July 25, 2011

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

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Room N-5653
U.S. Department of Labor
200 Constitution Avenue NW
Washington, DC 20210
Attention: RIN 1210-AB45

Re: Comments on Amendments to Interim Final Rule on Internal Claims and Appeals and External Review Processes (76 Fed. Reg. 37208; RIN 1210-AB45)

Dear Sir or Madam:

The HR Policy Association ("HR Policy" or the "Association") welcomes the opportunity to provide comments to the Departments of Health and Human Services, Labor, and Treasury (the "Agencies") regarding the amendments to the Interim Final Rule (the "IFR" or the "Regulation") for Group Health Plans and Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes under the Patient Protection and Affordable Care Act as issued in the *Federal Register* on June 24, 2011.[1]

HR Policy Association is a public policy advocacy organization representing chief human resource officers of major employers. The Association consists of more than 330 of the largest corporations doing business in the United States and globally, and these employers are represented in the organization by their most senior human resource executive. Collectively, their companies employ more than 10 million employees in the United States, nearly nine percent of the private sector workforce, and 20 million employees worldwide. The Association is filing these comments in response to the Agencies' request for comments on the revised Regulation. The comments include specific recommendations regarding the amendments to the Regulation, as well as requests for clarification on particular areas of the Regulation.

PPACA's Requirement for Internal Claims and Appeals and External Review Processes.

The Public Health Service Act (PHSA) § 2719, as added by section 1001 of the Patient Protection and Affordable Care Act of 2010 (PPACA),[2] established certain rules related to a group health plan's internal claims and appeals procedures and mandated that such plans would be subject to a new external review process. These new mandates only apply to non-grandfathered group health plans and take effect for plan years beginning on or after September 23, 2010. While certain provisions of PHSA § 2719 apply equally to fully-insured health group

[1] The Amendments to the Interim Final Rule for Group Health Plans and Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes under the Patient Protection Affordable Care Act, 76 Fed. Reg. 37208 (June 24, 2011).

[2] Pub. L. 111-148 (enacted on March 23, 2010).

plans and to non-ERISA plans, the Association's comments are directed to the amendments of the regulatory provisions affecting self-insured ERISA group health plans because the vast majority of our members sponsor such plans.

Federal External Review Process. Self-insured ERISA plans will be most affected by the new external review process. This is due to the fact that while many states currently have some form of an external review process for fully-insured plans, ERISA preemption has prevented a state's external review process from applying to self-insured plans. ERISA preemption has permitted large employers to administer their plans uniformly across state lines, thus significantly reducing the cost of providing employee health coverage. Under PPACA and the amended IFR, self-insured ERISA plans will continue to fall outside the purview of state external review processes (unless they expressly opt in), but such plans will now be subject to a new federal external review process.

External review processes are relatively new for most employers with self-insured ERISA plans. The IFR, and subsequent technical guidance, sets forth criteria for a plan to meet the requirements of the federal external review. For example, self-insured plans must implement an external review process established by the Agencies that is "similar" to the consumer protections in the NAIC's Uniform External Review Model Act.[3] This includes, among other things, contracting with a specified number of accredited Independent Review Organizations (IRO) to conduct a de novo review of a plan's internal benefit determination that has been appealed by a claimant under PHSA § 2719. This is also known as the "privately accredited IRO process."

The Association appreciates the Agencies' interim enforcement safe harbor (with its delayed enforcement) provided for self-insured plans to put these standards —which are very extensive[4]— in place and implement the regulatory guidance. Specifically, the Association supports the Agencies' June 22, 2011 Guidance extending the requirement that self-insured plans contract with at least two IROs by January 1, 2012 and with at least three IROs by July 1, 2012. Even so, the Association regrets that the Agencies did not provide for more flexibility in the federal external review processes.

Internal Claims & Appeals Procedures. PPACA also requires health plans to implement an effective internal appeals process for challenging adverse claim or coverage determinations.[5] This, most notably, requires plans to comply with the Department of Labor's longstanding ERISA regulations regarding internal claims and appeals procedures.[6] Self-insured ERISA plans are already complying with the current regulations on an internal plan's claims and appeals procedures. Yet, the Agencies felt the need to issue additional rules and revisions to the ERISA regulations. Indeed, the Association was disappointed in its hope that the Agencies would have used their regulatory discretion to ensure that self-insured plans could continue to maintain

[3] PHSA § 2719(b)(2)(b).

[4] Plans would be required to, among other things, amend existing claims and appeals procedures and adopt new external review procedures and provide notice to participants of the same, update required notices and administrative procedures, select three independent review organizations (IROs) to perform the external reviews, prepare agreements to govern the relationship between the plan and IROs, and determine the legal transfer of information between the plan and IROs. The other option to come within the safe harbor —complying with the relevant state's external review process— is equally unpalatable because a plan would no longer be able to uniformly administer its plan across state lines (i.e., effectively negating the benefits of ERISA preemption).

