HCCA HEALTH CARE COMPLIANCE ASSOCIATION

Compliance TODAY

July 2012

A PUBLICATION OF THE HEALTH CARE COMPLIANCE ASSOCIATION

WWW.HCCA-INFO.ORG

Meet Leon Rodriguez

Director of the Office for Civil Rights, of the U.S. Department of Health and Human Services

See page 16

Have you checked out HCCA's new website yet?

HCCA's website was recently redesigned and includes a more user-friendly experience. Check it out now!

New features and benefits:

- Online membership renewal
- Easily view and track your CEUs online
- Register for events with ease
- Order HCCA products to be shipped directly to you
- Enrich your experience by uploading your bio and profile picture
- Find content quicker and easier with a new search box and improved navigation

Get connected to HCCA now!

You will need your new HCCA login and password information to access the "My account" section of the website. You should have received an email in mid-May with this information.

If you are having trouble logging in or have website questions, call 888.580.8373 or email service@hcca-info.org.

www.hcca-info.org

by Roy Snell, CHC, CCEP-F

The Morgan Stanley Case

*Contact **Roy Snell** at roy.snell@hcca-info.org.*

One of the most significant events in the history of the compliance profession?

Kudos to the Department of Justice. For 20 years there has been the notion that those who implement a compliance program should be treated differently than those who don't. The Federal Sentencing Guidelines suggest that if an organization has a problem, as Morgan Stanley did, and the organization made an effort to prevent the problem, as Morgan Stanley did, they should be treated differently than an organization that made little-to-no effort. The USSC suggested in Chapter 8 of the FSG that the implementation of a compliance program would be considered making an effort. This has long posed a challenge for the DOJ.

Snell

The DOJ has been in a tough spot, because a compliance program is a somewhat new concept. For some time, it was deemed difficult to know how much effort was enough effort. As time went on, the DOJ gained more experience with compliance programs. My guess is, the DOJ has concluded that determining how much effort a company is making is easier than one might think. There are many companies who have done little to nothing, or their compliance officer is under the thumb of some other department and was a compliance officer in name only. The real question has always been: how much effort is enough effort? The DOJ seems to be saying that they can now better tell the difference between little to nothing and something materially better than nothing.

This has been a long time coming. Ironically, several very talented compliance professionals and I were in DC about a month before this announcement, visiting with Lanny Breuer from the DOJ, Robert Khuzami from the SEC, and about a dozen other government staffers. We talked about many things. One of the issues that came up was the notion of companies getting a break because they implemented a compliance program. It is unlikely that our visit had anything to do with the Morgan Stanley announcement; however, many people have worked hard and for a long time to get to where we are now. And where we are now is much better than where we were before the Morgan Stanley case. And many of us are thrilled.

Thank you!

Has someone done something great for you, for the compliance profession, or for HCCA? If you would like to give recognition by submitting a public "Thank You," please send it to margaret.dragon@hcca-info.org. Entries should be 50 words or fewer.

Contents

July 2012

FEATURES

COLUMNS

DEPARTMENTS

> OIG also found that incident reporting systems were unsuccessful in identifying 86% of events that caused patient harm, often because staff did not interpret the event as a cause of harm.

See page 38

ARTICLES

Compliance TODAY

EXECUTIVE EDITOR: Roy Snell, CHC, CCEP-F, CEO, HCCA, roy.snell@hcca-info.org

NEWS AND STORY EDITOR/ADVERTISING: Margaret R. Dragon, 781-593-4924, margaret.dragon@hcca-info.org

COPY EDITOR: Patricia Mees, CHC, CCEP, 888-580-8373, patricia.mees@hcca-info.org

COPY EDITOR: Brook Matthiesen, 888-580-8373, brook.matthiesen@hcca-info.org

DESIGN & LAYOUT: John Goodman, 888-580-8373, john.goodman@hcca-info.org

Compliance Today (CT) (ISSN 1523-8466) is published by the Health Care Compliance Association (HCCA), 6500 Barrie Road, Suite 250, Minneapolis, MN 55435. Subscription rate is $295 a year for nonmembers. Periodicals postage-paid at Minneapolis, MN 55435. Postmaster: Send address changes to *Compliance Today*, 6500 Barrie Road, Suite 250, Minneapolis, MN 55435.

VOLUME 14, ISSUE 7

Newly elected Executive Committee assumes office

The Health Care Compliance Association (HCCA) Board of Directors voted to approve the 2012 slate of officers during a meeting on April 28, 2012. The newly elected Executive Committee assumed office on May 1, 2012.

Shawn Y. DeGroot, CHC-F, CCEP, CHRC, and Vice President of Corporate Responsibility at Regional Health in Rapid City, will serve as HCCA President for a one-year term through April 2013. DeGroot, a long-time member of HCCA, joined its Board of Directors in 2002 and has previously served on the board as Vice President, Second Vice President, Treasurer, and Non-Officer Board Member of the Executive Committee.

"The key to our rapid growth and success can be attributed to many things; however, one of the most significant factors contributing to our success is the quality of our volunteers and our board. These individuals have selflessly devoted countless hours to help compliance professionals improve their professional skills and help them implement effective compliance programs. On behalf of the membership, I also want to thank Frank Sheeder for his service as President last year, and I look forward to working with Shawn DeGroot during her term," said Roy Snell, HCCA Chief Executive Officer.

Serving with Ms. DeGroot on the HCCA Executive Committee are

- Vice President John Falcetano, CHC-F, CIA, CCEP-F, CHRC, CHPC, Chief Audit/Compliance Officer for Vidant Health;
- Second Vice President Gabriel L. Imperato, JD, Managing Partner, Broad and Cassel;
- Treasurer Sara Kay Wheeler, JD, Partner, attorney at law, King & Spaulding;
- Secretary Urton Anderson, PhD, CCEP, Chair, Department of Accounting and Clark W. Thompson Jr. Professor in Accounting Education, McCombs School of Business, The University of Texas at Austin;
- Non-Officer Board Member Sheryl Vacca, CHC-F, CHRC, CCEP, CHPC, Senior Vice President/Chief Compliance and Audit Officer, University of California;
- Immediate Past President Frank Sheeder, CCEP, JD, Partner, attorney at law, DLA Piper.

Physician and business man charged in diagnostic fraud scheme

On May 24, 2012, the U.S. Attorney for the Southern District of Texas announced that Dr. Donald Gibson II of Sugarland, Texas, and Sunday Joseph Edem of Richmond, Texas, were arrested for health care fraud and conspiracy to commit health care fraud relating medically unnecessary diagnostic testing and physical therapy.

According to the indictment, returned Thursday, May 17, 2012 and unsealed on May 24 upon their arrests, Gibson ordered, prescribed, and authorized medically unnecessary diagnostic tests and other procedures which included allergy tests, pulmonary function tests, vestibular tests, urodynamic tests, and physical therapy, among others. These services were then billed to Medicare and Medicaid for payment under Gibson's billing number.

Read the latest news online ▶ www.hcca-info.org/news

OIG releases Semiannual Report

Late in May, the Department of Health and Human Services (DHHS) Office of Inspector General (OIG) released its Semiannual Report to Congress. The Semiannual Report keeps the Secretary of DHHS and Congress currently informed about OIG's most significant findings, recommendations, and activities for specific 6-month periods. Historically, about 80% of OIG's resources are directed to work related to Medicare and Medicaid. This is mirrored in the organization and content of the report.

The Spring Semiannual Report to Congress covers October 1, 2011 to March 31, 2012. In addition to the full-text version, the OIG also provides smaller breakout files of the major parts of the document.

In its Summary of Accomplishments, the OIG noted "expected recoveries of about $1.2 billion consisting of $483.1 million in audit receivables and $748 million in investigative receivables (which includes $136.6 million in non-HHS investigative receivables resulting from the OIG's work in areas such as the States' shares of Medicaid restitution.)"

OIG also reported "exclusions of 1,264 individuals and entities from participation in Federal health care programs; 388 criminal actions against individuals or entities that engaged in crimes against HHS programs; and 164 civil actions, which include false claims and unjust-enrichment lawsuits filed in Federal district court, civil monetary penalties settlements, and administrative recoveries related to provider self-disclosure matters."

Use this link to download the complete report: *http://oig.hhs.gov/reports-and-publications/archives/semiannual/2012/spring/sar-S12-fulltext.pdf*

Chiropractor sentenced for health care fraud

U.S. Attorney for the Southern District of Texas Kenneth Magidson announced on May 25, 2012 that Justina Okehie (aka Dr. Tina Collins) of Richmond, Texas has been sentenced to federal prison for her role in a multi-million dollar health care fraud scheme. Okehie pleaded guilty October 27, 2011. U.S. District Judge Nancy F. Atlas, taking into consideration Okehie's health as well as her cooperation with the government, handed her a 24-month term of imprisonment and further ordered her to pay restitution of $1,894,938 to the Medicare program and $258,893 to the Texas Medicaid program.

2012 HCCA Compliance Institute keynote address

Health and Human Services Inspector General Daniel R. Levinson spoke at the 16th Annual HCCA Compliance Institute on April 30, 2012.
For more information:
http://oig.hhs.gov/compliance/101/index.asp#hcca

To read the complete transcript:
http://oig.hhs.gov/newsroom/podcasts/2012/hcca-trans.asp
To view the video:
www.youtube.com/watch?feature=player_embedded&v=SmjxwCkw29E

News from CMS

Additional information on home health face-to-face encounter requirements

On May 7, CMS released an MLN article designed to provide education on the contents of the home health certification, including homebound criteria and requirements for the face-to-face encounter and documentation. The article includes guidance that physicians, non-physician practitioners, physician support personnel, and home health agencies can use to ensure that all certification requirements are understood and met. In addition, on May 4, updated face-to-face encounter Questions & Answers were posted and are available through the CMS Home Health Agency (HHA) Spotlight page.

Prior authorization demonstration update

CMS will conduct a demonstration that will implement a prior authorization process for certain medical equipment for all Medicare recipients who reside in seven states with high populations of fraud- and error-prone providers (California, Florida, Illinois, Michigan, New York, North Carolina, and Texas). This is an important step toward paying appropriately for certain medical equipment that has a high error rate. This demonstration will help ensure that a beneficiary's medical condition warrants their medical equipment under existing coverage guidelines. Moreover, the program will assist in preserving a Medicare beneficiary's right to receive quality products from accredited suppliers. This demonstration will begin Summer 2012.

To read more about the demonstration, visit the Prior Authorization of Power Mobility Devices (PMD) Demonstration webpage. Stakeholders may submit questions to *PAdemo@cms.hhs.gov*.

Home health claims selected for review with dates of service October 1– December 31, 2011

CMS issued V3210 of the home health (HH) Prospective Payment System (PPS) Grouper effective for dates of service October 1, 2011 and later. New diagnosis codes 294.20 and 294.21 were not initially approved for addition to the V3210 of the HH PPS Grouper. In V3312, CMS has added these two diagnosis codes for dates of service October 1, 2011 and later. V3312 of the HH PPS Grouper, effective January 1, 2012, will update the HH PPS Grouper so that OASIS records submitted with these diagnosis codes will produce the appropriate set of scores and HIPPS code for dates of service October 1, 2011 and later.

Regional Home Health Intermediaries (RHHIs) have received technical direction from CMS that provides the necessary information for their use in reviewing home health claims with a date of service between October 1, 2011 and December 31, 2011 that contain diagnosis codes 294.20 and 294.21.

Home health agencies may want to review any claims within these dates of service submitted from October 1, 2011 through December 31, 2011 to make a business decision whether or not to adjust the claim based upon a different HIPPS score determination made by V3312 of the HH PPS Grouper.

Read the latest news online ▶ www.hcca-info.org/news

In Memorium: Dinh Van Nguyen (March 18, 1949–May 7, 2012)

***Lynda Hilliard**, CCEP, CHC (Lynda.Hilliard@ucop.edu) is the Deputy Compliance Officer at the University of California in Oakland.*

It was such a distressing surprise to learn several weeks ago that our friend Dinh Nguyen passed away suddenly, the result of a massive stroke. The surprise was filled with bittersweet thoughts of a man who was so dear to many of us within the health care compliance community. His passing only goes to show the fragility of life and how little control we have over our days on this Earth and the need for us to more fully live our lives.

Dinh was such a gentle man and more importantly, a gentleman. I have personally known Dinh on a professional basis for a number of years and was always glad to run into him at any one of the HCCA-sponsored events. He was a consummate professional who treated everyone with respect and dignity —a role model for young professionals joining the workforce these days. Even though I never met his family, he spoke of his wife Rebecca and son Don Van lovingly, and his concern for them was foremost on his mind. I am sure they are sorely missing their husband and father, and their grief will take time to ease. A sudden passing of such a young and vibrant person is always hard to understand and reconcile.

For those of you who haven't met Dinh, he was born in Vietnam and immigrated to the United States. He received his Bachelor's and Master's degrees from Bowling Green University in Ohio.

I met Dinh when he was the Corporate Compliance and HIPAA Officer at Santa Clara Valley Health and Hospital System in San Jose. The organization was in the throes of planning for enacting the HIPAA Privacy and Security Rules, and Dinh was leading the system-wide effort. Through the years, we both changed positions, but we didn't lose touch with each other. He was always a familiar face at educational events sponsored by HCAA, and he was an ardent supporter of networking and educating oneself on the nuances of the new regulations continuing to face our industry. Finally, he and I had the opportunity to at least be in the same organization —the University of California—however, we were about 400 miles apart. He was at the UCLA Health Sciences Compliance Office and I was at the system-wide Ethics and Compliance Program. However, it was close enough, and I was privileged to call him my colleague.

I could go on describing my encounters with Dinh, but I will save that for private conversations with friends sharing a bottle of wine. However, I wanted to recognize his contributions to our industry and specifically, HCCA. I do wish him peace and rest wherever his spirit exists, and would have liked just one more time to see his smile, give him a hug, and tell him how much I cared for him.

Read the latest news online ▶ www.hcca-info.org/news

With a clear view of your compliance you can see straight through to performance improvement.

When you're forced to rely on point solutions or worse—a system retrofitted to the health care industry—for managing your governance, risk and compliance program, the lack of visibility can make it seem as if the program is managing you.

MediRegs ComplyTrack™, created specifically for the health care industry by Wolters Kluwer, is a complete solution for complete visibility. With web-based workflow software, the most comprehensive regulatory content in the industry, and support at every level by health care compliance experts, you can move beyond reacting to changing compliance landscape to proactively improving performance throughout your organization.

Visit **MediRegs.com** and see how our solution can help turn your organization from reactive to proactive, starting today.

ComplyTrack™ delivers industry-leading solutions for professionals in:

- Compliance
- Risk
- Internal Audit
- Privacy & Security
- Audit & Compliance Committee
- Legal
- Health Information Management

Wolters Kluwer
Law & Business

HCCA *conference news*

Fraud & Compliance Forum: September 30–October 2

The Fraud & Compliance Forum is jointly sponsored by HCCA and the American Health Lawyers Association (AHLA). The conference will include sessions designated as "compliance focused" or "legally focused." An individual could attend all "compliance" sessions or all "legal" sessions for the entire program, or select diverse sessions and network with an expanded group of individuals. Draft agenda is available at *www.fraudcomplianceforum.org*.

Clinical Practice Compliance Conference: October 14–16 *(formerly known as the Physician Practice/Clinic Compliance Conference)*

Register before September 7 and save $300

Participants will learn about:

- Compliance program development and management as it relates to physician practices
- Current government initiatives in the field of health care compliance specific to physicians and their group practices
- Correct documentation
- Billing and coding practices for physicians
- Best practices utilized in physician practices

Basic Compliance Academies

Due to the popularity of our Academies, we have added one more for the 2012 year. It will take place November 12–15 in Orlando. For more information and other dates visit *www.hcca-info.org*.

Research Academy: August 13–16

This Academy focuses on compliance issues related solely to research. With a wide range of research-related issues becoming hot topics with enforcement agencies, this Academy provides attendees with the opportunity to get information on many areas that affect research compliance officers and their staff on a day-to-day basis. A small audience encourages hands-on educational techniques, small group interaction, and networking. For more information visit *www.hcca-info.org*.

Privacy Academy: October 22–23

This Academy covers a broad spectrum of laws and regulations that affect health care organizations. Topics include areas such as HIPAA Privacy, the Federal Privacy Act, Graham Leach Bliley, and more. The faculty has many years of experience in health care compliance and is well versed in health care privacy. In addition to participant experience in the privacy arena, this Academy will provide the information to prepare a participant for the health care privacy certification exam (CHPC). For more information visit *www.hcca-info.org*.

Regional Conferences

Attendees at Regional Conferences gain the ability to network with compliance professionals within their region and to hear the latest updates. Visit *www.hcca-info.org* for the remaining 2012 dates and locations.

Find the latest conference information online ▶ www.hcca-info.org/events

HCCA *website news*

Contact Tracey Page at 952-405-7936 or email her at tracey.page@hcca-info.org with any questions about HCCA's website.

Events

Registering online for events is easier than ever. You can choose the event you want to attend from the event calendar or on the Event page. You can update your own badge information and even register your coworkers for the same event. *www.hcca-info.org/events*

Invoices

The HCCA website offers a new feature. You can view and print your past invoices right from your "My Account" page online. Once you log in, you can click on My Account, then Transaction History, where you will see any paid or unpaid invoice. You can print them off or pay them right online. *www.hcca-info.org/myaccount*

Resources

HCCA's resources have been organized and made user friendly. You can now sort the resources by type (*Compliance Today*, TWCC, library article, and news article) or you can search for a specific topic and see all the different resources that come up. *www.hcca-info.org/resources*

Advertise

If you are looking to advertise, either online, in *Compliance Today* or *This Week in Corporate Compliance*, at a conference, or even on our social network, check out our advertising section on hcca-info.org. We list all the different advertising options at affordable prices. It's the best way to get your name out to compliance professionals. *www.hcca-info.org/advertise*

Certification

The certification features online have expanded in the last couple months. We now allow all users to go online and submit outside CEUs for approval. You can submit web conferences and take *Compliance Today* quizzes. We even allow you to renew your certifications. All of this can be done from the My Account page, under My Certification. *www.hcca-info.org/myaccount*

New Website

Check out HCCA's new website. There are many new features that will make membership renewal, entering CEUs, and event registration easier. The first time you log on to the new website, you will be prompted to reset your password. For more information on the website and passwords, please contact *service@hcca-info.org* or 888-580-8373.

Find the latest HCCA website updates online ▶ www.hcca-info.org

HCCAnet[SM] news

Contact Eric Newman at 952-405-7938 or email him at eric.newman@hcca-info.org with any questions about HCCAnet.

HCCAnet *(www.hcca-info.org/HCCAnet)* is the most comprehensive social network for health care compliance professionals, now with over 10,200 members. Subscribe to discussion groups and get your compliance questions answered. Stay informed on the latest health care compliance news and information.

Remember to update your profile

- For instructions on how to update your *HCCAnet* profile using your *LinkedIn*® account, go to *http://bit.ly/hccaprofile*

Popular HCCAnet discussions

- 2012 HCCA Compliance Institute
  - Dealing with OIG Exclusions: *http://bit.ly/oigexclusions*
  - Just a note from the Trenches - Day 2: *http://bit.ly/day2hccaci*
  - Aaron Beam Keynote Presentation: *http://bit.ly/aaronbeam*
- Auditing and Monitoring Health Care
  - Medicare Credit Balance reporting: *http://bit.ly/medicarecredit*
- Chief Compliance and Ethics Officer Health Care
  - Compliance and EMR Implementation: *http://bit.ly/complianceemr*
  - Vendor gifts to nonprofit foundation: *http://bit.ly/vendorgifts*
- Ethics Health Care
  - Billing question: *http://bit.ly/ethicsbilling*
- Healthcare Billing and Reimbursement Group
  - Place of Service codes: *http://bit.ly/servicecodes*
- HIPAA
  - Medical Records: *http://bit.ly/medicalrecordrequest*
- Physicians Compliance Professionals
  - How or where to obtain fair market value (FMV) data: *http://bit.ly/fmvdata*
- Privacy Officer's Roundtable
  - Open sharing of PHI with other CEs: *http://bit.ly/sharingphi*
  - Personally Identifiable Information (PII) Policy: *http://bit.ly/piipolicy*
  - Providing PHI to covered entities: *http://bit.ly/phice*

Compliance Today Needs You!

Every month *Compliance Today* offers health care compliance professionals information on a wide variety of enforcement, regulatory, legal, and compliance program development and management issues.

We are particularly interested in articles covering compliance concerns involving hospitals, outpatient services, behavioral health, rehab, physician practices, long-term care/homecare/hospice, ambulatory surgery centers, and more.

Articles generally run between 1,000–2,500 words; this is a guide, not a limit. The author's contact information must be included in the article as well as the article title. Submit your article as a Word document with limited formatting.

Email margaret.dragon@hcca-info.org with your topic ideas, format questions, and more.

AUTHORS EARN CEUs: CCB awards 2 CEUs to authors of articles published in *Compliance Today*.

Find the latest HCCAnet updates online ▶ www.hcca-info.org/HCCAnet

PEOPLE *on the* MOVE

▶ **Marlin R. Mattson**, MD, Associate Vice Chair for Compliance, Department of Psychiatry, New York-Presbyterian Hospital (American Psychiatric Association Representative) was elected Secretary of URAC. URAC is one of the nation's premier health care accreditation organizations.

▶ Home Health International, Inc. recently announced it has named **Elizabeth Velozo**, BSN, MSNH, COS-C as the President and Chief Executive Officer of the company. Velozo is the founder of Integrity Health Advisors, a health care consulting firm specializing in highly complex AHCA, Medicare, and Joint Commission surveys. She is an expert in all aspects of home health care, including regulatory issues, survey processes, and compliance standards.

▶ Achillion Pharmaceuticals, Inc., a leader in the discovery and development of small molecule drugs to combat the most challenging infectious diseases, recently announced the promotion of **Gautam Shah**, PhD, to Executive Vice President. Dr. Shah maintains his position as Chief Compliance Officer; he had previously served as Senior Vice President.

▶ **Donna K. Thiel**, a health care lawyer with extensive experience in Medicare coverage, payment and compliance, and **Theresa E. Weir**, a lawyer specializing in health care regulatory matters, have joined King & Spalding's health care practice as a Partner and Counsel, respectively, the firm recently announced. Thiel and Weir joined King & Spalding's Washington DC office from Baker, Donelson, Bearman, Caldwell & Berkowitz, where Thiel was a Shareholder and Co-chair of the Drug, Device and Life Sciences industry group, and Weir was a Counsel.

▶ Received a promotion?
▶ Have a new hire in your department?

If you've received a promotion, award, or degree; accepted a new position; or added a new staff member to your Compliance department, please let us know. It's a great way to keep the Compliance community up-to-date.

Send your updates to margaret.dragon@hcca-info.org.

Help Keep Your Compliance Program Fully Staffed

List Your Job Openings Online with HCCA

It's hard to have an effective compliance program when you have openings on your team. Help fill those openings quickly—list your compliance job opportunities with the Health Care Compliance Association.

