HR POLICY ASSOCIATION®
The Association of Chief Human Resource Officers

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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 Interim Final Rule on Internal Claims and Appeals and External Review Processes (75 Fed. Reg. 43331; 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 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 July 23, 2010.[1]

HR Policy represents the chief human resource officers of over 300 of the largest employers doing business in the United States. Representing every major industrial sector, HR Policy's members employ more than 18 million people worldwide and collectively spend more than $75 billion annually providing health insurance to millions of American employees, their dependents and retirees. The Association is filing these comments in response to the Agencies' request for comments on the Regulation. The comments include specific recommendations regarding the proper regulatory process, suggested changes to the Regulation, as well as requests for clarification on particular areas of the Regulation.

The Agencies Should Retract the IFR and Use a Different Regulatory Procedure to Implement the New Statutory Requirements.

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 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, 75 Fed. Reg. 43331 (July 23, 2010).

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

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

Federal External Review Process. To be sure, 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 IFR, self-insured ERISA plans will continue to fall outside the purview of state external review processes, but such plans will now be subject to a new single federal external review process.

External review processes are relatively new for most employers with self-insured ERISA plans and most employers are not ready to implement them. It is important to highlight the fact that employers who sponsor group health plans that are subject to these new mandates do so voluntarily and many such employers believe that the costs and administrative burden related to the federal external review will be considerable. Indeed, many of our member companies are very concerned that this new federal external review process —and the regulations implementing it— will have a detrimental impact on their ability to continue to offer efficient, effective, and affordable health coverage to employees, their dependents, and retirees.

The IFR, admittedly, has very few rules implementing the federal external review process. Instead, the Agencies have noted that more guidance will be forthcoming in the "near future." Such guidance should not be issued through an IFR, but instead, the Agencies should issue an Advance Notice of Proposed Rulemaking (ANPRM) or Notice of Proposed Rulemaking (NPRM) so the public, including large employers who have been voluntarily offering health coverage for decades, can be heard regarding the proposed rules governing the new federal external review process *before* a final regulation is issued on the matter. Indeed, the Association believes that by issuing the Regulation as an IFR, the Agencies have missed a valuable opportunity to get comments from employers who sponsor plans that provide health coverage to millions of Americans *before* issuing the Regulation. Thus, the Agencies should retract the IFR to the extent it deals with the federal external review process and instead issue an ANPRM or NPRM.

The Association recognizes that the Agencies are limited, to some extent, in their approach by the statute because PPACA dictates that PHSA § 2719 is effective for plan years beginning on or after September 23, 2010. Moreover, we recognize that the Agencies have issued a Technical Release regarding the federal external review process that provides an interim enforcement safe harbor for self-insured group health plans until the Agencies can issue further guidance on the federal process.[3] While HR Policy appreciates the attempt to provide a safe harbor, the steps

[3] Availability of Interim Procedures for Federal External Review and Model Notices Relating to Internal Claims and Appeals and External Review under the Patient Protection and Affordable Care Act; Notice, 75 Fed. Reg. 52597 (Aug. 26, 2010); Employee Benefits Security Administration Technical Release No. 2010-01 (Aug. 23, 2010).

necessary to satisfy the safe harbor requirements are daunting – particularly because of how soon these requirements become effective.[4]

Given the difficulty of meeting the requirements of the safe harbor and the fact that the Agencies should use a different regulatory process (as discussed above), the Association recommends that the Agencies issue a "good faith" interim enforcement safe harbor for the federal review process until an effective, circumspect regulatory rule can be issued and implemented. This safe harbor would apply to self-insured plans which did not have an external review process on the date of PPACA's enactment (the vast majority of plans) and which are attempting, in good faith, to establish an effective external review process. For those self-insured plans which were already using an external review process on the date of PPACA's enactment (a minority), the Agencies should use their "deeming" authority under PHSA § 2719(c) to determine that such plans are in compliance with the statutory external review requirements, at least, until the Agencies can issue further guidance.

