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Submitted via Federal Rulemaking Portal: http://www.regulations.gov

Attention: OCIIO-9986-NC
Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Affordable Care Act; Federal External Review Process; Request for Information

The Business Roundtable ("BRT") is an association of chief executive officers of leading U.S. companies. Together, our members' companies employ more than 12 million individuals and provide health care coverage to over 35 million American workers, retirees, and their families. BRT is invested in addressing health care costs that hamper essential economic growth. For that reason, BRT has been critically engaged on the issue of health care reform, and has an interest in seeing an implementation of the Affordable Care Act that provides employers with the flexibility they need to continue providing critical benefits to employees and their families.

We are submitting these comments in response to the Federal External Review Process, Request for Information ("RFI") published on November 17, 2010.[1] The Department of Health and Human Services ("HHS") and Department of Labor ("DOL") have requested comment on operational issues associated with the implementation of a Federal external review process for health coverage in States that do not have an applicable external review process that meets minimum federal standards. Section 1001 of the Patient Protection and Affordable Care Act ("Affordable Care Act"), Pub. L. No. 111-148 added a new section 2719 to the Public Health Service ("PHS") Act.

[1] Affordable Care Act; Federal External Review Process; Request for Information, 75 Fed. Reg. 70160 (November 17, 2010).

Section 2719(b)(1) of the PHS Act, and the regulations implementing the provision, provide that if a State external review process includes at least the consumer protections set forth in the Uniform External Review Model Act ("Model Act") issued by the National Association of Insurance Commissioners ("NAIC"), then the issuer is not required to comply with the new Federal external review process. Earlier this year, the Departments of Health and Human Services, Labor and the Treasury published interim final regulations governing the external review procedures for health plan denials.[2]

We strongly encourage the agencies to use their broad latitude under statute and regulation to deem as compliant the independent external review procedures typically used by self-insured group health plans and in effect on March 23, 2010. Furthermore, we urge similar flexibility with respect to the federal appeals applicable to the external review procedures of self-insured group health plans adopted after March 23, 2010. Part I of these comments describes current external review procedures typically followed by large self-insured group health plans. Part II recommends that the agencies provide considerable flexibility in the way the details of the external reviews are structured, so long as the result is a timely, fair, full review of denied medical claims.

I. Current External Review Process of Self-Insured Group Health Plans

Although there is no requirement to do so, many self-insured plans already voluntarily provide for an external review of denied medical claims. We are, therefore, able to provide insight into the practices most often employed by these health plans.[3]

Though we know of no broad statistical data on this subject, it is our belief that as many as 30% - 40% of large employers with self-insured group health plans provide some form of external review for certain medical claims. Just as one finds variation among states in their requirements for independent external review for insured health plans, similarly there is considerable variation among self-insured plans in the procedures they use for external review. Among self-insured group health plans that provide external review, those plans typically employ the following procedures.

- Outsource the role of claims and appeals fiduciary to an outside third-party to ensure that the decision maker is an independent entity.

- Review complex medical necessity claims or claims for benefits that could be considered experimental or investigational. (Some State procedures follow a similar approach.)

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[2] 75 Fed. Reg. 43330 (July 23, 2010).

[3] BRT has benefitted from the work of the benefit consultants at Aon Hewitt in analyzing the practices of these plans.

- Pay costs for an independent review that are usually expressed on a per case basis and may vary depending on the complexity of the medical claim. A typical average cost per case might be in the range of +/- $700 to $800, with some very complex claims costing several thousand dollars.

- Use a reviewer who is usually a physician with clinical expertise in the area of medicine in question. Typically, this is a physician specialist, and often a nationally recognized expert, in the field.

- Consider all clinical information, including the claimant's medical records, peer-reviewed evidence, and any other information that will aid in making a determination.

- No consideration by the reviewer of the plan's prior determinations in making a determination of whether a particular treatment is medically necessary.

- Provide the claimant with ample time and flexibility to file a request for external review and often deliver a final decision within 4 – 6 weeks after the external review is requested. Flexibility is important, as the complexity of the case may influence that timeline, depending on, for example, the extent and the availability of peer-reviewed medical evidence on the medical issue in question. In most cases, the treatment has already been provided to the patient. The issue at appeal is the coverage of the treatment by the plan.

- Without making the decision binding in all instances, acceptance and payment of decisions on claims in favor of the patient by the self-insured plan. The independent opinion is respected and, as a practical matter, it would raise the risks of unwanted litigation if the plan sponsor were to deny a claim after a respected independent reviewer selected by the plan finds, for example, that the treatment is medically necessary and appropriate.