Benefits include:

- Listing is posted for 90 days to maximize exposure
- Targeted audience
- Your ad is also included in our monthly HCCA Jobs Newsletter, which reaches more than 14,000 emails

Don't leave your compliance positions open any longer than necessary. Post your job listings with HCCA today.

Visit www.hcca-info.org/newjobs
Or call us at 888-580-8373

HCCA
HEALTH CARE COMPLIANCE ASSOCIATION

Leon Rodriguez

Director of the Office for Civil Rights, of the U.S. Department of Health and Human Services

an interview by Jenny O'Brien

Meet Leon Rodriguez

This interview was conducted by Jenny O'Brien, member of the HCCA Board of Directors, and took place in April 2012. Jenny *(jennifer.obrien@uhc.com)* is Chief Medicare Compliance Officer, UnitedHealthcare Medicare & Retirement in Minnetonka, MN.

JO: On behalf of HCCA, thanks for speaking with me about the Office for Civil Rights (OCR) and sharing initiatives the Office is focused on for 2012. Please tell us a little about yourself, your experience, and the path that led you to become the Director of the Office for Civil Rights.

LR: I was born in Brooklyn, New York, not long after my parents emigrated from Cuba. We moved to Miami when I was four, and there I grew up in a community of immigrant strivers. Hard work and achievement were respected, no matter what your background. I was fortunate to go to Brown University and then Boston College Law School; both of those experiences have played a significant role in shaping my worldview and professional priorities.

After graduating from law school, I started out in 1988 as Assistant District Attorney in Brooklyn, where I was a street prosecutor doing stints handling sexual assaults cases, organized crime, and official corruption. My wife and I moved to Washington DC in 1994 for her to pursue a residency in obstetrics and

gynecology, and then to Pittsburgh, where she completed her training. In Washington, I went to work as a trial lawyer in the Criminal Section of the Civil Rights Division of the U.S. Department of Justice. In Pittsburgh, I was an Assistant U.S. Attorney specialized in health care fraud cases. We returned to the DC area in 2001, and I went into private practice with Ober Kaler for the next six years, representing health care providers in a variety of litigation and investigation matters. In 2007, I was appointed County Attorney for Montgomery County, the county where we live. I served in that position until I became the Chief of Staff at the U.S. Department of Justice, Civil Rights Division.

JO: You have a very impressive background. Are there certain influences that helped shape your successful career?

LR: Many colleagues, mentors, professors, teachers, books, and even newspaper articles have helped shape my career and life choices, but really, the most important influences are the people closest to me. My parents, who came to this country in 1961, taught me not only the importance of hard work, but through their example, taught me that all human beings are basically the same, no matter their wealth or their background and, because of that, are entitled to dignity and respect. My wife is a physician who has been my teacher, counselor, and inspiration from the very day we met 23 years ago. And I am inspired by my genuinely wonderful children, to whom I feel responsible for, as best I can, living a life worthy of emulating.

My parents, who came to this country in 1961, taught me not only the importance of hard work, but through their example, taught me that all human beings are basically the same, no matter their wealth or their background and, because of that, are entitled to dignity and respect.

JO: Can you tell us about the Office for Civil Rights and its overall mission and vision?

LR: Fundamentally, our work at OCR is like that of any part of the Department of Health and Human Services, and is about making sure that all Americans can lead healthy lives free of barriers to getting the care and services that they need. OCR's specific mission is to promote compliance with the federal laws that prohibit discrimination by entities funded by HHS, and to protect the privacy of health information. The anti-discrimination laws include Title VI of the Civil Rights Act of 1964, through which we address health disparity issues, particularly those arising out of non-compliance with requirements for serving limited English-proficient populations, and also the Americans with Disabilities Act, which prohibits discrimination based on disability and, among other things, protects rights to language assistance and the utilization of service animals.

We are the federal agency responsible for enforcing the HIPAA Privacy and Security Rules, as well as the enhancements to HIPAA under the HITECH Act. We discharge this

overall mission through three basic activities: enforcement, policy development, and education. Our central vision is that by reducing discriminatory activity in federally funded health programs and increasing patient trust in the confidentiality of their health information, we promote better health outcomes for individuals and communities.

JO: Is there an aspect of your current role that has been especially surprising to you? And what would you say are the greatest challenges and rewards?

LR: The level of unfinished business is far greater than I would have guessed, and that's true across OCR's areas of responsibility. We see widespread security vulnerabilities for health information. We see continuing barriers to language access for patients and human services clients. It means that one of the most critical tasks for the OCR leadership team is to be strategic about how we utilize our resources, so that we are maximizing the impact of our work, while at the same time providing meaningful customer service to our citizen complainants and other stakeholders. We're doing all that while our train is in motion, and I am already seeing progress in terms of accelerated enforcement and an increased attention by regulated entities to compliance issues in all our areas of jurisdiction. Since the start of 2012, OCR has publicized settlements with five entities—two of which concerned civil rights violations under section 504 of the Rehabilitation Act, one focused on Title II of the Americans with Disabilities Act, and two concerned violations of the HIPAA Security Rule. Covered entities can anticipate more enforcement actions coming. We hope that each of our press releases tells a story that is meaningful to the industry in their efforts to comply with the various laws that we enforce.

We hope that each of our press releases tells a story that is meaningful to the industry in their efforts to comply with the various laws that we enforce.

JO: What are the Office for Civil Rights' main initiatives aimed at enforcing the Privacy and Security Rules?

LR: We have several initiatives, most of which I think are known to your readers. The one that I would particularly like to underscore is the consolidation of our monetary enforcement program. The Privacy Rule became effective in 2003, the Security Rule in 2005, and HITECH became law in 2009. Among other things, HITECH dramatically increased the scope and amount of penalties for HIPAA violations. The clear enforcement mandate in HITECH comes at the conclusion of a pretty lengthy ramp-up period for covered entities to come into compliance. Consistent and principled monetary enforcement is one of the most important tools, in my experience, to ensure that covered entities "get it" that the expectation of compliance is current and real. HITECH authorizes OCR to retain the penalties it collects to fund restitution for victims and also for application to enforcement activities. We intend to use those proceeds in a principled and transparent manner. We also want to continue to use our breach notification program in an effective way to identify privacy and security vulnerabilities and make sure that, both on an individual entity level and on an industry-wide level, we work to close gaps.

For example, we announced an important settlement on March 13, 2012, with Blue Cross and Blue Shield of Tennessee (BCBST), detailing an agreement under which BCBST agreed to pay $1.5 million and enter into a 450-day Corrective Action Plan (CAP) to address its HIPAA compliance issues. BCBST settled following an investigation triggered by the report of a "breach"—57 unencrypted hard drives, including patient records for over a million patients, were stolen from a leased facility in Tennessee. As required by the HITECH Act, we are engaged in a HIPAA audit pilot that is looking at a small group of randomly selected entities. The pilot will teach us lessons that will aid us in deciding the shape of a permanent audit program and will also supplement the function of the breach program to identify common vulnerabilities. While we are doing this, we also need to continue to develop our education and technical assistance so that patients understand their rights and providers their responsibilities and the resources available to them to comply with those responsibilities, and much, much more.

JO: The Office for Civil Rights also protects individuals from discrimination in certain health care and social service programs. Can you share more about the programs this includes and current areas of focus for 2012?

LR: We will continue to focus on health disparities, particularly but not only in the context of limited English-proficient persons, and making sure that entities receiving federal funds are in compliance with those Title VI requirements. At the same time, we are continuing to look at other ways to utilize Title VI as a framework to attack disparities. Our Americans with Disabilities Act (ADA) work continues to focus on language assistance and service animal issues, but is also expanding into issues such as discrimination based on HIV status. We are also dedicating

considerable resources to developing capacity to enforce requirements under the ADA that promote community living for persons with disabilities, requirements which were then enshrined in the 1999 *Olmstead* case. While the Department of Justice Civil Rights Division will continue to play a large enforcement role on Olmstead cases, we believe that OCR has a critical role to play in partnership with the Department of Justice in enforcement, policy development, and education. Finally, we are working on implementing important new anti-discrimination authorities found in Section 1557 of the Affordable Care Act, which among other things prohibit, for the first time, discrimination based on gender in federally funded programs.

Enforcement will be a critical part of creating that trust, giving covered entities incentives to come into genuine compliance, and making sure patients understand that those who view their obligations casually will be subject to sanction.

JO: What do you see on the horizon? Can you share trends you see developing in the health care enforcement area?

LR: I think one clear trend is going to be a continued and growing emphasis on HIPAA privacy and security. As we move into more integrated electronic health information systems, it is going to be critical that consumers of health care trust that their information is truly confidential. Enforcement will be a critical part of creating that trust, giving covered entities incentives to come into genuine compliance, and making sure patients understand that those who view their obligations casually will be subject to sanction. And it's important to remember that OCR is not the only enforcer in this arena. As required under HITECH, we have trained a number of state Attorneys General on HIPAA requirements and have also consulted with a portion of them as they work to develop their own privacy and security enforcement programs.

On the civil rights side, the drive to fulfill the community integration mandate of the Americans with Disabilities Act will mean a growing utilization of enforcement tools to fulfill that mandate.

I also think there is going to be a growth in awareness of the civil rights implications of health disparities. For example, as understanding grows on the critical role of provider-patient communication, including for limited English-proficient populations, in preventing adverse outcomes and promoting optimal ones, we believe that this will grow as a compliance priority.

JO: As you know, HCCA's members are compliance professionals. How will these trends impact compliance programs and the role of compliance officers?

LR: The role of compliance officers will be more critical than ever. In the privacy and security area, compliance officers have a crucial role to play in designing and then ensuring the implementation of their organizations' policies and procedures. Their most important role, however, given the nature of the vulnerabilities that we see here in OCR, is to ensure that all employees in their organizations take

ownership of compliance issues—from the leadership to the employees who handle protected information in their day-to-day work. For Title VI and ADA requirements, there is a real need to conduct an assessment of the covered entities' business, particularly the nature of the population an entity serves and also the nature of the service it provides. Based on that assessment, entities need to be sure that they have adequate language assistance plans both for limited English-proficient persons and persons with disabilities.

JO: What guidance or advice would you give to health care compliance professionals who are working to help their organizations meet regulators expectations?

LR: I think an important thing that needs to be understood about all of our jurisdictional areas is that they are all really grounded in common sense and are designed to be adaptable to different types and sizes of entities. I know that compliance officers understand that, but I think it would be very helpful for them to help their organizational leadership understand that as well. So while the initial reaction might be "That it's too hard" or "It's too expensive," an understanding that these are not exotic requirements and that they do improve the quality of care will help organizations come into compliance.

At the same time, compliance professionals can help deliver the message that we at OCR take our enforcement responsibilities seriously and that there may be significant consequences to non-compliance.

JO: What are some key indicators your investigators look for when determining whether an organization has demonstrated that it has an effective compliance program?

LR: The first thing our investigators examine is whether an organization has a living plan to address the particular regulatory area we're examining. Underlying many of the worst violations is an on-going failure to take compliance responsibilities seriously. We look to see whether an entity has assessed its compliance risks, issued appropriate policies and procedures, trained its staff, implemented safeguards and processes consistent with its policies and procedures, and maintained employee disciplinary policies to ensure compliance.

JO: HCCA has reached over 7,000 members and the compliance profession continues to grow, while enforcement efforts continue to intensify. What areas of opportunity do you see for HCCA, the government, and the health care industry to better collaborate?

LR: I have been familiar with HCCA since starting in private practice 11 years ago, and they do an excellent job of promoting understanding of compliance issues. We certainly see opportunities to engage in dialogue and collaboration to make sure that OCR is providing optimal technical assistance and that our compliance message goes far and wide.

JO: Leisure time—we all like to think about that! Please share any hobbies or favorite activities you are involved in.

LR: My duties as OCR Director and my family responsibilities keep me pretty busy. I do enjoy leisure activities with my wife and children—biking, eating out, working in the garden, cooking, and listening to Latin music.

JO: Thank you, Leon. We appreciate the perspectives and insights you have shared and look forward to continued collaboration with the Office of Civil Rights.

2012 BASIC COMPLIANCE ACADEMIES

BASIC COMPLIANCE ACADEMIES

New York, NY SOLD OUT
August 6–9, 2012

Orlando, FL (Session A)
November 5–8, 2012

Las Vegas, NV
September 10–13, 2012

Orlando, FL (Session B) JUST ADDED
November 12–15, 2012

Boston, MA
October 1–4, 2012

San Diego, CA
December 10–13, 2012

RESEARCH BASIC COMPLIANCE ACADEMY

Boston, MA
August 13–16, 2012

PRIVACY BASIC COMPLIANCE ACADEMIES

Orlando, FL
October 22–25, 2012

Learn more & register at
www.hcca-info.org

Registration for each Academy is limited to 75 attendees

HCCA's Compliance Academy is a four-day intensive program focusing on subject areas at the heart of health care compliance practice. Courses are designed for participants who have a basic knowledge of compliance concepts and some professional experience in a compliance function.

Certification exams are offered following each Academy

Be recognized for your experience and knowledge in health care compliance! Take advantage of the opportunity to sit for an optional certification exam on the last day of your Academy. Get Certified in Healthcare Compliance (CHC)® at the Basic Compliance Academy, Certified in Healthcare Research Compliance (CHRC)® at the Research Academy, or Certified in Healthcare Privacy Compliance (CHPC)® at the Privacy Academy.

HCCA
HEALTH CARE COMPLIANCE ASSOCIATION

by Pamela Tyner and Amy Lerman

RAC attack: How providers can be prepared

» RACs recovered $797 million in Medicare overpayments in FY 2011.
» In FY 2012, the reach of the RACs extends further.
» CMS is working to implement Medicare Part C and D RACs.
» State enforcement efforts will increase with the introduction of Medicaid RACs.
» Providers must prepare by evaluating and modifying corporate compliance programs.

Pamela Tyner *(PTyner@ebglaw.com) is a Member of the Health Care and Life Sciences practice of Epstein Becker Green's Houston office.* ***Amy Lerman*** *(ALerman@ebglaw.com) is an Associate in the Health Care and Life Sciences practice of Epstein Becker Green's Washington DC office.*

A word of caution to health care providers—RACs are here to stay and their reach only continues to extend. In fiscal year (FY) 2011, Recovery Audit Contractors (RACs) recovered $797 million in Medicare overpayments. During the same period, the RACs returned $142 million in underpayments to hospitals and other providers participating in Medicare Part A and Part B.[1] Moving into the early part of 2012, the government appears to be continuing its focus on auditing, investigating, prosecuting, and excluding health care providers for fraud. RACs recovered $398 million in Medicare overpayments during the first quarter of FY 2012, a 44% increase from the $277 million recovered the previous quarter, according to a recent report released by the Centers for Medicare & Medicaid Services (CMS). During the same period, the RACs returned $25 million in underpayments to hospitals and providers, a 68% decline from the $77 million returned in the fourth quarter of FY 2011.[2] As such, RACs and their contractor counterparts—the Comprehensive Error Rate Testing (CERT) program and Zone Program Integrity Contractors (ZPICs)—will continue to be key instruments in the government's fight against health care fraud.


Tyner


Lerman

What can health care providers do to be prepared? Providers that have embraced the responsibilities of compliance by developing and adopting robust compliance programs are best positioned to weather these enhanced regulatory threats. By contrast, providers that have not fully embraced compliance as a culture, returned overpayments routinely, or corrected potential problems, should consider implementing a robust compliance program.

A brief history of the RAC program

The RAC program was created through the Medicare Modernization Act of 2003 (MMA) to identify and recover improper Medicare payments paid to health care providers. In Section 306 of the MMA, the U.S. Department of Health and Human Services (DHHS), through CMS, was required to conduct a 3-year demonstration program to determine whether the use of RACs would be a cost-effective means of

adding resources to ensure correct payments are being made to providers and suppliers. The demonstration project began in 2005 and operated in New York, Massachusetts, Florida, South Carolina and California, before ending in March 2008. Under Section 302 of the Tax Relief and Health Care Act of 2006, DHHS was required to establish the program for all states by January 1, 2010.

RACs are currently reviewing claims from all Medicare fee-for-service (FFS) billers that participate in the Part A and Part B programs. The RAC program divides the country into four jurisdictions, each under the control of a separate contractor:

- Region A (New England and Mid-Atlantic states): audited by Diversified Collection Services;
- Region B (Midwestern states): audited by CGI;
- Region C (Southern and Southwestern states): audited by Connolly, Inc.; and
- Region D (Western and Pacific states) audited by HealthDataInsights, Inc.

Each RAC may subcontract portions of its region. PRG Shultz subcontracts for portions of Regions A, B and D, iHealth Technologies and Strategic Health Solutions also subcontract portions of Region A, and Viant subcontracts portions of Region C.

RACs review claims on a post-payment basis and according to the same Medicare guidance and policies (National Coverage Determinations, Local Coverage Determinations, and CMS Manuals) used by Carriers, Fiscal Intermediaries and Medicare Administrative Contractors (MACs). The RACs may apply their own internal methods and tools to identify potential claims for review. However, the RACs may not develop or apply their own coverage, coding, or billing policies. RACs may conduct two different types of review: (1) automated, where no medical records are needed, and (2) complex, where medical records are required. RACs are able to review claims that date back to October 1, 2007, but may only review three years from the date the claim was paid. RACs must have a staff consisting of nurses, therapists, certified coders, and a physician certified medical director (CMD).

The RACs are paid on a contingency fee basis and the amount of the fee is based on the amount of money recovered from, or reimbursed to, the providers. The fee is a percentage of the dollar amount of the improper payment and is paid to the RAC once the money is recouped or refunded. In FY 2009 and FY 2010, the contingency fees ranged from 9% to 12.5%. If a RAC is paid a contingency fee for a particular over- or underpayment and it is subsequently overturned at any level of appeal, the RAC must return the fee.[3]

What we have learned from the RACs so far

FY 2010 was the first year during which the RACs actively identified and corrected improper payments through the national Recovery Audit Program. In FY 2010, the program included only Medicare FFS audits. During FY 2010, the RACs identified and corrected $92.3 million in both overpayments and underpayments. However, during the same time period, the RACs actually demanded $135.6 million in overpayments. To date, only 2.4% of claims collected during FY 2010 have been both challenged and overturned on appeal. The RAC program has recovered $1.27 billion in overpayments and has returned $184 million in underpayments to providers since the program began in October 2009.[2]

CMS has been tracking major findings of the RACs, known as vulnerabilities, for the purpose of developing corrective actions. CMS has posted the top vulnerabilities on its website and also publishes quarterly newsletters to educate providers. Examples of "top issues" identified by the RACs include:

- **Ventilator support of 96+ hours:** Ventilation hours begin with the intubation of the patient (or time of admittance if the patient is admitted while on mechanical ventilation) and continue until the endotracheal tube is removed, the patient is discharged/transferred, or the ventilation is discontinued after a weaning period. Providers are improperly adding the number of ventilator hours, resulting in higher reimbursement. (Region A – Incorrect Coding)
- **Extensive operating room procedure unrelated to principal diagnosis**: The principal diagnosis and principal procedure codes for inpatient claims should be related. Errors occur when providers bill an incorrect principal and/or secondary diagnosis that results in an incorrect Medicare Severity Diagnosis-Related Group (MS-DRG) assignment. (Region B – Incorrect Coding)
- **Durable medical equipment, prosthetics, orthotics and supplies** (DMEPOS) **provided during an inpatient stay**: Medicare does not make separate payments for DMEPOS when beneficiaries are in covered inpatient stays. Suppliers are inappropriately receiving separate DMEPOS payments when beneficiaries are in covered inpatient stays. (Regions C and D – Billing for Bundled Services Separately).[3]

CMS has put processes in place for identifying and tracking the issues that the RACs examine. For example, when the RACs submit claims information to the Data Warehouse, they report information such as the number of claims with improper payments, a description of the issue(s), provider type, error type, and whether an improper payment was identified through automatic or complex review. Additionally, the RACs must report to CMS the dollar amounts collected or refunded, and any related appeals statistics. Further, with each new review, the RACs provide CMS with a short description of the improper payment, the codes affected, and a reference that describes why the issue resulted in an improper payment.

What's on the horizon for RACs?

The Patient Protection and Affordable Care Act (ACA) expanded the reach of the RAC program, to cover Medicare Part C and Part D in 2012. The ACA specifically requires that RAC contractors for Medicare Part C and Part D be engaged by the Secretary of DHHS:

- to ensure that each Medicare Advantage plan and Part D plan has an anti-fraud plan in place and to review the effectiveness of the plan;
- to examine claims for reinsurance payments to determine whether prescription drug plans that submit these claims incurred costs in excess of the allowable reinsurance costs permitted under ACA;
- to review estimates submitted by prescription drug plans by private plans with regard to the enrollment of high cost beneficiaries, and to compare these estimates with the numbers of beneficiaries actually enrolled by the plans.[4]

CMS has taken several steps towards the implementation of Part C and Part D RACs. In December 2010, CMS published a solicitation for public comments, requesting industry feedback on several key issues arising under the pending RAC program expansion.[5] In January 2011, CMS awarded a contract for Part D recovery auditing to ACLR Strategic Business Solutions. As of July 2011, a specific date for initiation of recovery audits had not yet been established; however, prior to launching the expansion of the RAC program, the Part D RAC has been working to fulfill CMS systems access requirements, developing outreach plans

to Part D sponsors, and working with CMS to establish priorities for recovery auditing.

Section 6411 of the ACA also required that states and territories establish Medicaid RAC programs by December 31, 2010. In October 2010, CMS issued a State Medicaid Director Letter to provide initial guidance on the implementation of these RAC programs. Each state and territory was required to submit a State Plan Amendment (SPA) to CMS, in order to establish a state Medicaid RAC program subject to the exceptions and requirements provided by the Secretary of HHS. As of May 2011, CMS had granted a total of 14 exception requests from states and territories. The two largest sub-categories of exceptions were (1) requests from states for delay of implementation, and (2) complete exemption from implementing a RAC program on the basis of Medicaid claims system infrastructure challenges. CMS published a Notice of Proposed Rule Making in November 2010 and subsequently issued the final rule in September 2011.[6]

The originally proposed implementation date of April 1, 2011 was delayed in order to allow states sufficient time to develop their RAC programs. States have been working to implement their Medicaid RAC programs and CMS continues to provide support to the states during the implementation process. In February 2011, CMS launched its "Medicaid RACs At-A-Glance" website (www.cms.gov/medicaidracs), which has basic information about the status of each state's RAC program and details related to the exception requests that were submitted. CMS intends to enhance the website with information regarding state Medicaid RAC program performance, and will be working with states to establish performance measures for the state Medicaid RAC programs.

CMS announced in late December 2011 that the agency will delay a demonstration project that would have allowed RACs to review claims before they are paid.[7] The demonstration project, announced in November 2011, would allow RACs to conduct pre-payment reviews on certain types of claims that historically result in high rates of improper payments. The reviews would focus on a group of seven states with higher-than-average numbers of fraud and error prone providers (California, Florida, Illinois, Louisiana, Michigan, New York, and Texas) and an additional four states with high claims volumes of short inpatient hospital stays (Missouri, North Carolina, Ohio, and Pennsylvania). RACs will review claims before they are paid to ensure that the provider complied with all Medicare payment rules. The intent behind the demonstration project is to help lower fraud and error rates by preventing improper payments, rather than relying on the traditional "pay and chase" methods of looking for improper payments after they have occurred. In late December 2011, CMS announced that this demonstration project is delayed until further notice.