Internal Claims & Appeals Procedures. The statute also requires health plans to implement an effective internal appeals process for challenging adverse claim or coverage determinations.[5] This, most notably, requires health plans to comply with the Department of Labor's existing ERISA regulations on 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 and, given the extensive compliance with the existing ERISA regulations, there is little urgency for the Agencies to issue new or revise existing regulations through an IFR as the Agencies have done. The Agencies, therefore, should retract the IFR and follow the more traditional route of issuing the Regulation through an ANPRM or NPRM with respect to the internal claims and appeals procedures.

As previously mentioned, section 2719 of PHSA does not apply to grandfathered plans. The Association's concern over the IFR would be considerably less if the Agencies had used the significant regulatory discretion provided by the statute and adopted a more flexible approach with respect to how a plan maintains grandfathered status. However, because of this overly-narrow approach, many of our members who have self-insured plans expect to lose grandfathered status very soon and will be subject to the strict new mandates under the IFR implementing PHSA § 2719. Thus, the Association recognizes that while the Agencies are somewhat constrained by the statute, they should use their regulatory discretion in the final Regulation to ensure that that self-insured plans can continue to offer efficient, effective, and affordable health coverage to employees, their dependents, and retirees.

Notwithstanding the Association's position that the Agencies should retract the IFR with respect to the federal external review process and the internal claims and appeals procedures, use

[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.

a different regulatory process such as an ANPRM or NPRM to issue a final regulation, and adopt a good faith compliance safe harbor, we will provide comments on the current IFR.

Limited Guidance on the Federal External Review Process.

As noted above, one of the most concerning aspects about a plan losing its grandfathered status is that it will be subject to the new federal external review process. PHSA § 2719 provides that fully-insured group health plans comply with State external review process which must, at a minimum, include the consumer protections in the Uniform External Review Model Act promulgated by the National Association of Insurance Commissioners (NAIC).[7] Self-insured plans, however, 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.[8]

The Agencies have a fair amount of discretion in interpreting the word "similar" as applied to the NAIC's Uniform External Review Model Act. Congress did not use the words "the same" or even "substantially similar".[9] Accordingly, the Association recommends that the Agencies adopt a relatively broad view of the word "similar" and, as noted above, provide employers an opportunity to comment on rules governing the federal external review process *before* a final regulation is issued either through an ANPRM or NPRM.

As noted above, an alternative regulatory procedure would be particularly appropriate for the IFR because it does not describe, in detail, or provide a great deal of significant guidance regarding the federal external review process. Indeed, the IFR is generally directed towards establishing the minimum standards for state external review processes which will apply to fully-insured plans. In fact, the Agencies note in the IFR that further guidance will be issued "in the near future" setting forth the details of the federal external review processes.[10]

HR Policy is very concerned to the extent that the requirements in the EBSA's Technical Release on the interim enforcement safe harbor for the federal external review processes represents the approach the Agencies will take in formulating the federal external review process rules.[11] These rules create significant administrative burdens, which do not currently exist and will be costly and difficult to implement. Overly burdensome rules will make it more difficult for employers to offer or to continue to offer affordable employee health coverage. Even though, at this time, it is not possible for self-insured plans to gauge how onerous the new federal external review process will be, there are some general statements of rules and principles in the IFR, its Preamble, and statements by Department officials on which the Association seeks clarification and wishes to comment.

<u>Clarification on the Use of the New Federal External Review Process and the Binding Nature of an IRO Decision Under is Needed</u>. The IFR provides 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

[7] PHSA § 2719(b)(1).

[8] PHSA § 2719(b)(2)(b).

[9] The word similar may be interpreted many ways. For example, Merriam-Webster's Dictionary Collegiate Dictionary defines the term "similar" as "(1) having characteristics in common; (2) alike in substance or essentials; (3) not differing in shape but only in size and position." The application of each variation of the definition would appear to yield a different result in the substance and procedures of a federal external review process.

[10] 75 Fed. Reg. at 43332.

[11] Employee Benefits Security Administration (EBSA) Technical Release No. 2010-01 (Aug. 23, 2010).

that other remedies are available under state or federal law[12] such as a denial of benefit claim under ERISA § 502(a)(1)(B). It is important to point out, however, that the statute simply provides that the IROs decision will be binding.[13] There is no statutory exception reserving other legal remedies or causes of action.