- In a very limited number of instances, if the independent reviewer denies the medical claim on appeal, the plan sponsor may choose to look at the claim again, and may in some instances decide that a denied claim should be paid, but the plan sponsor does so outside of the plan benefit. The company, for example, might pay the claim in this instance out of general revenues, and the amount paid would not be tax free.

In current practice, many of the self-insured plans currently using independent reviews contract with an outside reviewer that the plan has selected. Increasingly, however, there appears to be a greater movement toward using independent review organizations with which the self-insured plan's Third Party Administrator ("TPA") contracts.

II. Federal Regulations Should Provide Flexibility in Deeming External Review Procedures as Satisfying the External Review Requirement for Non-Grandfathered Self-insured Group Health Plans

Section 2719(c) of the ACA gives the Secretary the authority to deem the external review process of a group health plan or health insurance issuer, in operation as of March 23, 2010, to be in compliance with a state external review process or the federal external review process, as applicable. Neither the interim final regulations nor EBSA Technical Release 2010-01 explains how determinations will be made regarding whether an existing external review process complies with the ACA.

Business Roundtable believes that the independent external review procedures typically used by self-insured group health plans fulfill the goals of having a timely, full, fair and impartial review of denied medical claims. Accordingly, the agencies should use broad latitude in deeming as compliant existing external review procedures in effect on March 23, 2010, and similarly provide flexibility with respect to the federal appeals rules applicable to self-insured group health plan external review procedures adopted after the DOE.

Why Regulatory Flexibility is Appropriate

The experience of our members demonstrates the importance of agencies using their discretionary authority to provide flexibility in the application of the deeming rule to self-insured group health plans and for external review procedures adopted after the DOE. First, it is critical to note that the statute allows for flexibility by stating that existing third party reviews need **not** be identical to the NAIC Model Act. While the ACA requires that the federal external review process be "similar to" the NAIC Model Act, the law does not require the federal process to be identical to the NAIC Model Act. As long as existing practices achieve the agencies' goals of a timely, full, fair and impartial review, BRT believes that those practices would be appropriately deemed to satisfy the statutory requirement of the ACA with respect to external review procedures in effect as of DOE. Indeed States themselves, like self-insured group health plans, have historically taken varying approaches in structuring the details of State external reviews tailored to their particular State circumstances.[4]

Second, the lack of national uniformity across State review procedures presents problems for our members. Although self-insured group health plans are permitted under the interim final rules to follow a state's external review process, those processes are not nationally uniform.

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[4] See, for example, the discussion of state laws on external appeals in the August 2005 publication by the Kaiser Family Foundation and Consumers Union,, *A Consumer Guide to Handling Disputes with Your Employer or Private Health Plan, 2005 Update*, which includes information about how consumers can take advantage of their health plans' internal processes to resolve disputes, as well as external review processes as allowed under state laws. http://www.kff.org/consumerguide/7350.cfm Also see the earlier May 2002 Kaiser Family Foundation study *Assessing State External Review Programs and the Effects of Pending Federal Patients' Rights Legislation* http://www.kff.org/insurance/externalreviewpart2rev.pdf

They are therefore not the preferred approach for multi-state self-insured employers that need to have the flexibility to structure their own approaches that can be applied consistently to all participants and beneficiaries in different locations throughout the United States.

Although federal DOL regulations will provide national uniformity, the regulations should provide enough flexibility to allow a multi-state employer to utilize its current external review process if it meets the general goals set forth in the federal rules. For example, if the self-insured group health plan's external review process provides final decisions within 4 – 6 weeks from the time that an external review is requested, that time frame should satisfy the general standard set forth in the regulations for self-insured plans. It is overly prescriptive to set the specific sub-deadlines within that 4–6 week period as provided in the NAIC model act for fully insured health plans. As long as the decision is made in a timely manner and is fair to the claimant, it seems unnecessary to impose strict sub-deadlines within an overall decision deadline and attach consequences for a delay in any of the sub-deadlines. The DOL internal claims and appeals procedures provide an outside time frame by which decisions must be made but do not require specific deadlines within that time frame, giving employers flexibility in designing their internal claims and appeals processes. We believe that the rules for independent external reviews should follow that same practice. The federal regulations should also allow for a longer time frame for completing the independent medical decision if the medical determination required is extremely complex or if the self-insured group health plan under some circumstances voluntarily allows a participant to seek external review even after the regulatory time limit for filing such a request has expired. Likewise, the rules should not bar a self-insured group health plan from taking another look at a claim for benefits denied by the independent external reviewer, as some plans do today.