What can providers do to be prepared?

As the efforts of the RACs continue to expand around the country, it is more important than ever for providers to make sure their processes for documentation, billing, and coding are accurate and comprehensive. To avoid the reach of RACs, providers must take the important steps to analyze and evaluate their compliance programs. After this review, providers must adopt any updates to their compliance programs, such as policy revisions, staff training, and regular audits to ensure processes are thoroughly implemented. Efforts made by providers to assess and prepare for the reach of the RACs will be time and effort well spent.

As state enforcement efforts increase with the introduction of Medicaid RACs, providers need to be aware of any state-specific requirements, because the audit rules will vary by state. Providers must exercise due diligence to understand the rules of each of the Medicaid RAC programs in states where they have entities, as far as types of claims audited, number and frequency of medical record reviews, response timeframes for additional documentation requests, external validation of RAC finding accuracy, additional RAC requirements, and possible exemptions.

1. Centers for Medicare & Medicaid Services: *Medicare Fee-for-Service Recovery Audit Program: FY 2011.* Available at http://cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Recovery-Audit-Program/Downloads/FY2011Corrections.pdf
2. CMS: *Medicare Fee-for-Service National Recovery Audit Program Quarterly Newsletter* (Oct. 1, 2011-Dec. 31, 2011). Available at http://cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Recovery-Audit-Program/Downloads/RecoveryAuditProgram_1st_qtr2012_vj.pdf. *See also* CMS: *Medicare Fee-for-Service National Recovery Audit Program Quarterly Newsletter (July 1, 2011-Sept. 30, 2011.* Available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Recovery-Audit-Program/Downloads/FY2011QtrlyReport.pdf
3. CMS: *Implementation of Recovery Auditing at the Centers for Medicare & Medicaid Services: FY 2010 Report to Congress as Required by Section 6411 of Affordable Care Act*. Available at https://www.cms.gov/Recovery-Audit-Program/Downloads/FY2010ReportCongress.pdf (hereinafter, CMS FY 2010 Report).
4. Affordable Care Act, Section 6411(b)(5). The Affordable Care Act consists of H.R. 3590 (the Patient Protection and Affordable Care Act) and H.R. 4872 (the Health Care and Education Reconciliation Act of 2010).
5. *See* 75 Fed. Reg. 81278 (Dec. 27, 2010).
6. *See* 75 Fed. Reg. 69037 (Nov. 10, 2010); 76 Fed. Reg. 57808 (Sept. 16, 2011).
7. Rich Daley: "CMS Holds Off on Two Anti-Fraud Projects." *Modern Healthcare,* Dec. 30, 2011. Available at https://home.modernhealthcare.com.

More information

For more information about the Medicare RAC program, see *www.cms.gov/rac*.

For more information about the Medicaid RAC program, see *www.cms.gov/medicaidracs* and *www.medicaid-rac.com*.

HCCAnet℠

THE PREMIER SOCIAL NETWORK for health care compliance professionals

WHY SHOULD YOU LOG ON TO HCCANET?

- Get your questions answered in the community discussion groups
- Download compliance documents from our community libraries, or share your own
- Stay informed on the latest health care compliance news and guidance

HOW DO I GET STARTED?

- Visit ***HCCAnet*** at **www.hcca-info.org/hccanet**
- Login using your HCCA username and password
- Add a profile photo and ensure your profile information is accurate
- Go to My Subscriptions (Under Communities, Discussion Groups) and subscribe to the groups that pertain to your compliance profession

POPULAR GROUPS INCLUDE:

- Chief Compliance Ethics Officer Health Care
- HIPAA Forum
- Auditing and Monitoring Compliance Health Care
- Ethics Health Care
- Social Media Compliance

If you have any questions about HCCAnet, contact Eric Newman, Esq., CCEP, at 952-405-7938 or eric.newman@hcca-info.org

ALSO VISIT HCCA ON THESE POPULAR SOCIAL MEDIA SITES

JOIN OUR GROUP LinkedIn
hcca-info.org/linkedin

FOLLOW US ON twitter
twitter.com/hcca_news

Find us on Facebook
facebook.com/hcca

+1
hcca-info.org/google

YouTube
youtube.com/compliancevideos

by Shawn DeGroot

Stress Survey

***Shawn DeGroot**, CHC-F, CCEP, CHRC (SDegroot1@regionalhealth.com) is Vice President of Corporate Responsibility at Regional Health, Rapid City, SD. Shawn also serves as President of the HCCA Board of Directors.*

This article is not an interview, but it is dedicated to all of the compliance officers who stay the course and remember who they are and the positive impact they have on business integrity. Earlier this year, HCCA conducted a stress survey for compliance officers and the results were astounding. Roy Snell stated, "The number of calls and stories based on our results was unprecedented." Other associations and periodicals such as *Compliance Week*, *Report on Medicare Compliance*, *Modern Healthcare*, and *Human Resource Executive* published commentary on the topic. At the April Compliance Institute, Dan Levinson, Inspector General with Health and Human Services, commented in his keynote speech that the fact that 60% of compliance officers considered leaving their jobs in the past 12 months due to stress is "troubling."

DeGroot

Why all the fuss? Everyone has stress, whether it is professional or personal, and we all respond to stress differently. Yet, there is an unprecedented environment that is impacting the role of the compliance officer. Leadership, the government, and patients should all be concerned. In April, I attended a professional meeting consisting of managed care, physician executives, and compliance officers. In the evening, the approximately 100 professionals joined together for a dinner; however, the comradery immediately created a mortified silence when multiple and immediate "boos" were expressed in response to the announcement that compliance officers were one of the groups attending the dinner. Needless to say, after a long day of education and learning what we don't know, the networking social event resulted in diminished morale and sent quite a message.

At the HCCA Compliance Institute in Las Vegas, I talked to several compliance officers who are thankful and thrilled that we are focusing on stress as our key initiative this year. During the course of several conversations, I was informed that the compliance officers have many nicknames, some in jest, but a few that are not only unbecoming but deplorable—nicknames such as, "Compliance Cop," the "Velvet Hammer," the "Complaints Officer," and the "Compliance Nazi."

I think the above examples are only the tip of the iceberg in regard to the daily environment in which we live. The "value" of the compliance profession to the public we serve cannot be understood or appreciated if the organizational culture supports behavior as described above. Before HCCA can assist with solutions, we need to better understand the problems. The results of the survey were truly alarming and I challenge every member of your organization's board of directors and executive management to think about their house without a foundation based on compliance and ethics. With or without a perfect storm, weak foundations crumble when under pressure and cannot withstand unplanned environmental elements.

Society of Corporate Compliance and Ethics

SAVE $575 WHEN YOU REGISTER BY JULY 25*

11TH ANNUAL

Compliance & Ethics Institute

October 14–17, 2012 | Las Vegas, Nevada | ARIA in Las Vegas




OVER 90 SESSIONS AND MORE THAN 130 SPEAKERS

Join us at this year's annual meeting and hear from leading companies, including

Pepsi Co	Morgan Stanley
Microsoft	BAE Systems
UPS	Paychex, Inc
Molson Coors Brewing Co	Adecco
Allstate Insurance Company	Comverse
Waste Management	Lockheed Martin Corp
Bausch & Lomb	Qualcomm
The Boeing Company	Accenture
TIAA-CREF	Navistar, Inc

PLATINUM SPONSORS

ELT · ethics·point integrity at work · Global Compliance · The Network Integrated GRC Solutions

Learn more & register online at
www.complianceethicsinstitute.org

**Register on or before July 25, 2012 to save $575*

CEUs offered: **ACHE | CLE | CCB | NASBA/CPE | Nursing Credit**

by Myla Reizen

Readmissions and continuum of care: What is the role of compliance?

» The readmission issue is not just an issue for financial and operational experts to analyze.

» Readmissions should be part of the compliance plan of relevant providers.

» As a preventative approach, the underlying causes leading to readmission issues should be addressed with a clear plan.

» A compliance officer and/or regulatory attorney should be involved in evaluating each approach to each phase of the readmission process.

» These measures should be reviewed from both a hospital and/or post-acute provider perspectives, as applicable.

Myla Reizen *(mreizen@joneswalker.com) is a partner in the Miami offices of Jones, Walker, Waechter, Poitevent, Carrère & Denègre, LLP.*

Hospitals are currently addressing the new legislation that impacts their readmissions from both an operational and financial perspective. However, there are compliance issues that should be on the radar for this area as well. This article highlights some of the scenarios that a compliance officer should consider when evaluating this law and should be helpful for compliance officers at hospitals as well as post-acute providers.

Reizen

CMS has historically focused on readmissions in a number of ways. However, in the Patient Protection and Affordable Care Act (PPACA), Congress called for a number of provisions concerning hospital readmissions. One of the provisions, called the Hospital Readmission Reductions Program (HRRP) provides that payments to applicable hospitals will be adjusted to account for excess readmissions. Beginning in FY 2013, in general, hospitals with certain risk-adjusted readmissions rates for 30-days post discharge will receive reduced Medicare payments. The maximum payment reduction for individual facilities is 1% in FY 2013, increasing to 3% in FY 2015 and thereafter.

There are three main operational stages related to the readmission issue: inpatient care processes, effective discharge planning, and post-discharge steps. The compliance issues should be looked at from each stage in the process. For instance, the OIG Work Plan for FY 2012 (OIG Work Plan) highlights at least two of the operational stages and reads as follows:

> **Safety and Quality of Post-Acute Care for Medicare Beneficiaries.** We will review the quality of care and safety of Medicare beneficiaries transferred from acute-care hospitals to postacute care. We will evaluate the transfer process and also identify rates of adverse events and preventable hospital readmissions from post-acute-care settings. We will focus on three postacute settings: SNFs [skilled nursing facilities], IRFs [inpatient rehab facilities] and long-term-care hospitals. Average hospital stays for Medicare beneficiaries have fallen

steadily over several decades, resulting in increased transfers to postacute-care facilities. Patients recovering in these facilities often require substantial clinical care, and the capabilities of the facilities to care for residents vary by facility type and access to appropriate equipment and staffing. The hospital discharge planning process and the degree of communication and collaboration between acute-care and postacute-care providers also affect a beneficiary's experience and the ability of providers to ensure a smooth and safe transition.

From the post-acute setting to the hospital admission, the OIG Work Plan provides some guidance to other types of compliance officers, rather than just hospital compliance officers. For instance, a pertinent provision provides:

> **Hospitalizations and Rehospitalizations of Nursing Home Residents.** We will review the extent to which Medicare beneficiaries residing in nursing homes have been hospitalized and rehospitalized. We will also assess CMS's oversight of nursing homes whose residents have high rates of hospitalization. Hospitalizations and rehospitalizations of nursing home residents are costly to Medicare and may indicate quality-of-care problems at nursing homes. A 2007 OIG study found that 35 percent of hospitalizations during a SNF stay were caused by poor quality of care or unnecessary fragmentation of services.

Moreover, the Work Plan continues to have a focus on same-day readmissions.

> **Hospital Same-Day Readmissions.** We will review Medicare claims to determine trends in the number of same-day hospital readmission cases. Based on prior OIG work, CMS implemented an edit (a special system control) in 2004 to reject subsequent claims on behalf of beneficiaries who were readmitted to the same hospital on the same day. If a same-day readmission occurs for symptoms related to or for evaluation or management of the prior stay's medical condition, the hospital is entitled to only one diagnosis related group payment and should combine the original and subsequent stays into a single claim. (CMS's Medicare Claims Processing Manual, Pub. No. 100-04, ch. 3, § 40.2.5.) Providers are permitted to override the edit in certain situations. We will test the effectiveness of the edit. This work may also be helpful to CMS in implementing provisions of the Affordable Care Act.

As noted above, a compliance officer should include readmissions as part of the overall compliance plan. However, when evaluating the readmission issue, to the extent the hospital detects that there is a concern, a root cause analysis should be conducted to determine the cause of the issue. It is important to note that there are usually multiple causes leading to a readmission issue. For instance, one cause may be communication between the hospital and post-acute providers. Another cause may be a gap in the discharge planning process. These types of issues impact federal and state laws. In addition, other payors may be implicated, as well accreditation standards. Other recent legislation that impacts hospital payment may be implicated as well. For instance, under the Value-Based Purchasing rules, one item evaluated is discharge instructions.

Once an area is identified, it is important to develop an action plan tailored to the issue. The plan must cover all of the underlying issues with a specified date in which the issues

should be addressed. Some of the plans that hospitals have developed to address varying issues include education to admission coordinators, discharge planners, and care managers, and developing forms, policies, and processes to improve communications. The plan may also include improving communications and transitions between hospitals and post-acute care providers. This could range from developing standardized forms, providing education to both hospital and post-acute providers, and forming committees to improve quality and transition. Hospitals are also entering into certain agreements with post-acute providers to ensure a smooth transition. It is critical that all of these steps, which a hospital and/or other provider may take to address readmissions, is reviewed by the compliance officer and/or regulatory attorney, depending on the circumstances. These scenarios raise a number of compliance issues, from patient choice to fraud and abuse, depending on the scenario.

The compliance officer and/or regulatory attorney should be part of each concept to address readmissions. For instance, another area that hospitals have decided to target is high-risk patients. Hospitals and other providers are evaluating many proposals to serve this population. These patients may be provided education regarding medication management and/or diet, and/or certain equipment or services in order to prevent them from being readmitted to the hospital. One measure that hospitals are using is telemonitoring. This area raises a host of compliance issues that should be evaluated in addition to the ones identified above, such as licensure, credentials of the persons providing the care, physician involvement, and consents. Furthermore, other federal and state laws should be considered, such as the civil monetary penalties laws.

> A compliance officer should include readmissions as part of the overall compliance plan. However, when evaluating the readmission issue, to the extent the hospital detects that there is a concern, a root cause analysis should be conducted to determine the cause of the issue.

In summary, it is important to note that readmissions should be part of the compliance plan of relevant providers. As a preventative approach or when necessary, steps should be taken to address the underlying causes leading to readmissions issues with a clear plan as described above. When evaluating each approach to the issue in the context of each phase of the readmission process, and as alternatives are being developed, a compliance officer and/or regulatory attorney should be involved in the process. These measures should be reviewed from both a hospital and/or post-acute provider perspective, as applicable.

In conclusion, the readmission issue is not just an issue for financial and operational experts to analyze, but compliance officers and regulatory attorneys must be consulted as well.

When compliance training is this effective, you just can't get it out of your head.

Healthcare facilities that are serious about reducing risk choose HCCS.

Compliance is serious business. It takes a serious training program to increase awareness and change staff behavior.

Engaging, professionally designed multimedia content is more effective than page-turning text.

Engage your staff! An effective training program requires more than reading text from a website. HCCS online compliance and competency training courseware uses professional multimedia elements to create an engaging, interactive learning environment.

Adult learning works.

Research shows that retention is highest when the learner sees, hears and interacts with training content.

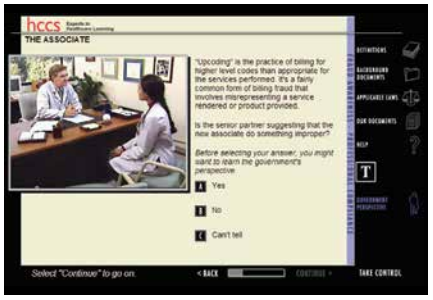
The top university hospitals in the country choose HCCS.

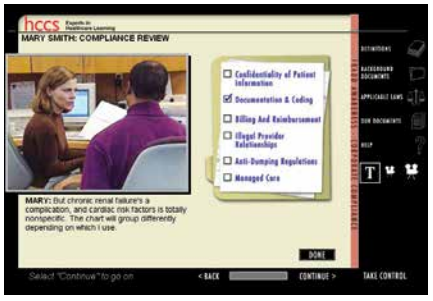
HCCS is the leading provider of online multimedia compliance and competency training courseware with over 1.5 million registered learners.

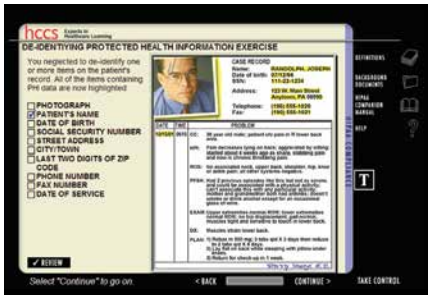
When employees pay attention, you reduce your risk.

Looking for a more effective training solution? Want to increase compliance? Take one of our free educational webinars or test drive our courseware yourself at www.hccs.com.

HCCS - Effective Compliance Solutions







hccs Experts in Healthcare Learning

For more information and a schedule of FREE training webinars call 877-933-4227 or go to www.hccs.com.

Medicare • Medicaid • HIPAA • Quality • Research • Conflicts of Interest

by Susan Nance, DCSW, CPHQ, CHC

Improving the effectiveness of patient safety

» OIG notes CMS has "missed opportunities" to incorporate patient safety issues.
» Most patient safety events are not reported in incident reporting systems.
» Increased emphasis is on effectiveness of programs, not just their presence.
» Surveys of "immediate jeopardy" complaints may open general quality-of-care issues.
» Quality and Compliance issues are overlapping.

Susan Nance *(susan.nance@healthsouth.com) works as Director of Quality and Risk at Vanderbilt Stallworth Rehabilitation Hospital in Nashville.*

The role of the Office of Inspector General (OIG) in activities of the Centers for Medicare & Medicaid Services (CMS) has expanded over the past few years, leading to an increased frequency of auditing by state agencies and accrediting organizations. Efforts to improve patient safety through identification of issues have also expanded, along with education of providers.

Nance

The missions of the agencies referenced in this article are worthy of consideration in this context. The Department of Health and Human Services (DHHS) is the United States government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. DHHS has several divisions, including the OIG, CMS, the Agency for Healthcare Research and Quality (AHRQ), and the Office of Civil Rights (OCR).

The mission of the OIG is to protect the integrity of the DHHS's programs as well as the health and welfare of beneficiaries served by those programs. OIG is responsible for audits, evaluations, investigations, and law enforcement efforts relating to DHHS programs and operations. The Office of Audit Services (part of OIG) conducts or oversees audit work done by others. These audits examine the performance of DHHS programs and are intended to provide independent assessments of its programs and operations.

The mission of CMS is to improve health care and ensure coverage for all Americans. One way of improving health care is to require that hospitals track and analyze adverse events as Conditions of Participation (CoPs). CMS does not require specific system characteristics, thus the system may lack effectiveness. State health departments oversee hospital licensing, minimum care standards, and conduct surveys in response to complaints. State agencies serve as the local arm of CMS, and are often the first responders in conducting audits.

AHRQ works to improve quality and safety of our health care system through research and implementation of evidence-based medicine. OCR oversees the Health Information Portability and Accountability Act (HIPAA) and the Patient Safety Rule that ensures privacy when patient safety events are analyzed to improve patient safety.

Accreditation organizations, such as The Joint Commission, Det Norske Veritas (DNV)

Healthcare, and the American Osteopathic Association, ensure CoPs are met.

Quality Improvement Organizations (QIOs) are private entities that contract with CMS to support quality-of-care issues. QIOs provide guidance and technical assistance to hospitals and other providers.

History

In 1999, the Institute of Medicine (IOM) published the seminal work, *To Err is Human: Building a Safer Health System*.[1] An "adverse event" is "any harm that comes to a patient as a result of medical care." IOM cited studies that used medical record reviews to identify adverse events when it found that almost 4% of hospitalized patients experienced adverse events, more than half of which were preventable. More than 6% of those adverse events resulted in death. IOM extrapolated the results to hospital admissions nationwide, concluding that adverse events caused between 44,000 to 98,000 deaths in US hospitals each year. IOM's recommendations were twofold: (1) to develop a nationwide system for collecting standardized data about serious medical errors or other events to hold hospitals accountable for performance; and (2) to provide information that could lead to improved patient safety. We are still working on those goals in 2012.

Congress enacted the Tax Relief and Health Care Act of 2006 as a response to the IOM publication. The Act mandated that OIG report to Congress the incidence of "never events" among Medicare beneficiaries, and includes payment, denial of payment, or recoupment of services for "never events." These are processes that CMS uses to identify events and deny payment; recommendations of potential processes which increase awareness about safety; how lessons learned from a root cause analysis will educate others while protecting patient privacy; and recommendations about methods to identify events.

OIG responded to the mandate by writing a series called "Adverse Events in Hospitals," based on surveys completed in 2008, which identified yet untouched opportunities and failures to improve patient safety in our health systems. Each article in the series was divided into the headings of Study, Findings, Conclusions and Recommendations of the OIG, a Summary Response from CMS and AHRQ, and copies of the original correspondence between the agencies on the recommendations of the article.

Overview of key issues

The first in the Adverse Events series, "Overview of Key Issues"[2] found four areas of significance to the overlap of quality of care and compliance issues. First, they estimated that the incidence of adverse events in hospitals fluctuates greatly and measurement is difficult. Some adverse incidents were discovered through patient and family interviews; however, the patients and families did not understand the definition of adverse events. Though not identified in hospital incident reports or medical record reviews, the lack of understanding of what defines an adverse incident encumbered this method of identification. Second, hospitals relied on staff to report incidents. Some staff, however, exhibited reticence to changing their practices, drawing attention to mistakes, or they feared punitive action, thus reducing reporting. Third, substantial underreporting of adverse events to oversight bodies is probable, due to apprehension of magnified attention by accrediting organizations.

Fourth, information to help prevent adverse events is widely available, but some providers may be hesitant to adopt or apply the recommended practices with consistency. Some providers may believe that the guidelines are not relevant to their setting and disregard them altogether. OIG recommended strategies to:

- identify a national body to lead patient safety efforts;

- focus on hospital use of recommended practices and evidence based guidelines;
- establish methods for measuring the incidence of adverse events;
- expand the use of the electronic health records (EHR) within and between hospitals; and
- evaluate the comparability of data reported across entities and streamline reporting mechanisms to reduce the burden on hospitals.

State reporting systems

In its efforts to make recommendations for improved health care and compliance with standards, OIG assessed state reporting systems of adverse events.[3] Only half of the states had adverse event reporting systems which varied in methods to identify events and efforts to improve patient safety in the state system. Some states used hospital reports of complaints, referrals, and other databases to identify under-reporting. Almost three-quarters of those states with reporting systems used the information to communicate with hospitals about best practices, provide early warning signals, and specific patient safety issues. OIG identified disparities in reporting data among the systems, making it impossible to identify national incidences and trends. CMS responded to the report by indicating that it would be helpful to identify other partners in reporting system efforts, such as AHRQ and Patient Safety Organizations. Because CMS is identifying partners, Compliance and Quality personnel could use the wealth of knowledge of discrepancies in coding or complaints to identify quality of care issues, and document the governing body's and the organization's response.

OIG also found that incident reporting systems were unsuccessful in identifying 86% of events that caused patient harm, often because staff did not interpret the event as a cause of harm.