[5] PHSA § 2719(a)(1).

[6] The DOL's current regulations governing ERISA plan claim procedures are found in 29 CFR 2560.503-1.

greater flexibility in plan design and procedures in order to offer more efficient, effective, and affordable health coverage to employees, their dependents, and retirees.

The Agencies initially issued an IFR on July 23, 2010, implementing PHSA § 2719. The initial IFR was followed by a host of sub-regulatory and technical guidance On September 21, 2010, the Association filed a comment letter in response to the initial IFR. The Association hereby incorporates the issues raised and the position set forth in its September 21, 2010 comment letter to the extent they were not completely addressed by the Agencies in the amendments to the final regulation.

Amendments to the Federal External Review Process.

The Association, in its previous comment letter, expressed several concerns relating to the federal external review process and it reiterates it earlier stated concerns and positions. However, this comment letter addresses the amendments made to the IFR.

The Narrowed Scope of the Federal Review Process. The initial IFR recognized one limitation on the scope of review of IROs under the federal external appeal process, which was that an IRO could not review a plan's denial, reduction, termination, or a failure to provide payment for a benefit based on a determination that a participant is not eligible for benefits under the terms of a plan (e.g., worker classification and similar eligibility issues).[7] The Association supported and continues to support the Agencies' position on this limitation.

The Association further supports the amended final regulation which narrows the scope of claims eligible for federal external review to those involving medical judgment (as determined by the external reviewer), or a rescission of coverage.[8] IROs tend to be better suited to rendering decisions on medical judgments but may not have much experience interpreting contracts or applying legal standards. Indeed, this scope limitation is more similar to the scope of claims subject to external review under the NAIC Uniform Model Act.

The Association, however, is concerned the external reviewer must make the assessment whether a claim involves "medical judgment" which will impose administrative costs and burdens for a plan. In addition, the Association is concerned with the manner in which the Agencies have chosen to implement a more narrow scope of review through a "suspension" of the very broad initial regulation, which remains in place and would become effective again if the suspension is lifted.[9] The limited scope of review should be permanent and not simply under suspension subject to reinstatement.

Clarification on the Binding Nature of an External Review. The initial IFR provided that under the federal external review process a reversal of a plan's internal adverse benefit decision by an independent review organization (IRO) will be "binding" on the plan, as well as the claimant, except to the extent that other remedies are available under state or federal law.[10] The Association appreciates the clarification that the parties to a dispute (i.e., a claimant and a plan) under the federal review process should have the right to seek judicial review of an adverse IRO ruling and such an appeal.[11]

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[7] 75 Fed. Reg. 43336, 43357; 29 CFR § 2590.715-2719(d)(1).
[8] 76 Fed. Reg. 37216; 29 CFR § 2590.715-2719(d)(1).
[9] 76 Fed. Reg. 37216; 29 CFR § 2590.715-2719(d)(1)(ii).
[10] 75 Fed. Reg. 43358; 29 CFR § 2590.715-2719(d)(2)(iv).
[11] 76 Fed. Reg. 37217.

Revisions to and Additional Rules for Current Internal Claims Procedures

PPACA, through PHSA § 2719, provides that a group health plan shall implement an effective internal appeals process for benefit determinations and that such internal claims and appeals processes must incorporate the existing regulations currently governing ERISA plans.[12] The statutory direction does not change existing law for most HR Policy member companies because employer-sponsored self-insured health plans must already comply with the Department of Labor's existing ERISA regulations governing a plan's internal claims procedures. The Agencies, however, issued new mandates in the initial IFR that supersede, revise or add to some of the longstanding ERISA regulations. These new mandates were, and continue to be, an area of concern for the Association and many of our member companies.

Shorter 24-Hour Deadline for Urgent Care Claims Not Retained. The initial IFR reduced the time period in which plans must notify claimants of urgent care benefit determinations from 72 to 24 hours after a claim has been submitted.[13] The Association recommended that the notification deadline should not be reduced to 24 hours because of the administrative problems it would create. Consequently, the Association supports the amendment to the regulations eliminating an absolute 24-hour decisionmaking and notification deadline for urgent care claims.[14] The amended final regulation provides a more sound administrative approach by allowing plans to follow the longstanding rule in DOL's claims procedure which advises that benefit decisions be made as soon as possible consistent with the medical exigencies involved but in no event later than 72 hours.[15]