Current External Review Procedures of Self-Insured Employers Satisfy Goal of Having an Independent Review

Existing external review procedures of large self-insured group health plans also typically satisfy the principle of ensuring an independent review with no conflict of interest. As noted above, some self-insured group health plans currently outsource the role of claims and appeals fiduciary to the group health plan administrator of a self-insured group health plan for *benefit* determinations (e.g., whether a particular service was "medically necessary"). (As stated in DOL reg. section 2590.715-2719(d) (1), the external review process does not apply to an adverse benefit determination where a participant or beneficiary fails to meet the requirements for eligibility under the terms of a group health plan.) This practice spread after DOL shortened the time frames for making initial benefit determinations and for benefit determinations on review as part of regulations issued on November 21, 2000. Employers delegated this authority to make benefit determinations to group health plan administrators because the latter were better equipped to comply with the new requirements, including the shorter time frames for making a decision.

Using the group health plan administrator to review a denied medical claim does not per se create a conflict of interest. In *Metropolitan Life Insurance Co. v. Glenn*, 128 S.Ct. 2343 (2008), the U.S. Supreme Court considered conflict of interest as a factor when determining whether a plan administrator has abused its discretion in denying benefits. Arguably, the addition of an external review was included in the Affordable Care Act to also address this concern. *MetLife v. Glenn* provides that if the payer of the benefit differs from the decision maker, then there is no per se conflict. This process is in place today for many employers who sponsor self-insured group health plans, where the self-insured plan is indeed "the payer" and the group health plan administrator is responsible for the final, mandatory benefit determination on review. Accordingly, in this situation, the self-insured group health plan should be deemed to be in compliance with the external review requirement. In effect, the independent fiduciary third-party review would be considered to be the external review for purposes of these rules.

In the absence of a conflict of interest, the safe harbor that requires plans to contract with 3 IROs and to rotate claims among them is too burdensome and prescriptive as a safe harbor. The safe harbor should instead focus on the goal of demonstrating that there is no conflict of interest with respect to the decision rendered by the independent reviewer. Currently, most health plan administrators already have one Independent Review Organization ("IRO") in place. In light of the guidance, many of them are pursuing further IRO contracting; however, there are only a limited number of *nationally* accredited IROs available. In addition, the EBSA Technical Release states that the IRO is responsible for preparing and sending the final determination directly to the claimant. The current processes used by large employers that have ceded the appeals fiduciary responsibility to the plan administrator, is that the plan administrator will arrange for the external review, manage the timing, and prepare and deliver the final notice to the claimant. IROs usually are not directly involved with claimants and may not be directly visible to claimants. If IROs become directly engaged with claimants, costs will rise to support follow up communications, etc. and may also make the role of independent reviewer very unattractive for the specialty physicians who typically are contracted to perform such independent reviews.

The Goal of a Full and Fair Review of Denied Medical Claims Does Not Require a* De Novo *Standard of Review

To ensure a full and fair review of the denied medical claim, both with respect to the deeming of existing procedures as compliant and for the purpose of the new federal rules applicable to self-insured plans that do not have an external review in place, the ACA does not require a *de novo* standard of review. In fact, the statute is silent with respect to *de novo* review and the agencies should not use their discretion to impose such a high legal standard where the plan's independent reviewer is already not bound by the internal claims and appeals decisions.

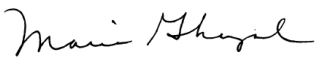
The *de novo* standard goes beyond the statutory requirements and even beyond the Model Act promulgated by the National Association of Insurance Commissioners (NAIC Model Act). By requiring a *de novo* review, the IRO is prohibited from giving any deference to the plan in making its decision. This review standard will have the effect of making the internal claims and appeals process irrelevant.

The NAIC Model Act states that in reaching a decision, the IRO "is not bound by any decisions or conclusions reached during the health carrier's utilization review process." However, the NAIC Model Act does not also require a *de novo* review standard. Therefore, although the IRO is not bound by the utilization review process, it can choose to follow the previous reviewer's decisions or conclusions. By adding the *de novo* requirement for self-insured group health plans, DOL has exceeded its authority by imposing a standard not required by law and that is stricter than for fully insured plans. Further, imposing the *de novo* standard will remove the deferential standard for employer-sponsored group health plans that are subject to ERISA. Historically, in determining the appropriate standard of review, courts were guided by principles of trust law, including whether to use a deferential standard versus a *de novo* standard.

Conclusion

We appreciate the opportunity to respond to this RFI. Again, BRT believes that both as a matter of law and policy our employees would benefit from rules that deem as compliant independent review procedures in existence on DOE, and from maximum flexibility with respect to external review procedures adopted after DOE. We are available to respond to any questions regarding these comments.

Sincerely,



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