Physician reviews

The study highlighted in the next report, "Case Study of Incidence among Medicare Beneficiaries in Two Selected Counties,"[4] described findings by physicians' review of the medical record. The physicians sought to determine if an adverse incident occurred, the level of harm, and if the events caused higher Medicare reimbursement. Lack of incident reports could prevent hospitals from tracing events, suggesting that incident reporting systems may be an unreliable source of information for national trending. Events that resulted in temporary harm, which increased length of stay or interventions, also were assessed for their preventability and cost. In the study, more than 13% of those hospitalized experienced adverse events during their hospital stay, and an additional 15% experienced events that required additional medication intervention.

The physician reviewers determined that almost half of adverse and temporary harm events were preventable. OIG also found that incident reporting systems were unsuccessful in identifying 86% of events that caused patient harm, often because staff did not interpret the event as a cause of harm.[5]

Methods for Identifying Events

OIG's recommendations in "Methods for Identifying Events"[6] included that CMS should use present on admission (PoA) indicators

in billing data to calculate the frequency of adverse events occurring within hospitals; and that medical record reviews conducted for other purposes, (such as CMS's Comprehensive Error Rate Testing and State Agency CoP surveys) should be considered as another source for identification of adverse events. CMS responded that it would work to strengthen its surveyor training programs, thus enhancing surveyor abilities to evaluate compliance with Quality Assessment and Performance Improvement requirements. Compliance officers should work with Quality officers to ensure that billing and charting mirror each other, and that areas of patient safety discovered through different methods are addressed and discussed at the level of the hospital's governing board.

The Tax Relief Act authorized more funding to make recommendations for legislation and administrative action related to conclusions in these publications. The Affordable Care Act passed, mandating that DHHS take a stronger stand to improve patient safety. The tone in public documents changed from looking for "findings" and "recommendations" to identifying what other agencies are not doing and offering more directional guidance. The OIG's mission to protect and promote the integrity and effectiveness of HHS programs includes the administration of Medicare and Medicaid services. Because OIG promotes the integrity of CMS, CMS reaches out to providers to ensure compliance with CoP standards and effectiveness of hospital programs in ensuring patient safety.

Recommendations found in "National Incidence Among Medicare Beneficiaries"[7] include suggestions that AHRQ and CMS should broaden patient safety efforts and develop guidelines for hospital reporting and prevention strategies. AHRQ should also continue to encourage hospital participation with Patient Safety Organizations and CMS should use PoA indicators in billing data to identify the occurrence of adverse events.

Immediate jeopardy complaints

OIG reviewed a random sample of "immediate jeopardy" complaints to identify serious adverse events, to which Medicare responded in its "Medicare's Responses to Alleged Serious Events"[8] publication. OIG found that state agencies and CMS "missed opportunities" to incorporate patient safety principles in their responses. Less than half the time, CMS directed state agencies to assess the CoPs on the topics of performance improvement and the governing body. There was little-long term monitoring to verify that the hospital's corrective actions resulted in sustained improvements. Hospitals were asked to submit performance data in fewer than 5% of complaints that required corrective action. State agencies did not always disclose the nature of complaints to hospitals, thus limiting the hospital's ability to learn from alleged events. OIG found that CMS informed The Joint Commission of almost a third of immediate jeopardy complaints, impeding The Joint Commission's oversight of its accredited hospitals. The hospitals were aware of 99% of complaints and investigated 85%. Two-thirds of hospitals began the investigation before the state agencies arrived onsite. State agency actions lent urgency, but caused disruption in the hospital's response. More than half the events resulted in the state citing the hospital for federal deficiencies. OIG recommended that CMS:

- require that all immediate jeopardy complaint surveys evaluate compliance with the CoPs on Quality Assessment and Performance Improvement (QAPI);
- limit the scope of the survey to the allegation and the QAPI CoP initially, and broaden the survey to evaluate compliance with the governing board's CoPs and other relevant CoPs, if problems are not addressed;

- ensure that state agencies monitor hospitals' corrective actions for sustained improvements.

A finding of the case study cited in "Methods for Identifying Events"[9] revealed that diagnosis codes were inaccurate or missing for more than half the Medicare hospital acquired conditions (HACs) identified. These inaccuracies could have resulted in Medicare overpayments and inhibited the use of billing data to monitor quality of care in hospitals. OIG recommended that CMS ensure that hospitals code claims accurately and completely to allow for identification of HACs affected by Medicare's payment policy.

Conclusion

The role of the OIG in assisting CMS to determine its effectiveness in increasing patient safety for Medicare beneficiaries has enlarged in the past few years. The OIG 2012 Work Plan[10] indicates an evaluation of 2010 data in researching the national incidence of adverse events. The departments of OIG, CMS, and AHRQ are working together closely to ensure patient safety for its beneficiaries. Compliance and Quality personnel should continue to share information to improve outcomes for the hospital and the patients it serves. Certainly more focus on that area will reveal more work to be done and more audits to come.

1. LT Kohn, JM Corrigan, and MS Donaldson, eds: "To Err is Human: Building a Safer Health System." Institute of Medicine. Available at http://www.nap.edu/catalog.php?record_id=9728
2. Department of Health and Human Services, Office of Inspector General. *Adverse Events in Hospitals: Overview of Key Issues.* OEI-06-07-00470. December 2008. Available at http://oig.hhs.gov/oei/reports/oei-06-07-00470.pdf
3. Department of Health and Human Services. Office of Inspector General. *Adverse Events in Hospitals: State Reporting Systems.* OEI-06-07-00471. December 2008.
4. Department of Health and Human Services. Office of Inspector General. *Adverse Events in Hospitals: Case Study of Incidence among Medicare Beneficiaries in Two Selected Counties.* OEI-06-08-00220. December 2008. Available at http://www.oig.hhs.gov/oei/reports/oei-06-08-00220.pdf
5. Department of Health and Human Services. Office of Inspector General. *Adverse Events in Hospitals: Case Study of Incidence among Medicare Beneficiaries in Two Selected Counties.* OEI-06-08-00220. December 2008.
6. Department of Health and Human Services. Office of Inspector General. *Hospital Incident Reporting Systems Do Not Capture Most Patient Harm.* OEI-06-09-00091. January 5,2012. Available at http://oig.hhs.gov/oei/reports/oei-06-09-00091.asp
7. Department of Health and Human Services. Office of Inspector General. *Adverse Events in Hospitals: Methods for Identifying Events.* OEI-06-08-00221. March 2010.
8. Department of Health and Human Services. Office of Inspector General. *Adverse Events in Hospitals: Medicare's Responses to Alleged Serious Events.* OEI-01-08-00590. October 2011.
9. Department of Health and Human Services, Office of Inspector General: *Adverse Events in Hospitals: Methods for Identifying Events.* OEI-06-08-00221. March 2010.
10. Department of Health and Human Services, Office of Inspector General: OIG Work Plan, FY 2012, Part 1: Medicare Part A and Part B

by Wade Miller and Angela Adams

Increasing accountability for individuals

» The government is increasing efforts to hold individuals accountable.
» OIG has the authority to exclude owners and managing employees from federal programs.
» Executives can be implicated by the responsible corporate officer doctrine, even without direct knowledge of a crime.
» Recent case law demonstrates the government's exclusion and prosecution efforts toward individuals.
» Specific steps can be taken to avoid government scrutiny and action.

Wade Miller *(wade.miller@alston.com) is a Partner and* ***Angela Adams*** *(angela.adams@alston.com) is a Senior Associate at Alston & Bird in Atlanta.*

Following a number of eye popping settlements by health care companies, the government is increasingly looking to change corporate behavior by holding individuals accountable. For the last 18 months, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) and the Department of Justice (DOJ) have raised the stakes for individuals in the health care industry. Among the most powerful tools in the government's arsenal is its authority to exclude owners and executives of health care companies from participation in federally funded programs and, in some cases, without a showing of wrongdoing. This article will first set forth the authority that the OIG and the DOJ have used in targeting executives and officers individually. Second, this article will highlight recent exclusions and prosecutions targeted toward individuals. Last, this article will provide practical tips that compliance officers can use to help their corporate officers and executives avoid the snare of the OIG and/or DOJ in this new era of individual accountability.

OIG exclusion authority

Since 1996, HHS-OIG has had the authority to exclude corporate officers and individuals from participation in federally funded health care programs pursuant to Section 1128(b)(15) of the Social Security Act (SSA), codified at 42 U.S.C. § 1320a-7(b)(15). The government, however, has rarely utilized this authority to exclude executives and officers of large health care companies until recently. In October 2010, the Office of Inspector General issued a Guidance signaling its intent to aggressively pursue individuals based upon their positions in companies excluded or convicted of certain crimes.[1]

Miller

Adams

The exclusion provisions under the Social Security Act provide for mandatory and permissive exclusion. The mandatory exclusion provisions provide for exclusion where an entity or individual has been convicted of certain enumerated crimes. Specifically, mandatory exclusion occurs upon conviction of program-related crimes, including Medicare and Medicaid, conviction for patient neglect or abuse in connection with health care services, felony conviction for health care fraud, and felony conviction related to controlled substances. Because these exclusions are mandatory, OIG has no authority to waive exclusion under these circumstances.

Of more immediate importance is the permissive exclusion authority that can be exercised by OIG, which has the discretion to exclude entities and individuals for a litany of reasons set forth in SSA § 1128(b)(1)-(16). Pursuant to SSA § 1128(b)(15), OIG has the authority to exclude individual owners, officers, and managing employees in sanctioned entities. A managing employee is defined as a "general manager, business manager, administrator or director who exercises operational or managerial control over the entity, or who directly or indirectly conducts the day to day operations of the entity."[2] Although the government has not used this provision to exclude a compliance officer to date, depending on their job responsibilities, compliance officers could be considered managing employees subject to the exclusion provision of SSA § 1128(b)(15).

> Among the most powerful tools in the government's arsenal is its authority to exclude owners and executives of health care companies from participation in federally funded programs and, in some cases, without a showing of wrongdoing.

In the October 2010 guidance, OIG explained the parameters of its individual exclusion authority under SSA § 1128(b)(15). OIG explained that it has the authority to exclude individuals who have an ownership or control interest in a sanctioned entity only if there is evidence that the owner knew or should have known of the conduct that led to the sanction. In contrast, as OIG explained, the burden for excluding officers and managing employees is much lower. OIG is not required to make a showing that an officer or managing employee had knowledge or was engaged in the sanctioned activity before excluding the officer or employee. In sum, management employees can be excluded simply by virtue of their positions during the time of the sanctioned activity.

In excluding individuals, OIG advised that it will operate with a presumption in favor of exclusion where there is evidence that the individual knew or should have known of the sanctioned conduct. This presumption, however, can be overcome if OIG finds that significant factors weigh against exclusion. In the guidance, OIG sets forth and explains the factors it will consider when deciding to exclude an individual, including:

- the circumstances of the misconduct and the seriousness of the offense;
- the individual's role in the sanctioned entity;
- the individual's actions in response to the misconduct, and
- information about the entity.

Though, historically, OIG has infrequently exercised its authority under SSA § 1128(b)(15) to exclude individuals, almost half of the exclusions (15 of 36) under this provision have occurred in the last two years.

The responsible corporate officer doctrine

The responsible corporate officer doctrine (RCOD), also sometimes referred to as the Park doctrine, holds corporate officers responsible for public welfare-based crimes committed by a company, without any proof that the officer or executive had knowledge or involvement in the illegal conduct. This theory is mostly

used in the prosecution of Food, Drug, and Cosmetics Act (FDCA) violations. The RCOD was first articulated in the 1943 Supreme Court case of *U.S. v. Dotterweich*,[3] in which the Supreme Court upheld the trial court's conviction of the president and general manager of a company for violations of the FDCA—namely, shipping misbranded and adulterated drugs. The company was acquitted. In this case, the Court explained that an "offense is committed . . .by all those who [have] a responsible share in the furtherance of the transaction which the [act] outlaws...though consciousness of wrongdoing may be totally wanting."[4]

The Supreme Court affirmed the RCOD theory established in *Dotterweich* with the 1975 decision in *U.S. v. Park*,[5] in which the Supreme Court upheld the conviction of John Park, President and CEO of Acme Markets, Inc., for violations of the FDCA. Specifically, the Court found that Acme, under Park's leadership, allowed food to be exposed to rodent contamination. In upholding the trial court's conviction of Park, solely based upon his position in the corporation and his ultimate responsibility for sanitation, the Supreme Court stated that the FDCA "imposes the highest standard of care and permits conviction of responsible corporate officials who . . . have the power to prevent or correct violations of its provisions."[6] The Court also noted that executives not only have "a positive duty to seek out and remedy violations when they occur, but also, and primarily, a duty to implement measures that will insure that violations will not occur."[7]

OIG noted that the decision in *Park* was one of the authorities relied upon in composing the factors it will consider when deciding whether to exclude an individual. It is important to note, that in addition to the OIG's authority to exclude individuals by virtue of their positions, OIG can also exclude individuals convicted of a misdemeanor relating to controlled substances, among other things. Therefore, in reviewing the RCOD in connection with OIG's permissive exclusion authority, it is clear than an individual can be held accountable by program exclusion and/or criminal conviction for the crimes or violations committed by others, absent any knowledge or wrongdoing.

Case law

Recent cases of individual exclusion and prosecutions include:

- **KV Pharmaceutical Chairman**

In a presumably strategic manner, just one month after it issued its guidance, OIG excluded Marc Hermelin, KV Pharmaceutical's former chairman and major shareholder, pursuant to its authority under SSA § 1128(b)(15). In early 2010, Ethex Corporation, a KV subsidiary, pled guilty to violations of the FDCA for failing to file field alert reports regarding its manufacture and distribution of oversized pills. The company paid a total of $27.6 million in fines, restitution, and forfeiture. Four months after his exclusion, Hermelin pled guilty to two federal counts of mislabeling the oversized pills pursuant to the RCOD. In the 2011 Annual Report on the Health Care Fraud and Abuse Control Program, HHS noted "[b]y virtue of his roles at KV and Ethex, Hermelin was a 'responsible corporate officer' with the authority and responsibility to prevent and correct FDCA violations at both companies." Hermelin was ultimately sentenced to 17 days in jail. He was also ordered to pay a $1 million fine and forfeit $900,000.[8]

- **Purdue Frederick executives**

In May 2007, Purdue Frederick Company pled guilty to FDCA felony violations of misbranding and marketing the drug OxyContin. In addition, three executives (the former CEO, chief scientific officer, and general counsel) pled guilty to misdemeanors pursuant to the RCOD. Unlike its charges against the company, the government's charges against the executives did not allege that

the executives knew of or participated in the illegal misbranding. In exchange for no jail time, Michael Friedman, former President and CEO, agreed to pay $19 million, Howard Udell, former General Counsel, agreed to pay $8 million, and Paul Goldenheim, Chief Scientific Officer, agreed to pay $7.5 million.

In November 2007, OIG notified the executives that they would be excluded pursuant to the earlier misdemeanor convictions under the RCOD. Specifically, OIG noted that exclusion was permissible under SSA § 1128(b)(1), which provides for permissive exclusion of individuals convicted of crimes "relating to fraud, theft, embezzlement, breach of fiduciary responsibility or other financial misconduct" and SSA § 1128(b)(3), providing for exclusion based upon convictions "relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance." The federal District Court for the District of Columbia upheld the exclusion of the three former executives in December 2010.

The executives appealed the district court's opinion to the U.S. Court of Appeals for the District of Columbia. The executives argue that the permissive exclusions under SSA § 1128(b)(1) and (b)(3) are not permissible and that the 12-year exclusion period is arbitrary. The government argues that the misdemeanor convictions under the RCOD are excludable offenses. Oral argument was held on Dec. 6, 2011 and many anxiously await the court's decision.

▶ InterMune CEO

In 2006, InterMune, a biotechnology company, was charged with one count of engaging in illegal off-label promotion of the drug Actimmune. InterMune later entered into a deferred prosecution agreement and paid $37 million to resolve civil and criminal charges. In 2009, its CEO, Scott Harkonen, was tried and convicted of wire fraud in the U.S. District Court for the Northern District of California for approving a press release relating to the clinical uses of the same drug. Following his conviction, Harkonen was excluded from federally funded programs in September of 2011. OIG imposed Harkonen's exclusion pursuant to the mandatory exclusion authority under SSA § 1128(a)(3), which requires exclusion of individuals convicted of felonies related to health care fraud. Harkonen has appealed his conviction to the Ninth Circuit and has also appealed his exclusion to an administrative law judge. In February 2012, Harkonen filed suit against the DOJ, alleging it published false and misleading statements about his case.

▶ Forest Laboratories CEO, non-exclusion

In April of 2011, OIG sought to exclude Howard Solomon, CEO of Forest Laboratories, for FDCA violations committed by Forest Labs. Previously Forest Labs had pled guilty to off-label promotions, among other things, and reached a global settlement with the DOJ for $313 million. During its investigation of Forest Labs, the government did not bring any charges against any individuals, including Solomon. Unlike the other examples of executive exclusion, Solomon was never charged with any wrongdoing.

After meetings with Solomon's lawyers, however, and reviewing information provided by Solomon, OIG decided to cease the exclusion efforts against Solomon. Presumably, OIG weighed the mitigating factors in light of the information presented by Solomon's attorneys and determined that exclusion was unwarranted.

▶ Synthes Executives

In June 2009, Synthes, Inc. and Norian Corporation, a wholly owned subsidiary of Synthes, and four former Synthes executives (the former chief operating officer, president of the spine division, director of regulatory and clinical affairs, and vice president of operations) were charged with shipping adulterated and misbranded pills and conspiracy to impair and impede the lawful functions of the FDA. Both of

the companies pled guilty and paid a combined settlement of $23 million. The four former executives pled guilty to one misdemeanor count of shipping adulterated and misbranded drugs in interstate commerce based, in part, upon their status as responsible corporate officers during the time of the sanctioned activity. The executives were sentenced to prison terms ranging from five to nine months.

Practical tips to avoid the OIG and DOJ

The best way to avoid individual or company exclusion or prosecution is to prevent conduct that would get the attention of the government. Compliance officers and executives should focus on prevention, rather than reaction. There are many scenarios that might initiate exclusion of individuals, most of which can be prevented. For instance, egregious quality-of-care deficiencies and systemic organizational compliance violations might indicate a lack of institutional control. Failure by executives to implement corrective actions, adhere to compliance oversight obligations, or be reasonably informed of compliance risks might signal bad faith on the part of the individual. Lastly, evidence of obstruction of justice directed or instructed by leadership will almost certainly get the attention of the OIG and/or DOJ.

The question that most compliance officers grapple with is: What can be done to remain free from OIG and DOJ scrutiny? The starting point is relatively simple—educate, monitor, and correct. Informing each officer and managing employee of the risks of compliance violations, including exclusion (which is seen as a career death knell for individuals working in the health care industry), will likely impart a sense of a personal responsibility for the culture of compliance within the company. Implementing and enhancing a compliance program, with well-articulated reporting, monitoring and disciplinary procedures can help the company identify and address risks. Once compliance breaches have occurred, immediate action must be taken to correct the problem and rectify any known and perceived harms. Below are few specific steps that can be taken:

- Take a proactive role in creating a culture of compliance.
- Implement continuing training for all corporate officers who are subject to exclusion under SSA § 1128(b)(15).
- Implement and enhance policies to identify and address compliance risks.
- Take immediate action when notified of a problem.
- Take a truthful and cooperative approach with government investigations.

1. OIG: Guidance for Implementing Permissive Exclusion Auth. Under § 1128(b)(15) of the Social Security Act. Available at http://oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf
2. 42 U.S.C. § 1320a–5(b).
3. *U.S. v. Dotterweich*, 320 U.S. 277 (1943).
4. *Id. at* 284.
5. *U.S. v. Park*, 421 U.S. 658 (1975).
6. *Id. at* 676.
7. *Id. at* 672.
8. The Dept of Health and Human Services and The Dept of Justice Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2011. Available at http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2011.pdf

MANAGE RISK

Health Law Resource Center™

Industry-leading health law news and analysis. Compliance guidance and enforcement insight. Practical tools, forms, and checklists. Keep an eye on the fast-moving health law landscape and focus in on the critical details you need — all with one comprehensive resource.

TO START YOUR FREE TRIAL CALL 800.372.1033 OR VISIT www.bna.com/hlrc-hcca

Bloomberg BNA

bna.com

by John Falcetano

Becoming Certified

***John Falcetano**, CHC-F, CIA, CCEP-F, CHRC, CHPC, CICA (jfalceta@vidanthealth.com) is Chief Audit/Compliance Officer for Vidant Health in Greenville, NC, and Vice President of the HCCA Board of Directors.*

It was wonderful attending the recent HCCA Compliance Institute in Las Vegas. It was a great time to see old friends, network with peers, and attend the many educational opportunities on a wide variety of compliance topics. One of the easiest ways for me to network is through exchanging business cards with my peers. I was amazed so see how many members are becoming certified. There are many benefits of certification. Earning the CHC, CHPC, CHRC, or CHC-F credentials demonstrates a commitment to high ethical standards. It also makes compliance professionals more marketable and raises the confidence of their employers and staff in their professional abilities.

Falcetano

Attending the HCCA Compliance Institute isn't the only way our members have to network. Another way is through HCCAnet,℠ our social networking site. For those of you interested in certification, the social network site provides information that candidates need to know, including details on the requirements candidates must meet in order to be eligible to sit for the exam. In addition, the site provides information on how to prepare for the examination, how to take the test, and how to maintain your certification. If you still have questions, you can post questions and get answers from other members.

I highly encourage everyone to consider becoming certified, but even if you are not ready to do that now, please visit the HCCAnet℠ site. Join in on a discussion, start a blog, download needed compliance documents, or just make new friends.

To participate in discussions or to just talk with your peers, visit the our social network at *http://community.hcca-info.org/HCCA/Communities/DiscussionGroups*

by Gary W. Herschman and Alexandra Miller Khorover

New Stark Law guidance: Court of Appeals decision in the *Tuomey* case

» The Fourth Circuit opinion provides some substantive Stark Law guidance.
» The technical component of personally performed hospital services is a designated health service.
» Considering the volume or value of anticipated referrals is impermissible.
» Inquiry is whether a contract "on its face" varies with referrals.
» Compensation should be fair market value for services actually performed.

Gary W. Herschman *(gherschman@sillscummis.com) is Chair of the Sills Cummis & Gross PC Health Care Practice Group and* ***Alexandra Miller Khorover*** *(akhorover@sillscummis.com) is an Associate in the firm's Health Care Practice Group in Newark, NJ.*

On March 30, 2012, the United States Court of Appeals for the Fourth Circuit overturned the district court's $45 million judgment in *U.S. ex rel. Drakeford v. Tuomey Healthcare System*. Although the decision was based on procedural grounds (violation of 7th Amendment right to jury trial), in its opinion remanding the case for further proceedings, the Fourth Circuit addressed two Stark Law issues which it felt were likely to be raised on remand: (1) whether a "referral" (as defined in the Stark Law) was made by the physicians in question; and (2) whether the contracts with the physicians implicated Stark's "volume or value" standard by taking into account anticipated referrals. The following article discusses the Fourth Circuit's holdings and the potential ramifications with respect to the structuring of future hospital-physician arrangements.