Revisions to the Broadening the Participant's Notice. The initial IFR provided new standards regarding rendering notice to participants. These new requirements were in addition to those already required under the DOL's longstanding regulatory scheme. For example, the notice must include information sufficient for the claimant to identify the claim involved including the provider, date of service, cost of service, diagnosis, treatment and denial codes.[16] The plan must also explain the reason for the adverse determination and provide a description of the internal appeal processes and external review processes available to the claimant. Most of these requirements have not been amended in the final regulation.[17]

HR Policy initially recommended that the Agencies reconsider the requirement mandating that plans provide diagnosis and treatment codes in the adverse benefit notice to claimants. Indeed, the amended rule is an improvement by eliminating the requirement to automatically provide diagnosis and treatment codes as part of a notice of adverse benefit determination or final internal adverse benefit determination. [18] Instead, the amended regulations, which requires plans to provide notice to participants of the opportunity to request diagnosis and treatment codes (and their meanings) in *all notices*, and provide this information upon request in the case of an adverse benefit determination.[19] While it is an overbroad administrative requirement to provide

[12] 75 Fed. Reg. at 43355; 29 CFR § 2590.715-2719(b)(i).
[13] 75 Fed. Reg. at 43333.
[14] 76 Fed. Reg. 37208, 37212.
[15] 29 CFR § 2590.715-2719(b)(2)(ii)(B).
[16] 75 Fed. Reg. at 43332.
[17] 29 CFR § 2590.715-2719(b)(2)(ii)(E)(1)
[18] 29 CFR § 2590.715-2719(b)(2)(ii)(E)(2).
[19] *Id*.

the notice of the opportunity to request diagnosis and treatment codes in *all notices*, the Association recognizes the improvement made by in the amended final regulation.

"Relaxed" Strict Compliance Rule Maintained. The initial IFR adopted a standard of strict compliance, under which a claimant will be deemed to have exhausted the plan's internal claims procedure if the plan fails to meet the requirements.[20] Failure to precisely follow the rules provides the claimant the opportunity to forego the internal claims and appeals process and go straight to the external review or federal court with no deference being given to the plan fiduciary's interpretation of its own plan. The Association expressed its concern with this new requirement because it rejected the well-established substantial compliance rule, which was that as long as a plan substantially complied with ERISA's regulations governing internal claims procedure, the plan fiduciary's interpretation of the plan and claim determination is generally granted deference by the federal courts.[21]

Unfortunately, the Agencies have retained the strict compliance rule, but the Agencies did amend the regulations to provide an exception to the strict compliance rule for plan errors that are *de minimis*, non-prejudicial, due good cause or matters beyond the control of the plan and that the violation occurred in the context of an ongoing, good faith exchange of information between the plan and the claimant.[22]

While this amendment is a slight improvement over the initial regulatory approach, the Association reaffirms its position and urges that the Agencies retain the well-established and longstanding substantial compliance approach. The substantial compliance approach ensures that more claims will be resolved in an expeditious manner through the administrative process and important resources are not squandered in litigation.

Comprehensive Revisions to ERISA Regulations Under Consideration. In the Preamble to the Regulation, the Agencies note that the DOL is considering further revisions to the existing claims procedure regulations, and that it expects to issue regulations in the future that propose "additional, more comprehensive" updates to the standards governing internal claims and appeals procedures.[23] The Association questions the wisdom of choosing to revise the longstanding ERISA claims procedure regulations while there is so much uncertainty and concern regarding the new mandates imposed by PPACA and the associated costs and burdens and it urges the DOL not to do so.

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[20] 75 Fed. Reg. at 43356; 29 CFR § 2590.715-2719(b)(2)(ii)(F).

[21] The DOL's longstanding position on the application of the substantial compliance doctrine as stated in guidance acknowledged that "not every deviation by a plan from the requirements of the [DOL claims procedure regulations] justifies proceeding directly to court." Thus, the agencies' strict adherence rule appears to be a reversal that may result in adverse consequences for even the most minor compliance failures. Frequently Asked Questions and Answers on Benefit Claims, Q/A-F2 (May 2002). *See also Lafleur v. La. Health Serv. & Indemnity Co.*, 563 F.3d 148 (5th Cir. 2009) (holding that technical noncompliance with ERISA procedures will be excused so long as the purpose of ERISA's claims procedure requirement has been fulfilled).

[22] 76 Fed. Reg. 37213; 29 CFR § 2590.715-2719(b)(2)(ii)(F)(2).

[23] 75 Fed. Reg. at 43332.

Thank you for the opportunity to comment on the amendments to the IFR and for considering our suggested recommendations. If the Association can be of further assistance, please contact Michael Peterson at 202-789-8659 or mpeterson @ hrpolicy.org.

Sincerely,

Michael Peterson
Vice President, Benefits & Employment Policy
Associate General Counsel
HR Policy Association