September 30, 2010

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: Interim Final Rules 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

Submitted electronically via e-mail to: E-OHPSCA2719.EBSA@dol.gov

Dear Sir or Madam:

I am writing to submit comments on behalf of the American Benefits Council ("Council") regarding the Interim Final Rules 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 ("Interim Final Rules"), which were published by the Departments of Labor, Health and Human Services, and the Treasury ("Agencies") on July 23, 2010 (75 Fed. Reg. 43,330).

The Council is a public policy organization representing principally Fortune 500 companies and other organizations that assist employers of all sizes in providing benefits to employees. Collectively, the Council's members either sponsor directly or provide services to retirement and health plans that cover more than 100 million Americans.

The Interim Final Rules implement a portion of section 1001 of the Patient Protection and Affordable Care Act ("PPACA"), which added new section 2719 to the Public Health Service Act ("PHSA"). New PHSA section 2719 requires health plans and health insurance issuers to implement an internal claims appeals process that meets specific requirements, based in large part on the current claims regulations for ERISA plans, as well as implement

a system that will provide claimants with either a State or Federal external review process. The Interim Final Rules apply to plan years beginning on or after September 23, 2010.

The Council appreciates the continued efforts of the Agencies to issue important and timely guidance with respect to PPACA generally and also with respect new PHSA section 2719. We also appreciate the issuance of clarifying guidance on August 23 in the form of Technical Release 2010-01 and again, on September 20, with respect to the issuance of "Questions regarding Affordable Care Act Implementation" and Technical Release 2010-02. Nonetheless, the Council continues to have significant concerns regarding the internal appeals and external review requirements of the Interim Final Rules and the ability of plans to implement within the short timeframes imposed by the effective date of the Rules. Our specific comments and recommendations are discussed in further detail below.

New Requirements for Internal Appeal Processes

Many of the new requirements under the Interim Final Rules for internal appeals process raise significant substantive and operational concerns for Council members, including, among others: (i) the rule imposing strict adherence on plans with respect to the new internal review requirements (ii) the requirement to include certain technical medical diagnostic codes on any notice of adverse benefit determinations or final adverse benefit determinations, such as Explanation of Benefits (EOBs); (iii) the reduction in the maximum time period for the evaluation of urgent care claims from 72 hours to 24 hours; and (iv) the new requirements regarding the provision of "linguistically appropriate" written materials.

In light of the foregoing, the Council urges the Agencies to withdraw the Interim Final Rules and for new requirements for internal appeals processes issue them in proposed form with an effective date in any final rule of no earlier than plan years beginning on or after January 1, 2012. Many of the provisions contained in the Interim Final Rules appear not to be mandated by new PHSA section 2719, but rather were incorporated into the Interim Final Rules at the discretion of the Agencies. Therefore, the Council requests that the Interim Final Rules be modified to eliminate these provisions and that such provisions be reissued as part of a proposed rule that provides for an appropriate comment period by all interested parties.

New External Review Process Requirements

Prior to the enactment of PPACA, there was no Federal requirement for ERISA group health plans to provide for external review. Although many states have established external review requirements, such requirements apply to insured health plans only. Self-insured plans, pursuant to existing section 503 of ERISA, are required to establish and maintain an internal claims and review process as set forth in Department of Labor ("DOL") regulation § 2560.503-1. While some self-insured ERISA plans may voluntarily

provide for some type of external review, it is our understanding that many self-insured ERISA plans do not provide for any external review.

Given the absence of any Federal law external review requirement, many employers who sponsor self-insured ERISA plans may have little to no experience administering an external review process. Moreover, such plans are unlikely to have in place the significant institutional framework associated with the establishment and administration of such a process. Accordingly, for purposes of complying with the Interim Final Rules, many plans will need to undertake a series of significant actions in order to establish a compliant Federal external review process (including identifying and contracting with three independent review organizations ("IROs"), unless a plan's third party administrator is willing to do so on behalf of the plan). Given that many plans are starting from "scratch" in building their external review processes, it is very likely that notwithstanding their best efforts, many plans may be unable to comply with the new Federal external review requirements for this upcoming plan year.