Background

At issue in the *Tuomey* case were a series of part-time employment agreements entered into between wholly-owned subsidiaries of Tuomey Healthcare System (Tuomey) and certain specialist physicians on its medical staff. By way of brief summary, the important facts of the case are as follows:


Herschman


Khorover

- Tuomey, faced with increased competition from physicians performing outpatient procedures in their offices and physician-owned surgery centers, offered part-time employment agreements to physicians practicing in a local gastroenterology group, as well as local orthopedists and other specialists. Pursuant to the employment agreements, the physicians would perform their outpatient procedures exclusively at Tuomey for a period of 10 years. The physicians acted in the capacity of employees only when they were performing surgical procedures.
- The agreements further included a 2-year, 30-mile post-termination non-competition provision. The physicians were paid a base salary tied to collections of personally performed services (see below), plus

a productivity bonus totaling 80% of collections and up to 7% of collections for meeting certain quality measures.

- The base salary involved "tiered" compensation, whereby each physician would earn a base of $5,000 for personally performed collections of up to $185,000, and an additional $5,000 in base compensation for each additional $25,000 of personal collections.
- The employment agreements also included a full-time benefits package for some of the physicians, including health coverage, malpractice insurance, and CME reimbursement.
- In developing a benchmark for physician compensation, Tuomey's compensation consultant calculated the value of potentially lost referrals with respect to a particular physician practice and divided it by the number of physicians in the practice.
- Tuomey received a fair market value report stating that the compensation paid to the physicians was justifiable so long as it did not exceed 150% of the 90th percentile —a methodology which was rejected at trial by both parties' experts.
- In tape recorded conversations with physicians, Tuomey executives represented that the payments functioned as "phantom ownership" in Tuomey's outpatient surgical center and that the hospital wanted to "shar[e] revenues with those people who might otherwise, frankly go out and compete with us…" In other conversations, hospital executives explained that it was reasonable for the hospital to lose money on the proposed employment agreements because the "hospital has other sources of revenue."
- The government argued that Tuomey's arrangements with the physicians constituted an indirect compensation arrangement under the Stark Law which did not meet the requirements of the indirect compensation arrangement exception, because the compensation paid to the physicians "took into account the volume or value of the physicians' referrals."

At trial, the jury sided with the government and found that a Stark violation had occurred; however, the jury found that Tuomey did *not* violate the Federal False Claims Act (FCA). In July 2010, on a post-trial motion, the district court entered a $45 million judgment against Tuomey for the equitable claims of payment by mistake of fact and unjust enrichment, based on the jury's finding that Tuomey violated the Stark Law. The district court also set aside the FCA verdict and granted the government's motion for a new trial on the issue of the FCA violation. Tuomey appealed the district court's judgment.

The parties' arguments on appeal

In its brief appealing the district court's decision, Tuomey argued that the Stark Law does not apply in the first instance to the financial relationship between Tuomey and the employed physicians. Both parties previously acknowledged that the only "financial relationship" under the Stark Law which is potentially applicable to the *Tuomey* case is an "indirect compensation arrangement." Under the Stark Law regulations, in order for an "indirect compensation arrangement" to exist, the referring physician must "receive aggregate compensation…that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician." The Stark Law definition of "referral" excludes any designated health services (DHS) personally performed or provided by the referring physician. Tuomey argued in its brief that the physicians were paid only for their personally performed professional services, and therefore, no indirect compensation arrangement existed.

In response to Tuomey's arguments, the government argued in its reply brief that the physicians' compensation varied with the volume and value of their referrals because the physicians only earned money for work (performing surgical procedures) that simultaneously generated a facility fee for the hospital. To advance this argument, the government contended that, despite the fact that the compensation was based on personally performed services, every time the physicians performed a procedure, the cash component of the physicians' salaries increased, as did the volume of referrals of the technical component of outpatient services to Tuomey. Thus, the government argued that because the physicians' salaries were expressly determined by the number or value of hospital outpatient procedures performed, the Stark Law was implicated. The government also argued that the arrangements with the physicians "took into account the volume or value" of the physicians' referrals because the compensation paid to the physicians was designed to exceed their personal collections and included an amount that represented a portion of their anticipated referrals of the technical component of the hospital outpatient services.

The Fourth Circuit's opinion

On March 30, 2012, the Fourth Circuit overturned the district court's judgment finding a violation of Tuomey's 7th Amendment right to a jury trial—because the district court set aside the jury verdict in its entirety, no factual basis existed to sustain the judgment against Tuomey on the equitable claims. The Fourth Circuit ordered a new trial.

Although the case was decided on procedural grounds, the Fourth Circuit's opinion addressed two Stark Law issues that were raised on appeal that the court felt were likely to recur on remand: (1) whether a "referral" was made by the physicians; and (2) whether the contracts with the physicians implicated Stark's "volume or value" standard by taking into account anticipated referrals.

Was a referral made?

This issue goes to the crux of Tuomey's threshold argument that the Stark Law is not implicated in the first place, because the physicians were paid for their personally performed services (i.e., the professional component of surgical procedures), which do not constitute "referrals" under the Stark Law. The Fourth Circuit, citing the preambles to the Stark Law, held that, in the context of inpatient and outpatient hospital services, personally performed professional services still generate a "referral" of the technical component of hospital services. Thus, the "facility" or "technical" component of a physician's personally performed services constitutes a referral and the Stark Law is implicated.

Was the volume or value standard implicated?

The Fourth Circuit stated that contracts that take into account anticipated referrals implicate Stark's volume or value standard. Although the court undertook a somewhat tortured analysis of the Stark definition of fair market value and various regulatory preambles, the Court ultimately determined that physicians should be compensated for the services they actually perform and not for their ability to generate referrals. Thus, the Fourth Circuit stated that on remand the jury must consider: (1) whether the contracts on their face took in account the volume or value of referrals; and (2) whether the arrangement violates the fair market value standard by taking into account anticipated referrals in computing physician compensation. If either of these factors is present, then the arrangement constitutes an indirect compensation arrangement under the Stark Law and must meet an exception. Further, the Fourth Circuit agreed with

the court in *U.S. ex rel Villafane v. Solinger*,[1] that "intent alone does not create a violation" of the Stark Law.

Implications of the Circuit Court's opinion

The Fourth Circuit Court's decision provides clarity in respect to several issues. First, the fact that an arrangement involves only the provision of personally performed services does not mean that the Stark Law can be ignored. In the case of inpatient or outpatient hospital services, a Stark analysis will always be necessary, because the personally performed services will automatically generate a "referral" of DHS. Further, it is clear that when establishing compensation methodologies, a hospital cannot compensate physicians for their anticipated referrals; rather, the compensation must reflect only the fair market value of the services actually being provided by the physicians.

However, the court's analysis also leaves several important questions unanswered. First, the court did not address whether an agreement for personally performed services that generate a corresponding technical component referral will always be considered to vary based on the volume or value of referrals. Arguably, a compensation arrangement could involve the provision of services that generate technical component referrals, but not necessarily vary based on the volume or value of such referrals—such as where a physician receives fair market value compensation based on work relative value units (wRVUs) or professional fee collections for personally performed services. In other words, it is not clear whether an arrangement involving a physician who is a bona fide full-time employee, with a substantial office-based practice and only a subset of services that are provided at the hospital, would be distinguishable from the arrangement in *Tuomey* where the physicians were part-time employees only when providing surgery at the hospital.

Moreover, it does not appear that the Court properly assessed if an "independent compensation arrangement" existed in the first place. The Court seemed to read a fair market value standard into the definition of an independent compensation arrangement where none exists in the regulatory wording of such definition.

Furthermore, the court did not address the government's assertion that an arrangement where a physician's compensation exceeds collections will necessarily implicate the volume or value standard, leading to continued ambiguity with respect to certain arguably bona fide arrangements, such as arrangements that involve the provision of a large amount of uncompensated care. Additionally, the court did not consider whether a fair market value compensation arrangement could still be deemed to take into account anticipated referrals by virtue of the hospital's general strategic objectives in entering into the arrangement.

These unanswered questions perpetuate the complexities of structuring hospital-physician arrangements in the wake of the *Tuomey* case and result in continued uncertainty in the context of indirect compensation arrangements between hospitals and physicians.

The views and opinions expressed in this article are those of the authors and do not necessarily reflect those of Sills Cummis & Gross PC.

1. *U.S. ex rel Villafane v. Solinger*. United States District Court, W.D. Kentucky, at Louisville, April 8, 2008.

by Sarah E. Swank, Esq. and Emily K. Weber, Esq.

Research records and EHRs: Five practical tips in a new compliance era

» Integrate research record issues into discussions of EHR functionality.
» Review clinical trial agreements for access, ownership, and confidentiality provisions.
» EHRs trigger additional HIPAA access and compliance concerns.
» Consider centralizing research compliance functions to address policies and procedures and monitor access to research records in EHRs.
» Conduct routine and for cause research-specific audits.

Sarah E. Swank *(seswank@ober.com) is a Principal in Ober|Kaler's Health Law Group in Washington DC.* ***Emily K. Weber*** *(Emily.Weber@tuhs.temple.edu) is Associate Counsel for Temple University Health System, Inc. in Philadelphia.*

Research record compliance used to be as easy as stepping foot into the Medical Records department and following their policies and procedures. With the widespread use of electronic health records (EHRs), ensuring the integrity, privacy, and ownership of research records just became more difficult. EHRs provide a valuable tool for researchers to identify potential subjects and to track those subjects once they enrolled in a study. Providing access to medical records for research purposes in an electronic environment means determining the level of access to records provided to sponsors and investigators. Below are five practical tips to ensure that your research records meet regulatory requirements without inhibiting human subject research at your organization.

Tip 1: Review your clinical trial agreements

Sponsor access to an organization's EHR often can be addressed before the clinical trial ever begins. Careful review of the clinical trial agreement between your organization and the sponsor by a contract management office, in-house counsel, or outside legal counsel is the first step to ensure that expectations are set from the beginning. The sections on access and ownership of records can be a hotly contested issue in clinical trial agreements, with both sides vying to protect their own interests to add the greatest protections to what each party owns. Several critical issues that the clinical trial agreement should address related to research records include:


Swank


Weber

- ownership of research records, including the research data contained in the EHR;
- ownership of medical records in the EHR;
- sponsor and monitor access to medical records, including time and place;
- types and format of records to be disclosed; and
- intellectual property issues.

Defining the legal "medical record" owned by an organization compared to research data of the sponsor is an important provision of the

clinical research agreement. Records can be broken up into two categories:

- **Research records**, which often includes the study data, study results, and what was traditionally the subject research "binder"
- **Subjects' medical records**, including any tests and procedures performed for the purposes of the trial and contained in the medical record

Often research records contained in the medical record will be copied into a subject research binder. The sponsor will usually retain ownership of the research binder, but will want to see the source data, which is often located in the subjects' medical record.

It is also beneficial to negotiate into the clinical research agreement the number of sponsor monitors that will be designated for the study. Sponsors often will state upfront that their monitors do not have authority to sign documents on behalf of the sponsor giving the monitor access the EHR, even though organizations only grant access to EHR after execution of individual confidentiality and security agreements. Advance discussion about how to proceed in such circumstances will save considerable time and aggravation later, once the study is underway at your organization.

Tip 2: Remember your HIPAA/HITECH obligations

HIPAA and research

It is no surprise that researchers are looking for data on the research subjects contained in your EHR, which may trigger privacy and security obligations. A covered entity's HIPAA[1] obligations begin when the researcher seeks to review the medical records in preparation for a research study or to use or disclose protected health information (PHI) as part of the study itself. HIPAA sets out the obligations for covered entities that are looking to design a study or screen subjects for a study. Researchers can stand in a treatment relationship with the research participant and be subject to HIPAA themselves as a covered entity. Research may also be conducted by non-covered entities using retrospective research of data stored in an EHR or other similar types of research, when the HIPAA obligation falls on the organization with the EHR. The HIPAA Privacy Rule applies to covered entities use or disclosure of PHI for any research purposes, regardless of funding source or whether the Food and Drug Administration or Health and Human Services regulates the research. Areas of HIPAA compliance in research should include a review of:

- preparations for research, when representations are obtained from investigators, including study recruitment and protocol development;
- decedents' information, when representations are obtained from investigators;
- authorizations signed by subjects;
- Institutional Review Board (or Privacy Board) waiver or alteration of the authorization;
- PHI de-identification;
- limited data set with data use agreement (DUA);
- protocols for data security and access;
- signed agreements with business associates, especially those related to research data and other IT functions; and
- delineation of quality activities in comparison to research activities.

Your organization should consider specific reviews of these compliance areas in relation to research, especially when they involve EHR access.

IRB's role in HIPAA oversight

After the study design is set, much of the compliance obligation and oversight may fall

to the IRB. For example, the IRB must review authorizations for the use and disclosure of PHI for research purposes, or may conduct a three-step analysis to waive in whole or part the requirement for an authorization under the HIPAA Privacy Rule. IRBs should carefully review protocols related to privacy and security to ensure they live up to the standards and policies of your organization. Whether or not your organization has an IRB, standard privacy and security safeguard checklists can be helpful to ensure consistency among studies and establishing expectations for sponsors and investigators.

EHR development and HIPAA compliance

Organizations with a commitment to research should consider research record obligations in the development of EHR to meet HIPAA and research compliance obligations. For example, organizations must ensure that they promptly integrate HIPAA authorizations into the medical record. With an EHR, this generally means ensuring the authorization makes it to the electronic record by way of timely scanning. Delays in scanning can create problems for the research, but also compliance problems. Patient safety issues also can arise if research records are missing from medical records when treatment decisions need to be made. Missing information on the use of an experimental drug in a patient record could cause medication errors or contraindications. In addition, your organization should be accounting for certain disclosures made outside of authorizations for research. Inform and educate your IT department of the special issues surrounding research records to integrate research record issues in to discussions of EHR functionality and audits.

HITECH breach reporting applies to research

The HITECH Act[2] promoted the adoption and meaningful use of health information technology. In addition, HITECH expanded the existing HIPAA regulatory framework to include mandatory data breach notifications, additional business associate obligations, increased enforcement, and increased penalties for violations. Under HITECH, covered entities have the following reporting obligations in the event of a breach:

- **Individual notice.** Covered entities must notify affected individuals following the discovery of a breach of unsecured PHI. Notification must occur without unreasonable delay and no later than 60 days following the discovery of a breach.
- **Media notice.** Covered entities that experience a breach affecting more than 500 residents are required to provide notice to prominent media outlets serving that state or jurisdiction. Notification must occur without unreasonable delay, but no later than 60 days following the discovery of a breach.
- **Notice to the Secretary of HHS.** If a breach affects 500 or more individuals, a covered entity must provide the Secretary with notice of the breach without unreasonable delay, but no later than 60 days from discovery of the breach. For breaches that affect fewer than 500 individuals, a covered entity must provide the Secretary with notice annually within 60 days of the end of the calendar year in which the breaches occurred.

A breach is impermissible use or disclosure of PHI under the HIPAA Privacy Rule that compromises the security or privacy of the affected individual and poses a significant risk of financial, reputational, or other harm, with certain exceptions. HIPAA applies in the research context for both covered entities and business associates. The proposed changes to the Common Rule[3] may expand these HIPAA obligations to all research—even to non-covered

entities—including a proposal to apply similar breach notification provisions.

Increased HIPAA penalties

The Enforcement Interim Final Rule[4] under HITECH amends the HIPAA regulations related to civil money penalties to include HITECH violations and tiered ranges of penalty amounts. The Enforcement Rule also revised limits to the Secretary's authority to impose penalties from $25,000 to $1.5 million per year. The Office for Civil Rights of the Department of Health and Human Services (OCR), charged with enforcing HIPAA, has increased enforcement and imposed penalties with these higher limits on both large health care organizations and small physician practices.

Tip 3: Determine internal access to records

Internal access to records by those conducting and overseeing research can create both a HIPAA Security Rule issue and operational problems. Organizations should create policies and procedures discussing how to give non-organization personnel access the EHR. This is especially important when dealing with EHRs, because unless the proper controls are in place, the monitor could have access to the entire organization's EHR system, including access to not just non-research related records for the subject, but all other patients in the EHR system. The functionality of certain EHRs may make limiting access within a specific record nearly impossible. The policies and procedures should address the:

- purpose of the policy;
- scope, including to what EHR systems and persons the policy applies;
- records subject to the policy, including both paper and electronic, such as charts, outpatient office records, and study reports, as well as records in different media, such as x-rays and MRIs;
- access controls to the EHR, including role-based access, passwords, and hours;
- adherence to policies and procedures for HIPAA and HITECH compliance;
- any additional documents, such as confidentiality and security agreements that need to be signed to ensure HIPAA and HITECH compliance;
- any audit procedures;
- research staff oversight over third-party access to the EHR, including logs of who accesses the EHR; and
- monitoring of specific requirements.

One point to address beforehand with a sponsor is the requirement that their employees and agents must sign a confidentiality and security agreement. Sponsors often do not permit their employees and monitors to sign agreements, such as an organization's HIPAA Privacy and Security agreement, on behalf of the sponsor. However, the organization usually requires the monitor to sign these agreements in advance of giving the monitor access to data, as a method to track its security processes, such as creating the monitor's unique EHR login. In addition, the organization seeks documentation that the monitor is bound by the organization's privacy and security policies and the monitor acknowledges ownership and control by the organization of its records. These agreements should include provisions that:

- require access to only authorized records,
- subject them to auditing,
- detail password and record confidentiality,
- set out an agreement to follow security and privacy policies, and
- describe ownership of EHR systems and other proprietary information.

An organization can provide direct access to the EHR, but may also provide paper copies of the medical records. If the organization

offers the monitor or sponsor paper copies of the EHR, the organization should consider creating a short one-page certification document. The certification can state that the paper copies are true and accurate representations of the information printed from the EHR as of the date listed in the certification. The certification form and signature authority should be addressed in a policy and procedure.

Tip 4: Track in-person monitoring

Once the organization and sponsor have agreed to the terms of EHR access, the monitor may come onsite to access the EHR system or other research related records. Onsite visits can occur just once during the entire trial or up to once a week during the entire length of the trial. Your organization should designate one of its personnel to oversee and train the monitor on how to use and navigate the EHR, as well as coordinate the execution of the confidentiality agreement and conduct policy and procedure training. Organizations should consider limiting monitors' access to research record information contained in the EHR to information listed in HIPAA authorizations or consistent with HIPAA requirements. One method is to create an inbox or separate section in the EHR and drag the research record portion of the study subject's medical record into the inbox. The monitors are then only able to access the inbox and not the entire EHR system, thus providing some security and ability to monitor what was accessed.

In addition, organizations should require that research sponsors designate just one monitor who has EHR access during the entire study. This alleviates the burdens on the organization by not having to create multiple EHR logins for multiple monitors and ensuring they are not using each other's passwords in violation of security policies. Limiting the number of monitors onsite also creates a more efficient review by not having to train multiple monitors on how to use the specific EHR system.

Tip 5: Audit for compliance

As with any other area of compliance, auditing plays a key role. It is better to audit before the IRB, sponsor, FDA, or OHRP find compliance problems at your organization. Research compliance may fall into various areas of your organization or departments. To the extent possible, centralize the auditing function or create an oversight committee for research records. For example, there is a movement toward integrating research compliance functions into compliance programs. Consider integrating a research record audit into HIPAA Security and Privacy audits to ensure that role-based access parameters for your EHR are set and followed in your organization. Whether your organization de-centralizes research compliance or not, audits should include:

- randomized review of the medical records of research subjects;
- record access audits;
- research agreement audits;
- informatics and research billing audits;
- safeguards and data integrity audits;
- IRB record audits, including authorizations, waivers, protocols, minutes, and records;
- HIPAA compliance audits; and
- grant compliance audits.

These audits may be regular or routine audits, but organizations should also conduct audits for cause when a specific incident arises. Once a possible systematic issue is identified, an audit assists in finding the source of the compliance problem, enabling your organization to act quickly to mitigate the risk and put in place institutional changes to ensure future compliance. Oftentimes, policies and procedural changes are needed along with job specific research compliance training. It is recommended that compliance audits be conducted under attorney-client privilege.

Depending on the type and scope of the audit, consider contacting outside counsel to oversee the audit or to conduct training.

Increased enforcement

Enforcement in the area of research is on the rise. The changes to the Common Rule likely will provide additional hurdles for compliance related to records, with increased application of HIPAA principals to non-covered entities and consent requirements for de-identified biospecimens. HIPAA itself will soon change, providing additional security protections for both paper and electronic medical records. Organizations should position themselves to avoid downstream research compliance issues related to research records by using preventative steps, such as reviewing research agreements with sponsors and EHR implementation planning.

1. Health Insurance Portability and Accountability Act of 1996 (PL 104-191) and the Privacy and Security Standards (42 CFR 160 and 164)
2. Health Information Technology for Economic and Clinical Health Act, enacted as part of the American Recovery and Reinvestment Act of 2009 (PL 104-191)
3. 45 CFR 46
4. 74 FR 56123

by Kristen R. Taylor, CPC, CHC

Anatomic pathology: Basic coding, documentation, and teaching physician documentation

» Understand the general difference between clinical and pathology lab services.
» Become familiar with the basic terminology for coding and billing for pathology services.
» Appreciate unbundling logic for pathology specimen billing compliance.
» Know compliant documentation requirements for teaching physician pathology services.
» Be able to identify common compliance vulnerabilities when billing pathology services.

Kristen R. Taylor *(kristen.taylor@altegrahealth.com) is a Senior Consultant in the Compliance and Audit Services of Sinaiko Healthcare Consulting, Inc., a wholly owned subsidiary of Altegra Health in Los Angeles. She has more than 19 years' experience in coding and revenue cycle processes and compliance.*

Pathology is a medical specialty which includes two areas of focus based on the specimen type and work performed: clinical and anatomic. Clinical pathology is the diagnosis of disease based on the laboratory analysis of bodily fluids such as blood and urine. Anatomic pathology is the diagnosis of disease based on gross and microscopic examination of an organ or tissue. Anatomic pathology encompasses many subspecialties, including surgical pathology (the study and diagnosis of disease of surgical specimens) and cytopathology (the study and diagnosis of disease at the cellular level).

In surgical pathology, the gross examination includes a visual observation of the tissue with the naked eye. The results report would include a description including size, shape, and distinguishing characteristics of the specimen. This examination is considered the initial review of the specimen and is used to identify the areas of the specimen that should be processed for a more extensive examination, based on the expertise of the pathologist. In some cases, based on the order from the referring qualified health care professional, the gross examination is the most complex examination needed (e.g., removal of a breast implant or identification of the weapon used in a stabbing incident). The additional and more extensive examination includes microscopic visualization of the tissue.