HR Policy agrees with the Agencies' interpretation that the parties to a dispute (i.e., a claimant and a plan) under the federal review process should have the right to appeal an adverse IRO ruling and such an appeal would presumably be made under Section 502(a) of ERISA. It is our understanding that some Agency officials have indicated that the IFR provides a claimant with the right to challenge a plan's adverse benefit decision through the external review process and appeal an adverse IRO decision in federal courts under ERISA § 502(a)(1)(B). The rationale for this position was that ERISA remedies would still be available to claimants who are participants or beneficiaries under ERISA § 502(a).

However, Agency officials have not indicated that the same right should be extended to an employer (or plan fiduciary) to challenge an adverse IRO external review determination. HR Policy requests that the Agencies confirm that employers —more particularly plan fiduciaries— will also have the right to bring an ERISA action in federal district court to contest an adverse IRO ruling. Section 502(a) of ERISA not only permits suits by participants and beneficiaries, but also fiduciaries are permitted to bring claims. In fact, while participants (or claimants) can clearly bring a suit for denial of benefit under ERISA §502(a)(1)(B), plan fiduciaries may file claims under §502(a)(3) seeking injunctive relief or restitution improperly awarded benefits.[14] Thus, the Agencies should clarify that plan fiduciaries may, in fact, appeal adverse IRO decisions under ERISA.

The Federal External Review Rules Will Create Additional Costs, Administrative Burdens, and Inefficiencies. While the Association appreciates that the new federal external process will be uniform across the nation, we are very concerned about the additional costs, administrative burdens, and uncertainty associated with the new process. For example, the IFR provides that a participant may file an urgent care claim simultaneously under a plan's internal claim procedure and with the federal external review board. Consequently, the IFR contemplates two different bodies making a decision over the same set of issues at the same time. Indeed, permitting the dual filing on urgent care claimants appears to render a plan's internal claim and appeals process useless. The need for providing a simultaneous filing option does not appear necessary and will only drive up costs and the Association requests that the Agencies reconsider and require urgent care claimants to exhaust a plan's internal claim procedure before filing an appeal of a decision that has not even been rendered by the plan.

Similarly, the IFR appears to permit a claimant to contest a plan's adverse benefit decision through the federal external review process and then —or even concurrently— challenge the adverse decision in federal courts such as a denial of benefit claim under ERISA § 502(a)(1)(B). Permitting claimants to pursue claims in such a manner makes the external review process an unnecessary additional layer of administration that will increase costs and complexity. Once

[12] 75 Fed. Reg. at 43358; 29 CFR § 2590.715-2719(d)(2)(iv).

[13] PHSA § 2719(b)(1).

[14] *See e.g., Heller v. Forti Benefits Ins. Co.*, 142 F.3d 487 (D.C. Cir. 1998) (plan fiduciary recovering under ERISA § 502(a)(3) a disputed improperly paid benefit to a participant by an ERISA welfare benefit plan).

again, the IFR seemingly permits two different decision makers (i.e., federal review IRO and federal district court) to consider the same set of issues simultaneously.

HR Policy recommends that the Agencies require claimants to follow a step-by-step process. This would begin with receiving a final decision under a plan's internal claims and appeals procedure, which could be appealed to an IRO under the federal external review. The decision, in turn, could be reviewed by a federal court under ERISA. The redundancies in the IFR should be eliminated and these differing levels of review should be sequential.

Maintain the Limitation on the Scope of the Federal Review Process. The IFR recognizes one limitation on the scope of review on internal claims and appeals decisions under the federal external appeal process. The federal external review process is not available for 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).[15] The Association supports the Agencies' position on this limitation.

Revisions to and Additional Rules for Current Internal Claims Procedures

PHSA § 2719 also 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.[16] 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, have issued new mandates in the IFR that supersede, revise or add to some of the current ERISA regulations. These new mandates are an area of concern for HR Policy and many of our member companies.

