *Id.*

VII. Conclusion

Procedural protections available in public and private forums vary from forum to forum. They are similar in that they focus on aspects of (1) timeliness, (2) decisionmaker neutrality, (3) the appeal process, and (4) communication and empowerment. They are different in the ways they approach these procedural protections. These differences between

forums create patchwork protections that do not reach the level of fundamental fairness. Fundamental fairness involves more than specific procedural protections. Fundamental fairness requires that the entire system promote fairness for each individual and entity within the system. Fundamental fairness involves a balance of power and interests to achieve equitable results based on reasonable guidelines. While procedural protections exist in both public and private forums for consumer managed care appeals, the available protections are not sufficiently uniform or widespread to protect fundamental fairness.

Any system that is implemented should be evaluated based on fundamental fairness criteria that go beyond procedural protections. First, systems should include minimum standards based on procedural protections. Second, the processes should treat all people equally rather than having different standards for different people in different health plans. Third, the procedural protections should include provisions for contract exclusions and medical necessity denials so that there is less disparity of impact, more effective early communication, and more notice of these provisions. Fourth, the system should focus on balancing power at all stages of the process from contracting to appeals. Fifth, the system should be easy for the consumer to use. Finally, the system should include health plan accountability through checks and balances to prevent health plan abuses. These fundamentals of fairness will promote consumer trust, hold health plans accountable, and encourage effective healthcare delivery. n505 Fairness criteria can be used to create a managed care appeal system that is fundamentally fair.

n505 Phil Nudelman, *Creating Standards: A Practical Approach*, in REGULATING MANAGED CARE: THEORY, PRACTICE, AND FUTURE OPTIONS 308-09 (Stuart H. Altman et al. eds., 1999).