Taylor

Once the specimen has been grossly examined ("grossed"), the pathologist places all or part of the specimen into a plastic cassette where it can be fixed in paraffin for processing. The slides are prepared by using a microtome to cut sections of the paraffin block. The sections are then placed on a slide, which is stained and subsequently viewed under a microscope. The stain typically used is haematoxylin and eosin (H&E). The use of stained slides is considered a core skill of anatomic pathology. In many cases, the pathologist can render his/her diagnosis

based on these examinations. When this is sufficient, no further examination is performed, and the impression and interpretation are documented, based on these observations.

If the case requires a more extensive exam and diagnostic data to render a decision, the pathologist may need to initiate additional techniques to test the tissue. This can be accomplished using special stains for microorganisms or immunohistochemistry stains for antibodies. These additional tissue tests can be instrumental in diagnosing a specific disease process, type of neoplasm, or whether it will respond to a particular treatment option.

Coding

When coding for surgical pathology services, there are a few important rules to remember. CPT guidelines state that "The unit of service for codes 88300 through 88309 is the specimen."[1] These codes represent the level of complexity of the specimen being examined by the pathologist:

- CPT code 88300 is used when the pathologist feels the gross examination is sufficient to accurately assess the specimen. This is part of every surgical pathology examination, but it is not appropriate to charge for this in addition to a more extensive examination. CPT 88300 is considered part of the more complex procedure (examination/diagnostic result).
- CPT codes 88302 through 88309 include the examinations for identification only, up to and including the comprehensive examination of organ resections. Each CPT code within this range includes a list of the specimens that would be included when reporting that code.

> Teaching physician documentation guidelines for diagnostic tests indicate that the teaching physician may not simply countersign the resident's documentation.

The specimen is identified as "tissue or tissue(s)" that require "individual and separate attention" and "individual examination and pathologic diagnosis."[1] It is not necessary for the specimens to be submitted in separate containers as long as they are separately identifiable, either by individual markings or by a description which would be included on the pathology requisition. When coding for these pathology services, it would be inappropriate, according to CPT, to separately report or "unbundle" specimens that are expressly linked together in the description of the code. For example, if the specimens were tonsils and adenoids. In one container, you received the left tonsil; in the second container, the right tonsil; and in the third container, the adenoids. CPT 88304 specifically states "Tonsils and/or adenoids," therefore, the three containers (for purposes of examination by this method) would only be considered two units of 88304, even though three containers were received.

Complexity of the specimen should also be considered when assigning a CPT code. Looking at the list of specimen descriptions included in each CPT code, you will see that some specimen types are found in multiple places. If the specimen is labeled "breast tissue," you must know the extent of the specimen. Specifically, CPT code 88305 is used for a breast biopsy, 88307 for breast excision requiring evaluation of surgical margins, and 88309 for breast mastectomy with regional lymph nodes. This is also true for the appendix, in which case you would need to know if it was an incidental appendix (asymptomatic appendix taken at the time of another surgery, code 88302) or other than incidental

(code 88304). These are considered some of the risk areas in pathology billing today.

Documentation

The College of American Pathologists (CAP), the leading organization of board-certified pathologists, suggests that the pathology report include the patient demographics, any clinical information provided by the requesting qualified health care provider, gross examination description observations, microscopic description, and observations. The observations may include comments or notes, interpreted diagnosis, or conclusions made. The pathology report should also include any recommendations based upon those conclusions. As noted earlier, in cases where a simple gross description of a foreign body is the reason for the encounter, the microscopic description and diagnosis would not be included in the pathology report, because the exam did not require a diagnostic conclusion.

When services are rendered in a teaching environment, documentation from the teaching pathologist is needed in order to bill for the service. The Federal Register at 42 CFR 415.170 states that "services furnished in teaching settings are paid under the physician fee schedule if the services are furnished by a resident where a teaching physician was physically present during the critical or key portions of the service."

Additionally, the CMS Claims Processing Manual states:

> Medicare pays for the interpretation of diagnostic radiology and other diagnostic tests if the interpretation is performed by or reviewed with a teaching physician. If the teaching physician's signature is the only signature on the interpretation, Medicare assumes that he/she is indicating that he/she personally performed the interpretation. If a resident prepares and signs the interpretation, the teaching physician must indicate that he/she has personally reviewed the image and the resident's interpretation and either agrees with it or edits the findings. Medicare does not pay for an interpretation if the teaching physician only countersigns the resident's interpretation.[2]

Therefore, Medicare teaching physician documentation guidelines for diagnostic tests indicate that the teaching physician may not simply countersign the resident's documentation. The resident may still document the pathology report results, but the teaching physician must personally document that he/she has reviewed the slides and the resident's diagnosis. The teaching physician must also document whether he/she agrees with or has edited the resident's findings or changed any conclusions as necessary. To ensure teaching physician guidelines are met, it is suggested that the pathology report contain a physician attestation statement that provides clear evidence that the teaching physician supervised the critical portion of the pathology service and allows for information be appended to the report prior to signature.

Conclusion

It is important to have a general understanding of how pathology services are provided to identify where compliance vulnerabilities may exist. Errors can occur when the basics of documentation, code assignment, and the involvement of the teaching pathologist are not clearly understood. These concepts can be simple, but pathology is not commonly understood. Be sure you know the basics, so quick identification of weaknesses can be identified when necessary.

1. Surgical Pathology section guidelines, 2011 AMA CPT Professional edition, p.436
2. Centers for Medicare & Medicaid Services: *CMS Claims Processing Manual*. Pub 100-04, Chapter 12, Section 100.1.2 (A6)

by Becky Osowski, MJ–Health Law, CIA, CAMS, CCEP

Here comes the Sunshine Act: Proposed rule CMS-5060-P

» Data collection on payments or transfers of value made to physicians/teaching hospitals is projected to begin after January 1, 2013.

» Specific identifying information about physicians/teaching hospitals is required.

» Data reported will be made publicly available by CMS via the Internet.

» Physicians/teaching hospitals should be proactively reviewing data submitted prior to publication.

» Physicians/teaching hospitals must understand state and federal transparency requirements and institutional conflict of interest policies.

Becky Osowski *(rosowski@morganlewis.com) is the Director of Healthcare Compliance with Morgan, Lewis & Bockius LLP in the firm's Washington DC office.*

In 2010, the Patient Protection and Affordable Care Act (PPACA) health care reform legislation passed, including Section 6002 – Transparency Reports and Reporting of Physician Ownership or Investment Interests.[1] These provisions had previously been proposed as the Physician Payment Sunshine Act in 2007 and again in 2009 by Senators Grassley and Kohl.[2] In December 2011, the Centers for Medicare & Medicaid Services (CMS) published the proposed rule related to the implementation of the Sunshine Act, referred to as CMS-5060-P or Transparency Reports and Reporting of Physician Ownership or Investment Interests.[3]

Osowski

Basic requirements under the proposed rule

The proposed rule requires applicable manufacturers of covered drugs, devices, biologicals, or medical supplies (covered products), operating within the United States, to track and report payments or other transfers of value provided to physicians or teaching hospitals (covered recipients) on an annual basis. Covered recipients include not only physicians and teaching hospitals that receive payments or transfers of value, but also any entities or individuals receiving a payment or transfer of value at the request of, or designated on behalf of, a physician or teaching hospital. CMS proposes to publish annually a list of institutions meeting the definition of teaching hospital, including the name and address information.

Additionally, applicable manufacturers and applicable group purchasing organizations (GPOs) will be required to track and report certain data components related to physician ownership and investment interests annually.

Data must be submitted to CMS and will subsequently be combined and published on a publicly available website in a format that is downloadable, searchable, and easily aggregated. As required, CMS will submit annual reports to Congress and each state summarizing the data reported. Failure to comply with the requirements under the proposed rule subjects applicable manufacturers and GPOs to civil monetary penalties ranging from $1,000 to $100,000 for each payment not reported, with a maximum of $1,000,000 per annual filing.[4]

Timing of the proposed rule

The proposed rule was open for public comment until February 17, 2012. More than 320

comments were received by CMS and are available for review on www.regulations.gov (by searching CMS-5060-P). Once the rule is finalized, organizations will have at least 90 days to implement the regulation and begin data collection.

Although the proposed rule initially projected issuance of the final rule within calendar year 2012 and initial data submission by March 31, 2013, CMS recently issued an update on its website, communicating that data collection requirements will not be required prior to January 1, 2013. In this update, CMS reinforces the intent to move forward with issuance of the final rule within the calendar year 2012. However, data collection requirements (and data submission) won't kick in until sometime after January 1, 2013. This delay in implementation was attributed, in part, to CMS's commitment to addressing the comments received during the rulemaking process.[5]

Specific data components required

Related to covered recipients

Under the proposed rule, the following data components will be required to be collected and reported by applicable manufacturers and GPOs:

Name	**Physician covered recipient** – first name, last name, and middle initial **Teaching hospital** – name as included on CMS published list
Business Address	**Physician covered recipient** – primary practice as listed in NPPES website **Teaching hospital** – address as included on CMS published list
Specialty	Applicable to **physician covered recipients** only – specialty from NPPES website
National Provider Identifier (NPI)	Applicable to **physician covered recipients** only – from NPPES website

Related to payments and other transfers of value

The following types of payments or other transfers of value will be captured and reported as required:

- Consulting fee
- Compensation for services other than consulting
- Honoraria
- Gift
- Entertainment
- Food and beverage
- Travel and lodging (including destination)
- Education
- Research
- Charitable contribution
- Royalty or license
- Current or prospective ownership or investment interests
- Direct compensation for serving as faculty/speaker for a medical education program
- Grant

To qualify for reporting, payments or transfers of value must be equal to or greater than $10 per interaction and must aggregate to more than $100 for the covered recipient during the calendar year. For each qualifying payment or transfer of value, information such as the amount of payment, date of payment, form of payment (e.g., cash, in-kind), nature or category of payment, associated product, and entity paid (if different from the covered recipient name) will be collected, along with the covered recipient data components, and will be reported as required by the proposed rule.[6]

One of the more complex reporting obligations outlined in the proposed rule is related to research. Applicable manufacturers must designate whether a research-related payment is direct or indirect, based upon the individual or entity receiving the payment.[7] If the research payment was made directly to a physician or teaching hospital, the payment

Key Terms

Covered products – products eligible for reimbursement under Medicare, Medicaid, or the Children's Health Insurance Program (CHIP) that, by law, require a prescription to be dispensed or premarket approval by or notification to the U.S. Food and Drug Administration (FDA).

Covered recipients – physicians (as defined within the Social Security Act) and teaching hospitals.

Teaching hospital – an institution receiving indirect medical education or direct graduate medical education during the most recent year.

would be recorded as a *direct* research payment. However, if the payment was made to a non-teaching hospital institution conducting research (e.g., a clinic) where the institution pays an investigator, it would be recorded as an *indirect* payment. The indirect payment will be reported under the investigator's NPI with a notation as to the identity of the institution, even though the investigator likely only received a portion of the payment as a salary. To further complicate things, for indirect payments made to a teaching hospital, applicable manufacturers are required to submit redundant reporting under both a direct payment to the teaching hospital and an indirect payment to the investigator. Without proper context, this information will likely be misinterpreted by consumers or others reviewing the data.

Another area of significant complexity surrounds the reporting of indirect payments through a third party. Although the proposed rule contemplates that such payments would be excluded from reporting if the applicable manufacturer is *unaware* of the identity of a covered recipient, the preamble suggests that if the identity of health care provider speaking at a third party event is publicized, the applicable manufacturer may reasonably be aware of the identity of covered recipients indirectly receiving payments through the third party, and would thereby be required to include such a payment as attributed to the covered recipient.[8] Numerous public comments submitted through www.regulations.gov urge CMS to reconsider this requirement, because it relates to industry funding of continuing medical education events, which is governed by guidelines already in place related to this activity. These standards (titled Standards for Commercial Support: Standards to Ensure Independence in CME Activities) are available on the ACCME website at www.accme.org.

Related to physician ownership and investment interests

In addition to the covered recipient data components (e.g., name, business address, specialty, NPI), the proposed rule requires that applicable manufacturers and GPOs report information related to physician ownership and investment interest. Additional data components include the dollar amount invested, value and terms of interest, and whether the interest is held by the covered recipient directly or by an immediate family member. The proposed rule proposes the following definition of an immediate family member: spouse; natural or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-, mother-, daughter-, son-, brother-, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

The preamble included within the proposed rule contains discussion around the consideration of an additional reporting requirement when ownership or investment interest is held by the immediate family member of a physician. CMS is considering whether to require additional information, such as the immediate family member's relationship to the physician (e.g., brother-in-law, grandson) as well as the immediate family member's name. CMS acknowledges that although the immediate family member's

name may be required for reporting to CMS, it would likely not be made public due to privacy concerns.[9]

What does this mean to you as a covered recipient?

Transparency is here to stay. The concept of transparency continues to be top of mind for health care providers, institutions, and industry manufacturers alike. Great efforts are underway by industry applicable manufacturers and GPOs to implement the robust infrastructure required to track and ultimately report accurate data related to interactions with certain health care providers. This infrastructure is a necessary investment in order to comply with the patchwork-like group of state (and now federal) transparency and/or marketing-related regulations.

Transparency is here to stay. The concept of transparency continues to be top of mind for health care providers, institutions, and industry manufacturers alike.

Although key data fields mentioned above will be disclosed as required, the proposed rule does not necessarily provide context as to the various relationships and resulting payment types, such as the valuable and essential collaboration between industry and health care providers when developing a new technology to address an unmet clinical need, developing surgical technique documentation for a new technology, or developing/administering face-to-face training to facilitate FDA-mandated training on the safe and effective use of a new technology prior to an attempt to implant such technology into a live patient. Although the proposed rule allows for the voluntary submission of an assumptions document to provide further explanation as to certain payments, this document is not slated to be made available to the public.

Additionally, there are regulations in place to govern potential conflicts of interest in the area of research that impacts institutions that solicit or receive Public Health Service (PHS) research funding. For example, recently revised regulations focused on the promotion of objectivity in research require more robust reporting or disclosure of significant financial conflicts of interest (SFI). Included in the recent revisions are (1) an investigator's annual disclosure of any SFI to the institution upon meeting certain threshold requirements; (2) the institution's subsequent financial conflict of interest (FCOI) report to PHS awarding component; and (3) public disclosure of both the institution's conflict of interest policy and detailed information regarding SFI held by senior and key personnel identified under the PHS grant application.[10] This public disclosure can be made via an accessible website or by written response to any requestor within five business days.

Review of data accuracy is essential

Given the various disclosure requirements for data submission to state or federal agencies, it is imperative that all reasonable efforts are made to ensure the accuracy of the data reported. It is conceivable that a consumer may search under his or her physician's name in one or more of these available databases and get varied information, especially given that there are disparate reporting obligations between the state requirements and the

upcoming federal requirements as outlined in the proposed rule.

Under the proposed rule, once an applicable manufacturer or GPO submits the required data by the deadline established, CMS will combine all the data sets and provide electronic access to physicians and teaching hospitals for a 45-day review period before the data is made available to the public at large. Covered recipients must be diligent in performing a thorough review of all data submitted under their NPI number or as attributed to the teaching hospital to ensure payments and other transfers of value, such as meals, are recorded properly. Although not currently a requirement, the proposed rule hints that a pre-submission review process between the applicable manufacturers and covered recipients may be beneficial.

The proposed rule outlines that any dispute regarding data accuracy must be handled between the covered recipient and the applicable manufacturer or GPO. If the data dispute cannot be resolved, CMS has proposed that the transaction be flagged as disputed, and that both figures be reported within the database.[11]

Covered recipients must be diligent in performing a thorough review of all data submitted under their NPI number or as attributed to the teaching hospital to ensure payments and other transfers of value, such as meals, are recorded properly.

Don't underestimate the effort involved

Although the proposed rule does not include a record-keeping requirement for covered recipients, records may be beneficial in validating the accuracy of data reported. If a covered recipient decides to perform some level of diligence, it is advisable to retain copies of any service agreements, statement or work documents, engagement orders, invoices, grant documents, payments, statements, etc. received from an industry manufacturer or GPO. This will allow the covered recipient to take reasonable steps to validate the accuracy of payments or transfers disclosed. These documents will likely also be useful during any subsequent dispute discussions with the applicable manufacturer or GPO.

Even in instances where a health care provider has no recollection of receiving any payments or transfers from an applicable manufacturer, he/she should log in to the CMS database during the 45-day review period to review data reported under his/her NPI number. This will help to verify that no payments or transfers were reported inadvertently, given foreseeable obstacles such as common names or familial name(s) in like professions (e.g., John Jacob Smith versus John Daniel Smith or John Smith, DDS and John Smith II, Periodontist).

CMS estimates that that on average, a physician would need one hour to review the data reported under his/her NPI number and up to 10 or 20 hours for dispute resolution. However, given the complexity of the data, this CMS average time estimate may be overly optimistic. The CMS average time estimate for review of data for a teaching hospital is 10 hours, with an estimated range of 3 to 60 hours for dispute resolution.[12]

Understand the data made publicly available

As required under the statute, all data submitted by applicable manufacturers and applicable GPOs will be compiled and made publicly available on a website. The data will be formatted in a way that is searchable, understandable, downloadable, and easily aggregated. The proposed rule also suggests that the website will include any enforcement activities taken in the previous year, as well as any other background information that is deemed to be helpful regarding relationships between industry and covered recipients. CMS is also proposing that this website will include verbiage to clearly indicate that the reporting of payments and transfers on the website is neither indicative of a conflict of interest or any wrongdoing, nor is it endorsed as a legitimate payment activity.[13]

Get familiar with conflict of interest policies

Health care providers should take a proactive approach to identifying and becoming knowledgeable about conflict of interest policies in place at their institution. If the institution at which the provider is employed has an active conflict of interest policy with disclosure requirements, he/she may want to reach out to conflict of interest personnel or the compliance officer to identify ways to utilize these public databases in the conflict disclosure process. Granted, additional information may be needed, but leveraging the data that is publicly available may be a good start.

Additionally, if the institution has prohibited certain interactions, providers should be educated on any applicable manufacturer reporting processes to ensure that data reported can be properly presented to the institution's personnel such that it is clear that the provider is in compliance with the policies in place. For instance, if an institution does not allow an industry-provided meal at a restaurant, but does allow industry representatives to sponsor journal club meetings with nominal snacks provided within the clinical setting, the data alone may be misunderstood if it is reported simply as "food and beverages" as outlined in the proposed rule.

Additional resources

- For a concise, teaching hospital guide to industry transparency reporting requirements, please visit the AdvaMed website at: *https://advamed.box.com/s/14ce6c59c26efc9971bb*.
- For a similar guide focused on physicians, visit: *https://advamed.box.com/s/a8a271b7685a74fd25cf*.
- To review the proposed rule in its entirety, visit: *www.gpo.gov/fdsys/pkg/FR-2011-12-19/pdf/2011-32244.pdf*.
- To review the Final Rule on Promoting Objectivity in Research for which Public Health Service Funding is sought, visit: *www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf*.
- For additional information and communications related to the proposed rule, visit the Morgan Lewis's Health Industry Transparency Compliance Resource Center at: *www.morganlewis.com/topics/transparencycompliance*

1. Patient Protection and Affordable Care Act (P.L. III-148) Titles VI through X. Available at www.mediregs.com/files/1007-1/FINAL-PPACA-VOL2.pdf.
2. Press Release, United States Senate Special Committee on Aging: Grassley, Kohl Continue to Disclose Financial Ties Between Doctors and Drug Companies (Jan. 22, 2009). Available at http://aging.senate.gov/record.cfm?id=307097.
3. CMS Proposed Rule CMS-5060-P; Transparency Reports and Reporting of Physician Ownership or Investment Interests. 76 Fed. Reg. 78724; Dec. 19, 2011.
4. Id. at 78757.
5. The Centers for Medicare & Medicaid Services Blog Site: *Information on Implementation of Physician Payments Sunshine Act*, (May 3, 2012). Available at http://blog.cms.gov/2012/05/03/information-on-implementation-of-the-physician-payments-sunshine-act/.
6. *Id*. at 78768, 78769.
7. *Id*. at 78749.
8. *Id*. at 78751.
9. *Id*. at 78752.
10. 76 Fed. Reg. 53256 (2011).
11. *Supra* note 3, at 78755.
12. *Id*. at 78761.
13. *Id*. at 78756.

by John E. Steiner, Jr., Esq. and Alan Peterson, Hon DBA

On mentoring, Part 2: The new informal approach

» A good mentoring program has risks and costs, as well as benefits, for everyone involved.
» Delegating accountability to protégés can help improve day-to-day operational efficiencies, motivation, and buy-in.
» The best leaders and supervisors are not necessarily the best mentors.
» Good mentoring requires preliminary planning, thoughtful implementation, and follow-up testing of the designs and results.
» Each department has unique challenges and capabilities that should be reflected in its mentoring program.

John Steiner *(John.Steiner@ctca-hope.com) is Chief Compliance Officer with Cancer Treatment Centers of America, Inc. in Schaumberg, Illinois.*
Dr. Alan Peterson *(apeterson@rwdconsulting.com) is a Managing Director with Robinwood Consulting LLC in Chicago.*

This is the second part of a two-part article on mentoring. The first part was published in the April 2012 issue of *Compliance Today*.

In the first part of this article, we reviewed a brief history of mentoring and how mentoring relates to the unique challenges of health care. Formal and informal mentoring programs each have their strengths and weaknesses, but without adequate resources and support from leadership, either style is likely to produce poor results. When done well, mentoring leads to tangible benefits for the protégé, the mentor, and the organization as a whole.

In the meantime, some recommendations and observations

Organizations should continue to recognize health care mentoring as very helpful and relevant, but in limited and carefully designed ways. In considering organizational change, there is a need to think not only of protégés, but also of all employees, leaders, mentors, and even to think like patients as well as their "families."


Steiner


Peterson

Health care mentoring is not about producing superstars or making "heroes" and achieving huge successes across-the-board.[1] Mentoring is not a panacea for leadership weaknesses, nor is it any kind of a "silver bullet." Similar to any change management initiative, mentoring has risks as well as costs. For the organization, the authors say, "Face them."

In their book, *Primal Leadership*, Golman et al discuss behavior analysis views on the absence of wise, fair, and effective leadership.[2] A leadership weakness can easily occur in the fast growth, fast changing, and uncertain world of health care. Our views rest on principled lessons and extensive field experience. In this article, your authors seek the benefits of motivation from mentoring, as well as high-quality health care. Following are some more examples of our "lessons learned" and our views to date.

One of those learned lessons that carries over to compliance program implementation and maintenance is to encourage protégés to express opinions and raise concerns. Before doing so with too much enthusiasm

however, protégés should be mentored to "do some homework." That is, a protégé should be responsible for some, not all, of the fact gathering, analysis, and preliminary recommendation(s). Moreover, protégés should learn that their efforts often lead to action steps that may apply to many persons across the organization.

The rationale or usefulness of mentoring varies and should be thoughtfully studied by the organization planning a mentoring improvement.

Communication challenges among people are incredibly important in health care—for lives, for effective care, as well as for efficiency. In mentoring, as with many management and service areas, good mentoring requires excellent communication.

Health care leaders should avoid or try to avoid an often-encountered perception that a personal mentor or mentors are a "per se ticket" to personal success, however defined. Likewise, protégés should not expect active mentoring to be the ticket to large and easily attained financial rewards in an organization.