Eliminate Required Notification of Urgent Care Determinations within 24 Hours. The IFR reduces the time period in which plans must notify claimants of urgent care benefit determinations (whether adverse or not) from 72 to 24 hours after a claim has been submitted.[17] It appears likely that this reduction in time, although not expressly addressed in the IFR, would also apply to the existing 72 hour deadline for internal *appeals* of urgent care claims. The Association recommends that the notification deadline should not be reduced from 72 to 24 hours. This drastic reduction of time will pose significant administrative problems. There are several important administrative steps that are necessary before notice of a benefit decision can be provided. For example, a plan must receive the claim, process it, and decide whether the claim is covered under the plan. Even the administration and determination of routine urgent care benefit claims takes time, let alone more complex and difficult benefit determinations. This requirement places significant pressure on plans and plan administrators to create and fund a 24/7 internal claim review process. The Agencies should reconsider the position adopted and maintain the current regulatory 72 hour requirement.

Eliminate Requirement to Provide Additional Considered Evidence to Claimants Prior to Benefit Determinations. PPACA requires plans to provide claimants with, free of charge, any new or additional evidence relied on or that will be considered by the plan in making the benefit

[15] 75 Fed. Reg. at 43336, 43357; 29 CFR § 2590.715-2719(d)(1).
[16] 75 Fed. Reg. at 43355; 29 CFR § 2590.715-2719(b)(i).
[17] 75 Fed. Reg. at 43333; 29 CFR § 2590.715-2719(b)(2)(ii)(B).

determination.[18] The IFR, however, expands this requirement by mandating that this information must be provided to claimants *before* the plan issues an adverse benefit determination.[19] The current ERISA claims procedure regulations provide that claimants must have access to and copies of "documents, records, and other information relevant" to their claim, but there is no requirement that this information be provided *before* a benefits decision is made.[20] There is no good policy reason to impose this requirement on plans. Moreover, this requirement will be particularly onerous when a plan has less than 24 hours to process and render a benefits determination on urgent care claims. The Association recommends that the Agencies revise the requirement that information be provided to claimants *before* an adverse benefit determination.

Broadening the Participant's Notice. The IFR provides new standards regarding providing notice to participants. These new requirements are in addition to those already required under the DOL's current 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.[21] 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.

HR Policy recommends that the Agencies reconsider the requirement mandating that plans provide diagnosis and treatment codes in the notice to claimants. Not all plans have the expertise to ensure that the proper codes are added to the notice and any mistakes would run afoul of the new strict compliance rule (discussed below). Moreover, there is simply no reason to provide such codes to claimants because they are technical identifiers for the description of services which is also required to be included on the notice.

Maintain the Substantial Compliance Rule. The IFR rejects the well-established substantial compliance rule, at least, with respect to the new additional internal claim and appeal requirements. Under this rule, 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.[22] The IFR, instead, adopts 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 or makes even a *de minimis* error.[23] 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 IFR's policy reversal will be particularly onerous given the additional new requirements and shortened deadlines. Moreover, the consequences of running afoul of the new rule —loss of

[18] PHSA § 2719; 29 CFR § 2590.715-2719(b)(2)(ii)(C)(1).

[19] 29 CFR § 2590.715-2719(b)(2)(ii)(C)(1).

[20] 29 CFR §2560.503-1(m); 29 CFR §2560.503-1(h).

[21] 75 Fed. Reg. at 43332; 29 CFR § 2590.715-2719(b)(2)(ii)(E).

[22]The DOL's most recent 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).

[23] 75 Fed. Reg. at 43356; 29 CFR § 2590.715-2719(b)(2)(ii)(F).

deference to a plan's interpretation of its own terms by federal courts— is particularly draconian. Accordingly, HR Policy requests that the Agencies retain the current and well-established substantial compliance approach.

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.[24] HR Policy questions the wisdom of choosing to revise the current 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. Assuming that the DOL will nevertheless push forward with such revisions and additions, HR Policy recommends that the Department provide effective and sufficient opportunities for comment by using an ANPRM or NPRM.

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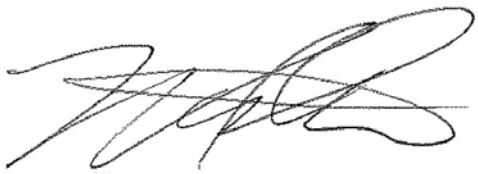
Thank you for the opportunity to comment on the IFR and for considering our suggested recommendations. If the Association can be of further assistance, please contact Michael Peterson at 202-789-8659 or mpeterson @ hrpolicy.org.

Sincerely,



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[24] 75 Fed. Reg. at 43332.