Health care leaders should avoid or try to avoid an often-encountered perception that a personal mentor or mentors are a "per se ticket" to personal success, however defined.

Moreover, both health care leaders and mentors must be appropriately independent. Generally, it is unwise to campaign too aggressively for one's protégés at the expense of others. Of course, this is a subjective topic where fairness for all may not be achievable.

Similarly, "copycat" notions among groups of health care employees should be avoided. Frequently, younger persons may have seen some version of mentoring in their or in their friends' and associates' jobs. A "We must need it" or "I want it too" attitude occurs. Remember, a weak organizational culture from copycat attitudes is itself a risk.

The mentoring plan should consider and reflect the organization's situation (e.g., management styles, finances, other competing projects, etc.) before setting up the mentoring improvement program.

Existing, important health care organizational problems should be prioritized. Address many of the other challenges first—and there are many. Among those are designing strategic and tactical plans to deliver ever increasingly sophisticated and larger amounts of health care to diverse patient populations.

We urge tackling health care mentoring improvement challenges thoughtfully and carefully. Good mentoring usually helps health care organizations get their jobs done more effectively. Mentoring can help improve day-to-day operational efficiencies and enhance employee awareness as well as buy-in. A good example of this part of compliance is: design, implement, and administer—in large part, through delegated accountability to protégés and others in the organization.

It should be recognized that health care mentoring can be introduced *serially* or a bit at a time. Test the installation of behavior change independently and aggressively, but do not rely on "shallow, short-term happiness stuff." Also, testing thoroughly and adequately over time is important; anticipate unexpected answers as mentoring change efforts proceed.

Hopefully, the leaders of the organizational mentoring change effort themselves

should already have some significant (and possibly sound) permanent experience or some cultural mentoring successes. Hopefully, this experience occurred at some other comparable organizations or in some relatively comparable circumstances. One extreme, but appropriate, current example would be a Marine Corps surgeon in Iraq in the fighting areas of Fallujah or in Afghanistan. Other examples would be in the Emergency Department, Level 1 trauma surgeon, etc.

Another concept-ratifying lesson learned is that every employee should have access to a mentor in a personal time of special need or personal opportunity (e.g., personal injury, loss of a loved one, coming increase in responsibility, etc.). Judgment remains essential.

But, every employee does not require a mentor at regular measurement points nor need to have a mentor at all times. Instead, one goal is to gauge a protégé's progress through specific examples and projects. Counting the used sponges may be relevant in surgery from a quality assurance point of view; counting the mentors in an organization may not. The answer for both is caring as well as leadership.

This particular view of the authors is realistic, but a tough one for some human relations executives to endorse or fully endorse (e.g., informal reporting becomes more difficult with less formality; progress either way is hard to convincingly prove, etc.). However, in the present challenging health care times, mechanical steps need to be avoided or limited for motivational reasons as well as for monetary reasons.

Equally, every health care supervisor should not try to be a mentor. Supervisors should aspire for leadership success, for quality care in health care, for excellence, etc. Nor should every supervisor be designated as a mentor. Some valuable supervisors lack sufficient interest or the ability to be mentors; the organization should not try to force them to change. Some will never find the time for mentoring; some will do a poor job, etc. Mentoring can, however, be a relevant area in personnel evaluations.

Mentoring by e-mail and telephone, totally or largely, will fail most of the time. Face-to-face interaction is essential for real success.

And culture issues to consider regarding mentoring improvement should include integration with pre-existing organizational practices, such as:

- Among providers or insurers, the bottom 15% of employee groups "go" (or are let go) annually, but this practice is not favored for government work; and
- Some providers or other service firms use "progress up or out" philosophies.

A successful health care culture that uses those styles of leadership should be carried forward and not hampered or destroyed by too much new mentoring "tinkering," if possible.

Some key mentoring system or approach decisions

The authors have mentored each other at significant times for a number of years. The crucial initial point is this: To make the "change in a big way or not change much" decision requires insight, experience, and planning.

Clear health care mentoring objectives are necessary first. There must be:

- sound efficiency, safety, and good outcomes in the delivery of health care to people and families;
- continued reasonable regulatory oversight and improving health care compliance;
- reasonable prudence of health care costs;
- appropriate cost analysis and reporting; and
- recognition that all health care departments within an organization are not the same or even very similar.

Hence, on the basic mentoring change, decisions typically should be based *on concepts, not mechanics*. Mentoring of departments with differing characteristics, such as the basic character of their respective roles, should be different, just as differences exist among entities.

The organization that is considering mentoring changes or revisions should carefully review and thoughtfully reassess the organizations' financial landscape—present and future. Funding any project in today's times may promise to be quite challenging. Special projects—even sound ones—are easy targets in any restructuring or budget reduction. We are well aware that good mentoring can be greatly beneficial as an organization goes through "hard times." Some health care mentoring can be done on a financial shoestring, and partial deferrals of otherwise desirable planned improvements do not necessarily undermine progress.

Mentoring that involves copying (often done to try to appear to respond to some younger employees) is unwise. Mentoring to try to save costs only, or to try to have "quick-hit" solutions to leadership problems, is unwise. Mentoring changes should stick to the substance of improvement in the organization or department at issue for quality mentoring. W. Edwards Deming, a founder of much of the quality management movement, for example, advocated striving for error reductions and, in a simple health care sense, promoted an approach of "find it, fix it, teach it."

Potential problems

Exaggerated expectations of quick benefits, per se, from mentoring are a potential problem, and quick benefits are unlikely. To "reach-out" is good, but the organization should do so carefully for long-term benefits. Mentoring improvements are not like a wall electric power switch—off, then on.

Badly understated costs for mentoring improvements and a poor scope-of-work for formal systems or the informal approaches are common potential problems. Badly understated time estimates or money costs for mentoring improvements, or both, are a similar and related challenge. Overstated and overly optimistic "front-end" benefits of the mentoring improvements in general are a challenge.

Then, there should be early-on discussion as to "how much to change" about an organization's mentoring approach. As indicated earlier, funding and leadership are very important. And, it may that a "bootlegged" try or informal modest approach at mentoring is all that can be afforded—something of financial interest.

Each individual person's health care mentoring decision should be mutual to the maximum extent possible, not a "corporate" decision or a Human Resources department allocation. Geography and available time should be considered, as should service line and personal goals, etc. But most of all, the organization should keep in mind that mentoring is essentially two people in a group of people delivering some part of health care in the U.S.

Major change vs. a more simple approach

During these times of significant health care uncertainty, great care in any new design will pay dividends to the organization in the form of improved patient care as well as to the organization's community. It is our view that there are no "cookie-cutter" mentoring formal systems or informal mentoring approaches in the market.

Following are some required outline steps for success. Knowing well the organization's health care leadership problems or challenges in advance will help the relevant understanding. The demographics must be understood, and knowing the team leaders, the costs of

organizational compliance, and other policies also are relevant.

Tailoring plans for the organization's setting in the market and tailoring mentoring by user groups, as well as the early design itself, are critical and essential. Often, too little effort is invested in getting and incorporating the appropriate user views throughout.

The new health care mentoring system or approach will require preliminary and early real plans. An organization should not forget or omit them.

In designing the organization's mentoring concepts, emphasizing the needs of individuals should be high priority, rather than focusing only on any group needs. Some folks get overly ambitious for their own progress and forget their teams as well as their organization's needs. Among the hoped-for group needs is "real caring" for an organizations' persons by leaders and supervisors.

In designing the organization's mentoring concepts, emphasizing the needs of individuals should be high priority, rather than focusing only on any group needs.

As we said earlier, the organization should avoid any notions that health care mentoring will be a beautiful panacea for problems of the entity or the application at issue. Good mentoring, with long-term success, will be a result of hard work with years of "start-up." It takes a good while to really get good mentoring enhancement into most organization's culture or cultures. Leaders should realize that the present odds of having a continuing and very successful formal mentoring program that is long-term are relatively low, based on history. Many entities start formal mentoring with exaggerated expectations, which tend to later die off with some negative consequences.

Many interesting and challenging situations arise in mentoring design. We will start these next comments by assuming compliance and nursing. Consider protégés in two situations: (1) a several-year employee/protégé in the investment function of a pre-paid health care insurer who seeks a mentor in health care compliance; or (2) a several-year employee/protégé at a provider hospital in nursing who seeks a mentor in property maintenance and property management. Both situations offer challenges.

Both formal and informal mentoring system designs must provide for the types of challenges described above—and many more—in several ways. The designs must include flexibility, caring, and experienced mentoring advisors. It will not be helpful to force "pigeonholing" the employees or the potential mentors into one "slot" or another. Safety valves must be provided for in the system or in the approach designs. A possible model could be universities and colleges, which often refer to and rely on their use of so-called ombudsmen or ombudswomen. The successful health care organization will plan to deal with these examples of mentoring challenges, depending on the facts (e.g., discussing the employees' real desires, the organization's mission and plans, appropriate learning opportunities, available resources, etc.). Good mentoring results likely can be achieved if reasonable choices are made.

Training can help. But, the types of challenges likely to be encountered need to be recognized early-on in order to maximize training benefits. Moreover, organizations

should understand that there will be new costs in the early years. In particular, the cost estimates for a health care improvement change project may vary from stage to stage.

Reverse our first assumption above regarding an investment protégé and instead, make it a compliance employee protégé who is seeking an investment function mentor. Our recommendations are the same: identify, discuss, and solve the challenge mutually; do so timely; and on an individual basis.

Or, reverse our second example (an employee seeking a property management mentor) and the authors' answer is the same.

Test and try out the organization's preliminary plans (on a best-efforts basis), confirm mentors, and begin training for health care teams who will work later on the project.

Great care must be exercised in the selection of the mentoring project teams' personnel. An organization training for the mentors as well as training for employee-protégés is necessary for the best project success. Again, prior experience will be valuable.

The organization should make appropriate health care mentoring changes to preliminary or early plans for improvement. Early plans must not be unduly rigid. Organizations are unlikely to accomplish real long-term mentoring improvements by forced, arbitrary, or unrealistic schedules. Confirm and reconfirm mentoring plans with the users, and remember, users deliver most of the relevant health care services.

The organization should create final early designs or approaches to mentoring, monitor costs, firm up designs, and then firm up later the teams to help with installation and integration, check out and debugging, etc. Opportunities and resources remain important in any health care mentoring improvement.

Other corporate health care policies and practices (e.g., compliance, pay and bonuses, personal recognition for good work, etc.) should be respected in each culture change design and especially in mentoring designs.

Use mentoring improvement prototypes in and among departments, organization units, etc., instead of creating large across-the-board situations (i.e., "shoot with a rifle bullet rather than a shotgun spray"). Departments can and should use differing mechanical methods as appropriate. Examples include:

- In a provider organization, nurses, prepaid health care insurance personnel, or government health care employees are not doing the same health care tasks.
- Employees in a provider's Pathology department, contract administration in the payor setting, or billing collection are not doing the same tasks.
- An insurer is not doing the same health care tasks, and, the provider's surgery protégés vastly differ from the insurers' Billing department employees.

Provider employees are reasonably comfortable with a relatively large depth of mentoring. Special training still helps generally in these times, but the concept of caring for patients remains of "throughput" type importance. More examples could be raised. As before, the experiences with mentoring of these groups differ and should differ.

Accordingly, test and try out mentoring work being done more and more throughout the design phases, especially with prospective users. And, understand that it's not wise in health care to carelessly try to trade a "value base" for a "volume base."

Make changes and adjustments to the preliminary mentoring designs—systems as well as the approaches—based on the testing feedback.

Create final mentoring designs or mentoring approaches as well as estimates of related costs. Compliance proof remains relevant.

Policies and especially practice revisions (including software, instructions, training materials, among other tools) are relevant. Communication among the line organization and the mentoring teams is important.

Mentoring change installation and implementation

Putting the new and improved systems or approaches in place requires some planning. Decide on a "grand slam" (i.e., all departments or large groups) versus serial methods (one or a few at a time) for the installation and implementation of a mentoring system or change approach. Continue to make adjustments, as much as practicable, so that the users' voices are heard and considered carefully. The more massive a contemplated conversion is, the more risks exist in installation and implementation. Install, implement, and train on the mentoring improvements. Train, train, listen, listen, revise, and train some more, as needed, for good mentoring results. Test the installation and implementation of mentoring work. Investigate and consider training on the coming near-term developments (e.g., known regulatory changes or proposed changes that may come shortly).

Go forward with the new formal mentoring improvement systems conversions or the informal improvement mentoring approach conversions.

Effective use of the new or improved mentoring system or approach

After the new system conversion or the new approach conversion, organizations should test the effectiveness of improved mentoring, as is reasonable. This is a step often omitted unwisely to try to reduce costs. The omissions rarely save money and often increase long-term health care costs. Test with health care users, the real care improvement interface, and with health care customers or patients. More tests will help. Also, the more tests the better, as a general rule.

Analyze costs and schedule(s) as appropriate; compare with the mentoring improvement goals and report. Modify the mentoring system or approach, as needed downstream, for effectiveness or efficiency.

Also, leaders should understand that reasonable integration of a new formal mentoring system will take years for "full blown" integration with relevant other systems in the organization (which will be seen as "always changing") as well as becoming a real and meaningful part of the organization's culture.

In health care, employees should understand—from their good leaders—that their own personal progress, growth, or success results in favorable reputations to their supervisors and mentors who need back-ups, successors, deputies for expansions, etc. ("We're in the improvement as part of a team.") This, too, is little understood in health care as broadly defined.

These are only a few of the mentoring improvement challenges.

In general, continue mentoring research; there is more to learn about mentoring, especially in health care. Health care organizations should keep national, local, and internal research moving forward on mentoring improvements. More can be learned. Academic efforts can and will help. Emphasis on mentoring research and attending to such research will be helpful to health care.

Specially, emphasis on research on "tailoring" mentoring to the organization's circumstances as well as to individuals' circumstances is important (e.g., providers vs. payers or government, etc.) and also on reducing overbroad inflictions of mentoring.

Health care organizations should also consider uncertainty in predictability—as contrasted to commodity types of services (commodities are more easily predicted) in

ongoing research. Broadly, as indicated, our nation is seeking greater predictability in health care systems (e.g., clinical pathways, treatment algorithms, evidence-based medicine, ICD-10, etc.) Leadership in mentoring and related process improvements can further progress toward more-but-wise predictability in health care delivery, including both the reduction of mistakes and errors as well as sound adoption of the better of clinical practices.

Health care organizations should consider "unique need" areas of research. Consider needed research on dealing with today's challenging employees' and professional persons' situations. Emerging negative or debilitating health care views are a problem (e.g., for health care practitioners, surgeons, nurses, technicians, therapists, payer billing supervisors, government supervisors, etc.) to the effect that increasing federal regulatory rules and roles are turning their personal professional work into commodities, a point briefly mentioned earlier. There is a lot of mentoring research to do in our health care world.

Conclusions

Mentoring is here to stay in a value-relevant sense as a part of leadership. As we have said, mentoring has been with us a long time. In going forward, our professional job should be judged on how well we do in bringing forth the best mentoring as well as the best leadership.

Our great nation can and must build more continuous improvement in our great health care world, its processes, and for our nation as a whole. There must also be protection of our health care finances as well as our wonderful skilled people in health care.

1. Dawn E. Chandler, Lillian Eby, and Stacy E. McManus: When Mentoring Goes Bad. *Wall Street Journal*, May 24, 2010. Available at http://online.wsj.com/article/SB10001424052748703699204575016920463719744.html
2. Daniel Golman, Richard Bosatzis, and Annie McKee: *Primal Leadership*. Harvard Business Review Press; 2002.

Congratulations,
newly certified designees!

Achieving certification required a diligent effort by these individuals. Certified individuals promote organizational integrity through the development and operation of effective health care compliance programs.

Certified in Healthcare Compliance (CHC)®

- Stacy Lynn Abebe
- Judith L. Adamson
- Terry S. Addison
- Deanna K. Allen
- Carol Lee Amick
- Kimberly Jill Anderson
- Jane L. Atkins
- Melissa D. Bailey
- Denise M. Barlage
- Christine Belle
- Anne Rene Bennett
- Camella B. Boateng
- Amy L. Bradshaw
- Lynn K. Briggs
- Cheryl L. Brooks
- Shallie J. Bryant
- Jenny Cardenas
- Alice A. Ceruzzi
- Barrett L. Cisney
- June Crawford
- Amanda Virdin Cross
- Nadine L. Crozier
- Shanley J. Curran
- Lisa Marie Davies
- Maureen R. De Armond
- Grant P. Dearborn
- Patricia A. Dearmey
- Elizabeth A. Downing
- Alice A. Ducey
- Debbie Lee Dutcher
- Catherine A. Eikermann
- Teresa M. Elia
- Terrie Bonita Estes
- Paul E. Flanagan
- Sharon Kay Flanigan
- Patricia Flora
- Natalie E. Fraser
- Robert Johnson Fulbright
- Kathleen Marie Gillespie
- Lela A. Goldwyn
- Shantelle Goodall
- Lindsay Gozzi
- Marlys Mae Grewe
- Margaret A. Grimaldi
- Kimberly Kristen Halva
- Catherine Hilton Heindel
- Danna L. Houseknecht
- Scot Joseph Houska
- James P. Howell
- Scott K. Intner
- Rachel M. Jones
- Susan C. Kalbach
- Patricia A. Kasmarek
- Denise Ann Kent
- Paula M. Koenig
- Tamara Rae Koller
- Harry T. Laughlin
- Leigh Levy
- Julie Ann Long
- Tracy Jean Masson
- Paul F. Mayer
- Jeffrey Mazik
- Jennifer L. Mcaleer
- Cara L. Merski
- Sherry D. Miller
- Detra Lynn Mills
- Melinda J. Mosser
- Joan Nurge
- Timothy Brandon Odom
- Lynn M. Owens
- Ravi Nathan Perumal
- Deanna M. Picotte
- Susan Marie Pitz
- Janelle H. Potter
- Diane Premeau
- Wayne Alan Purves
- Jacqueline Eynon Quam
- Donald E. Ray
- Ginger Sussman Reding
- Allison Christina Reuter
- Raul Michael Reyes
- Marilyn C. Robertson
- Jennifer M. Rogalla
- Jennifer E. Ruocco
- Beth A. Schindler
- Sean Antonio Scott
- Mildred W. Smith
- Matthew Harris Smith
- Matthew Soskins
- Tori K. Stafford
- Larry Alan Stahl
- James Dean Stumpf
- Caria Jean Texel
- Mary E. Thornton
- Dianne Tort
- Julie Lyn Van Alstine
- Alissa Miltenberg Vertes
- Susan L. Wagner
- Nancy Ann Waltermire
- Jessica Warshaw
- Kim Evelyn Watson
- Penny L. Weinhold
- Monica Gray Wilson
- Carl Douglas Winekoff
- Freida C. Winkley
- Alice N. Wong
- Andrew S. Woods
- Anita Joy Yager

Certified in Healthcare Privacy Compliance (CHPC)®

- Patricia J. Armstrong
- Paula Jene Barton
- Louis J. Bevilacqua
- Matthew O. Bourgeois
- Jill Zoz Choi
- Gregory Daly
- Kimberly Ann Dickerson
- Mary Elizabeth Donnelly
- Elizabeth Jane Dougharty
- Richard Michael Garpiel
- Tonya S. Gierke
- Catherine C. Gomez
- Ruth A. Gossard
- Sonja L. Haley
- Sharon A. Hoyle
- Tracey L.G. Hugel
- Margaret F. Lang
- Michelle Mayes
- Robert R. Michalski
- Iris M. Monrouzeau
- Rachel Anne Pol
- Geoffrey Premeau
- Tina M. Qualls
- Sabrina R. Ruminer
- Sandra L. Sessoms
- Victor Matthew Sterling
- Herschel Marvin Timmons
- Penny L. Weinhold
- John F. Wood

CCB offers these certifications: Certified in Healthcare Compliance (CHC)®, Certified in Healthcare Compliance Fellow (CHC-F)®, Certified in Healthcare Research Compliance (CHRC)®, and Certified in Healthcare Privacy Compliance (CHPC)®. To learn more, please contact us at ccb@hcca-info.org, visit *www.hcca-info.org/certification*, or call 888-580-8373.

Want to become

Certified in Healthcare Compliance (CHC)®?

BE RECOGNIZED for your experience and knowledge!

The Certified in Healthcare Compliance (CHC)® designation demonstrates expertise in the healthcare compliance field. Earn yours today:

- Meet eligibility requirements in both work experience and continuing education
- Pass the CHC exam
- Maintain your designation by earning approved continuing education credits

For more details on earning and maintaining this designation, please find the *CHC Candidate Handbook* or other information at www.hcca-info.org under the "Certification" tab.

CHC℠
Certified in Healthcare Compliance

Questions? Contact
ccb@hcca-info.org

COMPLIANCE CERTIFICATION BOARD℠

HCCA *welcomes* NEW MEMBERS

ALABAMA
- Ann Purdy, MedManagement, LLC

ALASKA
- Edgar Smith, Eastern Aleutian Tribes

ARIZONA
- Stanley C. Adams, Banner Health Corp
- Tim Blanchard, Kingman Regional Med Ctr
- Bahola DeLeon, Dept of Veteran Affairs
- Simi Dhaliwal
- Mary Mauldin, Maricopa Integrated Hlth Syst
- Kathleen Ross, Phoenix Hlth Plan/Abrazo Hlth
- Linda Steward, Health Net, Inc

ARKANSAS
- Jane Lynch, NEA Baptist Clinic
- Gilda Sharp, Sparks Health System

CALIFORNIA
- Allen Bellinghausen, Diablo Medical Billing
- Gina M. Bonica, Alliance HealthCare Svcs, Inc
- Maria Borje-Bonkowski, Kaiser Permanente
- Beth A. Borkenheim, Tri-City Medical Center
- Elsa M. Cisneros, Torrance Memorial Med Ctr
- Karen Darnall, Darnall Law Office
- Shilpa Dharwadkar, Tyler & Wilson
- Roman Diaz, Touchstone Compliance
- Linda G. Fenton, TriZetto Group
- Mary A. Goodloe, Torrance Memorial Med Ctr
- Sharmilla Govindsami
- Maria Groezinger, Safeway Inc
- Adam Gross, Medacta USA
- Rikki Haffner, Molina Healthcare
- Laura L. Hayth
- Patrick Huveldt, EMR Consulting Solutions
- Rachel G. Huveldt, EMR Consulting Solutions
- Iola Ireland
- Gerrie James, Sharp Health Care
- Douglas Killion, Southern California Permanente Medical Group
- Jyotsna Kumar, Kaiser Permanente
- Amanda S. Mudd, Kaiser Permanente
- Jeannie O'Donnell, Sinaiko Healthcare Consulting Inc
- Terence Ou
- Betina Peterson, Saint Agnes Medical Center
- Claire Pryor, Consultant
- Frank Salazar, County of San Bernardino
- Sean A. Scott, Health Net
- Jeanne Steensma
- Alan Young, Deloitte
- Mary Beth Zulauf, Alvardo Parkway Institute

COLORADO
- Allis Gilbert, Colorado State University Health Network
- Scot Houska, Community Hospital
- Deborah Linehan, Denver Health, Hospital & Physician Business Services
- Hayden Mallon, Kaiser Permanente
- Mel Robinson, Emergency Medical Specialists, PC
- Joan M. Van De Griek, Horizon Laboratory

CONNECTICUT
- Sean Barron, IVANS
- Katherine M. Curran, Connecticut Institute for Communities Inc
- Nichelle A. Mullins, Charter Oak Hlth Ctr Inc
- Laura E. Pederson, Western Connecticut Healthcare

FLORIDA
- Martha De Borge, Mednax Services, Inc
- Glennda Gutierrez, Estuary Enterprises
- Kevin Hinsdill, National Healing Corporation
- John F. Kapioski, Express Scripts
- Alicia Peters, Humana
- Debra Pinero
- Corie Tregoe, Health Integrated

GEORGIA
- Sharon Hall, InVentiv Medical Management
- Hope Hickman, Georgia Health Care Assoc

HAWAII
- Robyn K. Petersen, Hawaii Health Systems Corp

ILLINOIS
- Bruce Allain, AANA
- Judith Bitzer, Heritage Behavioral Hlth Ctr
- Eileen E. Erdos, Ernst & Young LLP
- Monique Gaines
- Jennifer Stuart, SmithAmundsen LLC
- Misty Ulmer, Greenville Regional Hospital
- Peggy Wagner, Takeda Pharmaceuticals

INDIANA
- Rebecca K. Hopson, Indiana University
- Brooke Ivey, Bloom Marketing Group
- Detra L. Mills, Reputation Matters, Inc
- Rob Sink, St Joeseph Regional Med Ctr
- Tamara Taylor, Indiana Health Centers Inc
- Jennifer Weddle, Indiana University

KANSAS
- Susan Thomas, Lawrence Memorial Hospital

KENTUCKY
- Lora Adams, Bluegrass Regional Mental Health - Mental Retardation Board, Inc
- Shawn L. Sams, Owensboro Medical Health System
- Doris L. Taylor, Pikeville Medical Center

LOUISIANA
- Dorothy R. Perkins, Riverland Medical Center
- Donna Talley, Acadiana Compliance

MAINE
- Dustin Carstensen, Martin's Point Healthcare
- Cindy Garcia, Martin's Point Health Care

MARYLAND
- Teresita Langreo, University of Maryland
- Carolyn L. Purcell, Total Health Care
- Joy Royes, Montgomery County Govt DHHS
- Joann Sherrer, Bon Secours Health System
- S J. Simmons, MedStar Health, Inc
- Tamsen Westmoreland, Kaiser Foundation Health Plan - MidAtlantic States
- Ranieka Weston, Lung LLC

MASSACHUSETTS
- Debra Blyth-Wilk, Spaudling Rehabilitation Hospital Boston
- Vincent Guarino, Calloway Laboratories, Inc
- Jeff Merselis, PointRight, Inc

MICHIGAN
- Harry T. Laughlin, University of Michigan Health System
- Jennifer L. Munro, Trinity Heatlh
- Rebecca Robichaud, Wachler & Assoc, PC
- Michael Ryan, Trinity Home Health Services
- Judy Suter

MINNESOTA
- Emily Aurand, UnitedHealthcare Community & State
- Rebekah Crosby, Leonard, Street and Deinard
- Mitchell W. Granberg, OptumInsight
- Bruce Lorenz, Grand Itasca Clinic and Hospital
- Cheryl Pasquarella, Life Link III
- Torri Schramm, Essentia Health

MISSISSIPPI
- Penny Lowery, University of Mississippi Medical Center

MISSOURI
- Stacy E. Bryant-Wimp, Accurate Rx Pharmacy

NEBRASKA
- Dana Steiner, Lexington Regional Health Center

NEVADA
- Kathleen T. Janssen, Bailus, Cook & Kelesis
- Karen Salm, Strategic Healthcare Consulting

NEW HAMPSHIRE
- Melissa Erickson, Wentworth-Douglass Hospital
- Teresa A. Haley, Huggins Hospital

NEW JERSEY
- Kimberly Baker, Fox Rehabilitation Srvcs
- Benjamin DiMarco, Medco Health Solutions
- Dawn L. Ericksen, CBI
- Yvonne B. Min
- Roberto Roche, Medco Health Solutions
- Robert Scharff, Fox Rehabilitation Svcs
- James R. Schiffer, Allegaert Berger & Vogel LLP
- Melanie A. Sponholz, Fox Rehabilitation
- Nancy Toll Perilstein, Deloitte

NEW MEXICO
- Francie R. Larsen, La Vida Llena

NEW YORK
- David Agan, PricewaterhouseCoopers
- Jinelle Aguiar, Orthonet
- Joanne Casado-Pabon, Urban Health Plan, Inc
- Ken Cohn, Allied Metro Medical
- Maria E. DiLeo, NS LIJ Health System
- Charmaine Fields, OMGEO LLC
- Peter J. Harrington, NYU Medical School
- Melissa Kamin, Hudson Valley Cerebral Palsy Assoc
- Maureen E. Krone Gough, Whitney M Young, Jr Health Services
- Emily Lombardi, YAI Network
- Eileen B. Murphy, PricewaterhouseCoopers
- Candace E. Murray, Catholic Charties of Onondaga County
- Cynthia Nappa, SUNY Upstate Medical Univ
- Jessica Nesbihal, East River Medical Imaging
- Camille D. Nixon, Easy Choice Health Plan New York
- Stephane Norman, St Josephs Medical PC
- Sheilah O'Donnell, MHA of Rockland
- Gregg Reisman, Somnia Inc

NORTH CAROLINA
- Shanna Deaton, Mission Hospitals
- Dawn M. Ralph, Brookdale Senior Living

NORTH DAKOTA
- Cindy Fischer, Catholic Health Initiatives

OHIO
- Jay Collier, Smith Clinic
- Christi Knox, Community Mercy Health Partners
- Kathleen Mannier, CompuNet Clinical Laboratories
- Cherise McDaniel, NeuroCare Center Inc
- Roxanne Williams, BVHS
- Denise Works, Emergency Medicine Physicians

OKLAHOMA
- Karen Aufdemorte, INTEGRIS Health

OREGON
- Wally Gwaltney, CHI
- Lauren A. Toda, Providence Health & Services

PENNSYLVANIA
- Natalie Bulger, The Children's Institute of Pittsburgh
- Matthew Case, RedPath Integrated Pathology
- Robert J. Cepielik, Deloitte
- Sandra Cole, Estuary Enterprises
- Bettina M. Ferraro, Trinity Health
- Timothy Murray, Catholic Health Initiatives
- Eric Schulties, ITXM
- Jeanie Wesner, Geisinger Health System
- Kate Woods, Excellerx Inc

SOUTH CAROLINA
- Janet DiNino, Agape Senior
- Pamela Duncan, Agape Senior
- Kevin McHugh, Agape Hospice
- Angela Nettles, KershawHealth

SOUTH DAKOTA
- Glen Lloyd, Avera Health

TENNESSEE
- Cheri Ballard, Catholic Health Initiatives
- Shannon Findley, Aegis Sciences Corp
- Susan Mitchell, HCA
- Arlene S. Moore, Vanguard Health Care Services

TEXAS
- Fadi B. Badaoui, MD Anderson Cancer Ctr
- Kelly A. Cameron, North Texas Rehab Center
- Jeanne S. Case, Orthofix, Inc
- Kimberly A. Christian, HeartPlace Dallas
- Julia C. Cruz, Doctors Hospital of Laredo
- Joe Fuentes, Houston Area Community Services Inc
- Nelson Gonzalez, Houston Area Community Services Inc
- Mary Guzniczak, Cardinal Health, Inc
- Shannon Jackson, AMPM, Inc
- Tressie Landry, PHBV Partners, LLP
- Charlotte P. Piontek, HCCS
- Cynthia L. Reed, AACOG
- Andrea Sanchez, Houston Area Community Services Inc
- Penny A. Stanton, MD Anderson Cancer Ctr
- Brian Stone, ID Experts Corp

UTAH
- Klay M. Kunz, IASIS Health Care

VIRGINIA
- Beryl Dennis
- James Lind, Eastern Virginia Medical School
- Jeffrey Renzulli, NMS Healthcare
- Marie Rosado, Mary Washington Healthcare
- Marla Patricia B. Santos, Prince William Ambulatory Surgery Ctr

WASHINGTON
- Jon Allen, Washington Dental Service
- Devoney Johnson, Premera Blue Cross
- William Waller
- Wendy Werner, Cowlitz County Human Services

WEST VIRGINIA
- Steve M. Meadows, United Hospital Center

WISCONSIN
- Wendy L. Ambrose, Saint Jude Healthcare
- Brandon Dycus, Brookdale Senior Living
- Julia Hix, Assurant Health
- Kathryn A. Krenz, Brookdale Senior Living
- Susan M. Lucas, Brookdale Senior Living
- Rebecca Sandborg, Aurora Health Care

PUERTO RICO
- Jimmy Rivera
- Maria D. Rodriguez-Berrios, MAPFRE PRAICO Insurance Co

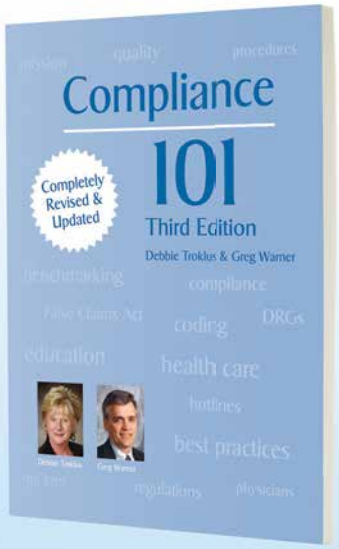
Newly Revised and Updated!

Compliance 101, Third Edition

HCCA's *Compliance 101* has what you need to begin building and maintaining an effective health care compliance program. This newly revised edition incorporates the latest changes to HIPAA brought about by the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act, as well as changes in the Federal Sentencing Guidelines' Sentencing of Organizations. This book is ideal for compliance professionals new to the field, compliance committee members, compliance liaisons, and board members.

Compliance 101 includes:

- The Seven Essential Elements
- Organizational Steps for an Effective Program
- Tailoring Your Compliance Program
- HIPAA and HITECH Privacy and Security Regulations
- Sample Compliance Materials
- Glossary of Compliance Terms



COMPLIANCE 101, THIRD EDITION

Qty		Cost
___	HCCA Members	$50
___	Non-members	$60
___	Join HCCA! Add $200 and pay the member price for your order *(New members only. Regular dues $295/year.)*	$200

TOTAL $ _____

CONTACT INFORMATION (PLEASE TYPE OR PRINT)

○ Mr. ○ Mrs. ○ Ms. ○ Dr.

HCCA Member ID

First Name M.I. Last Name

Title

Place of Employment

Street Address **(NO PO BOX NUMBERS)**

City State Zip

Telephone

Fax

E-mail

PAYMENT OPTIONS

○ Check enclosed (payable to HCCA) ○ *My organization is tax exempt*

○ Invoice me | Purchase Order # _____

○ I authorize HCCA to charge my credit card (choose below)

CREDIT CARD: ○ AmericanExpress ○ Diners Club ○ MasterCard ○ Visa

Credit Card Account Number

Credit Card Expiration Date

Cardholder's Name

Cardholder's Signature

Prices subject to change without notice. HCCA is required to charge sales tax on purchases from Minnesota. Please calculate this in the cost of your order. The required sales tax in Minnesota is 6.875%. All purchases receive free FedEx Ground shipping within continental U.S.

HCCA
HEALTH CARE COMPLIANCE ASSOCIATION

6500 Barrie Road, Suite 250
Minneapolis, MN 55435
888-580-8373 (P) | 952-988-0146 (F)
www.hcca-info.org | helpteam@hcca-info.org

Tear out this page and keep for reference, or share with a colleague. Visit www.hcca-info.org for more information.

RAC attack: How providers can be prepared

Pamela Tyner and Amy Lerman (page 23)

- RACs recovered $797 million in Medicare overpayments in FY 2011.
- In FY 2012, the reach of the RACs extends further.
- CMS is working to implement Medicare Part C and D RACs.
- State enforcement efforts will increase with the introduction of Medicaid RACs.
- Providers must prepare by evaluating and modifying corporate compliance programs.

Readmissions and continuum of care: What is the role of compliance?

Myla Reizen (page 31)

- The readmission issue is not just an issue for financial and operational experts to analyze.
- Readmissions should be part of the compliance plan of relevant providers.
- As a preventative approach, the underlying causes leading to readmission issues should be addressed with a clear plan.
- A compliance officer and/or regulatory attorney should be involved in evaluating each approach to each phase of the readmission process.
- These measures should be reviewed from both a hospital and/or post-acute provider perspectives, as applicable.

Improving the effectiveness of patient safety

Susan Nance, DCSW, CPHQ, CHC (page 36)

- OIG notes CMS has "missed opportunities" to incorporate patient safety issues.
- Most patient safety events are not reported in incident reporting systems.
- Increased emphasis is on effectiveness of programs, not just their presence.
- Surveys of "immediate jeopardy" complaints may open general quality-of-care issues.
- Quality and Compliance issues are overlapping.

Increasing accountability for individuals

Wade Miller and Angela Adams (page 41)

- The government is increasing efforts to hold individuals accountable.
- OIG has the authority to exclude owners and managing employees from federal programs.
- Executives can be implicated by the responsible corporate officer doctrine, even without direct knowledge of a crime.
- Recent case law demonstrates the government's exclusion and prosecution efforts toward individuals.
- Specific steps can be taken to avoid government scrutiny and action.

New Stark Law guidance: Court of Appeals decision in the *Tuomey* case

Gary W. Herschman and Alexandra Miller Khorover (page 48)

- The Fourth Circuit opinion provides some substantive Stark Law guidance.
- The technical component of personally performed hospital services is a designated health service.
- Considering the volume or value of anticipated referrals is impermissible.
- Inquiry is whether a contract "on its face" varies with referrals.
- Compensation should be fair market value for services actually performed.

Research records and EHRs: Five practical tips in a new compliance era

Sarah E. Swank, Esq. and Emily K. Weber, Esq. (page 52)

- Integrate research record issues into discussions of EHR functionality.
- Review clinical trial agreements for access, ownership, and confidentiality provisions.
- EHRs trigger additional HIPAA access and compliance concerns.
- Consider centralizing research compliance functions to address policies and procedures and monitor access to research records in EHRs.
- Conduct routine and for cause research-specific audits.

Anatomic pathology: Basic coding, documentation, and teaching physician documentation

Kristen R. Taylor, CPC, CHC (page 58)

- Understand the general difference between clinical and pathology lab services.
- Become familiar with the basic terminology for coding and billing for pathology services.
- Appreciate unbundling logic for pathology specimen billing compliance.
- Know compliant documentation requirements for teaching physician pathology services.
- Be able to identify common compliance vulnerabilities when billing pathology services.

Here comes the Sunshine Act: Proposed rule CMS-5060-P

Becky Osowski, MJ–Health Law, CIA, CAMS, CCEP (page 61)

- Data collection on payments or transfers of value made to physicians/teaching hospitals is projected to begin after January 1, 2013.
- Specific identifying information about physicians/teaching hospitals is required.
- Data reported will be made publicly available by CMS via the Internet.
- Physicians/teaching hospitals should be proactively reviewing data submitted prior to publication.
- Physicians/teaching hospitals must understand state and federal transparency requirements and institutional conflict of interest policies.

On mentoring, Part 2: The new informal approach

John E. Steiner, Jr., Esq. and Alan Peterson, Hon DBA (page 66)

- A good mentoring program has risks and costs, as well as benefits, for everyone involved.
- Delegating accountability to protégés can help improve day-to-day operational efficiencies, motivation, and buy-in.
- The best leaders and supervisors are not necessarily the best mentors.
- Good mentoring requires preliminary planning, thoughtful implementation, and follow-up testing of the designs and results.
- Each department has unique challenges and capabilities that should be reflected in its mentoring program.

HCCA's 2012 Upcoming Events

Learn more about HCCA's educational opportunities at www.hcca-info.org/events

August 2012

NO HCCA CONFERENCES ARE SCHEDULED IN JULY

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
			1	2	3	4
5	6 Basic Compliance Academy New York, NY	7	8	9 CHC® Exam New York, NY	10	11
12	13 Research Basic Compliance Academy Boston, MA	14	15	16 CHRC® Exam Boston, MA	17	18
19 *Eid-Ul-Fitr*	20	21	22	23	24	25
26	27	28	29	30	31	

September 2012

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
						1
2	3 HCCA OFFICE CLOSED *Labor Day*	4	5	6	7 New England Regional Conference Boston, MA	8
9	10 Basic Compliance Academy Las Vegas, NV	11	12 Early bird cut-off for Physician Practice/Clinic Compliance Conference	13 CHC® Exam Las Vegas, NV	14 Upper Midwest Regional Conference Minneapolis, MN	15
16 *Rosh Hashanah begins*	17	18	19	20	21 Midwest Regional Conference Overland Park, KS	22 *First Day of Autumn*
23	24	25 *Yom Kippur begins*	26	27	28	29
30 AHLA/HCCA Fraud & Compliance Forum Baltimore, MD *Sukkot begins*	1	2				

October 2012

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
	1 Basic Compliance Academy Boston, MA	2	3	4 CHC® Exam Boston, MA	5 North Central Regional Conference Indianapolis, IN	6
7	8 *Columbus Day*	9	10	11	12 East Central Regional Conference Pittsburgh, PA	13
14 Physician Practice/Clinic Compliance Conference Philadelphia, PA	15	16	17	18	19 Hawaii Regional Conference Honolulu, HI	20
21	22 Health Care Privacy Basic Compliance Academy Orlando, FL	23	24	25 CHPC® Exam Orlando, FL	26 Mountain Regional Conference Denver, CO *Eid-Ul-Adha*	27
28	29	30	31 *Halloween*			

Dates and locations are subject to change.

Upcoming Events in 2012

AHLA/HCCA Fraud & Compliance Forum

September 30–October 2 • Baltimore, MD

Clinical Practice Compliance Conference

October 14–16 | Philadelphia, PA

Basic Compliance Academies

August 6–9 • New York, NY — **SOLD OUT**

September 10–13 • Las Vegas, NV

October 1–4 • Boston, MA

November 5–8 • Orlando, FL

November 12–15 • Orlando, FL

December 10–13 • San Diego, CA

Research Basic Compliance Academies

August 13–16 • Boston, MA

Privacy Basic Compliance Academies

October 22–25 • Orlando, FL

Regional Conferences

New England • September 7 • Boston, MA

Upper Midwest • September 14 • Minneapolis, MN

Midwest • September 21 • Overland Park, KS

North Central • October 5 • Indianapolis, IN

East Central • October 12 • Pittsburgh, PA

Hawaii • October 19 • Honolulu, HI

Mountain • October 26 • Denver, CO

Mid Central • November 9 • Louisville, KY

Desert Southwest • November 16 • Phoenix, AZ

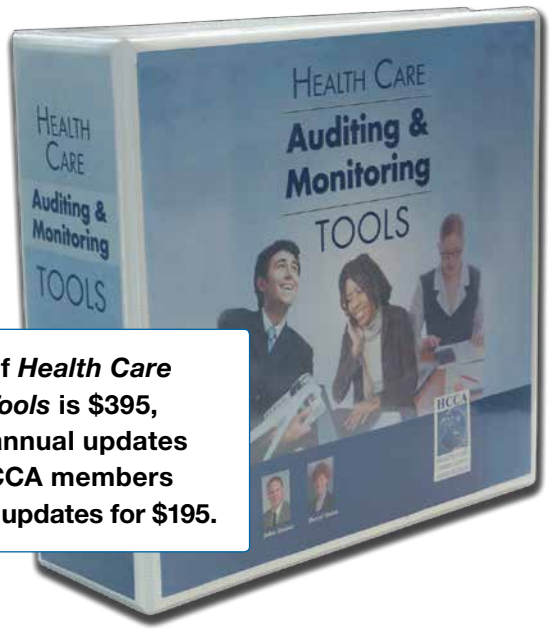
South Central • November 30 • Nashville, TN

Upper West Coast • December 7 • Oakland, CA

Health Care Auditing & Monitoring Tools, Second Edition

BUY NOW AND RECEIVE TWO BI-ANNUAL UPDATES FOR FREE!

This toolkit provides tool templates, report formats, model policies and procedures, and more to help establish or enhance your compliance auditing and monitoring efforts.



Find *just one tool* to help your program improve, and you've achieved *a positive return on your investment*.

The more than 1,000 pages of materials cover:

- Building a compliance program
- Risk assessment and plan development
- Policies and procedures
- Tools for specific program audits
- Program effectiveness reviews

The original purchase of *Health Care Auditing & Monitoring Tools* is $395, which includes two bi-annual updates for free. Afterwards, HCCA members can subscribe to annual updates for $195.

The print and CD-ROM format allows you to reference and tailor documents already created, tried, and implemented by your peers in the profession.

ORDER FORM *Health Care Auditing & Monitoring Tools*

QTY

__ Health Care Auditing & Monitoring Tools (HCCA Member price) $395.00

__ Health Care Auditing & Monitoring Tools (Non-Member price) $445.00

If you already own a copy and wish to update your subscription:

__ 1-year subscription HCCA Members $195.00

__ 1-year subscription Non-Members $225.00

TOTAL $ _____

PLEASE TYPE OR PRINT:

HCCA Member ID

First Name M.I. Last Name

Title

Organization

Street Address

City State Zip

Telephone Fax

E-mail

Mail check to: Health Care Compliance Association
6500 Barrie Road, Suite 250, Minneapolis, MN 55435

Or fax to: 952-988-0146

❑ Check enclosed

❑ Invoice me ❑ PO # _____

Charge my: ❑ MasterCard ❑ VISA ❑ American Express

Credit Card Account Number

Credit Card Expiration Date

Cardholder's Name

Cardholder's Signature

Please make your check payable to HCCA. Questions? Call 888-580-8373.
Prices subject to change without notice. HCCA offers free FedEx Ground shipping within the continental U.S. HCCA is required to charge sales tax on purchases from Minnesota. Please calculate this in the cost of your order. The required sales tax in Minnesota is 6.875%.

HCCA
HEALTH CARE COMPLIANCE ASSOCIATION

6500 Barrie Road, Suite 250
Minneapolis, MN 55435
888-580-8373 (p) | 952-988-0146 (f)
www.hcca-info.org | helpteam@hcca-info.org

Clinical Practice
Compliance Conference

(formerly known as the Physician Practice/Clinic Compliance Conference)

OCTOBER 14–16, 2012
PHILADELPHIA, PA

HCCA
HEALTH CARE COMPLIANCE ASSOCIATION

WHY YOU SHOULD ATTEND

- Get updated on government initiatives specific to physicians and their practices
- Network with your peers
- Learn the latest enforcement trends
- Topics to be addressed include correct documentation, billing and coding practices, and operating on a limited budget

www.hcca-physician-conference.org