Under the terms of the Interim Final Rules, plans are required to satisfy the safe harbor set forth in the Interim Final Rules[1] and related Technical Release 2010-01, subject to the enforcement safe harbor as provided for in Technical Release 2010-02. The implications for plans that fail to comply with the external review process requirements for this upcoming plan year are significant. Specifically, there is a real likelihood that plans could find themselves subject to ERISA litigation. This is because, notwithstanding the enforcement safe harbor set forth in Technical Release 2010-02, the Interim Final Rules in conjunction with Technical Release 2010-01 establish a standard of compliance for plans. Regardless of whether the standard set forth in the Technical Release is characterized as a safe harbor, it represents an enumerated standard of compliance that must be met by plans. Thus, to the extent that a plan fails to comply with this standard, it could find itself subject to a costly ERISA suit both with respect to claims for benefits, and also for failure to satisfy the standard itself.

The "strict adherence" requirement in the Interim Final Rules only serves to exacerbate this problem. Under this rule, as discussed in greater detail below, a claimant is deemed to have exhausted the internal claims and appeals process to the extent that a plan fails to strictly adhere to the new requirements for internal claims and appeal processes. Given the broad scope of these new requirements (which require plans to undertake a host of actions between now and the start of the next plan year, such as prepare to provide claimants with notice of an urgent care benefit determination within no more than 24 hours or the new coding requirements for EOBs and notices), and given the limited time in which plans have to undertake these actions, it is quite possible that many plans will find themselves, despite good faith efforts, in violation of the strict adherence rule; the result being that claimants would be able to go straight to external review or litigation. Coupled with the fact that plans are unlikely to have sufficient time to establish compliant external review processes, the likely end result is that claims, which most appropriately should have been

[1] Temp. Treas. Reg. § 54.9815-2719T(d); 29 C.F.R. § 2590.715-2719(d); 45 C.F.R. § 147.136(d).

resolved at the internal review stage, find themselves in State or Federal court, where resolution thereof is often very costly relative to the dollar amount of the claim itself and far from timely.

The Council appreciates the enforcement safe harbor provided in Technical Release 2010-01 with respect to the Federal external review standard. Nonetheless, the enforcement safe harbors do not address the serious litigation risk that exists for self-insured ERISA plans by reason of the issuance of the Interim Final Rules. Moreover, for many plans the enforcement safe harbors are unlikely to be of sufficient duration. The Council understands that plans are encountering significant difficulties in connection with establishing external review processes (including with respect to contracting with a qualifying IRO) and that many plans may need up to a full plan year to implement a compliant external review process. Therefore, the Council strongly recommends that the Agencies use their authority under new PHSA section 2719(c) to deem compliant any independent and unbiased external review process used by an ERISA plan as of March 23, 2010, the date of the PPACA's enactment, and provide for important transition relief for all other ERISA plans to provide them with sufficient time to implement a compliant external review process.

Specifically, the Council requests that the Agencies use their authority under new PHSA section 2719(c)[2] and issue guidance providing that self-insured ERISA plans are deemed to have in effect a compliant Federal external review process for purposes of new PHSA section 2719 to the extent they (or their third party administrator) had a contract with an IRO in effect as of March 23, 2010 that will continue through the plan year beginning on or after September 23, 2010.

In addition, we request that the Agencies provide for important transition relief for all other ERISA plans (*i.e.*, plans without an existing contract with an IRO) to provide them with sufficient time to implement a compliant external review process. This transition relief is critical to ensure that self-insured ERISA plans are afforded sufficient time to comply with the new external review requirements. The Agencies provided similar transition relief to States with respect to the establishment of compliant State external review laws, in recognition of the fact that some States have no mandated state external review processes at all (thus they are very similar to ERISA plans that currently lack external review programs). According to the Preamble to the Interim Final Rules, "at least six States did not have external review laws when [PPACA] was enacted; therefore, issuers in those States were not required to implement an external review process".[3]

Given the critical need for transition relief from the Interim Final Rules for ERISA plans that currently lack any external review programs, and given the Agencies' willingness to

[2] Specifically, PHSA section 2719(c) provides that "[t]he Secretary may deem the external review process of a group health plan or health insurance issuer, in operation as of the date of enactment of this section, to be in compliance with the applicable process established under subsection (b), as determined appropriate by the Secretary."

[3] 75 Fed. Reg. 43339.

provide similar relief to the States, the Council requests that the Agencies issue guidance providing a transition rule for self-insured plans that did not have an external review program in place as of March 23, 2010. These plans would be required to enter into a contract with at least one IRO (or where the plan has a contract with a third party administrator that, in turn, contracts with an IRO) prior to July 11, 2011 to provide an independent, unbiased external review of eligible claims no later than plan years beginning on or after January 1, 2012.

Lastly, the Council understands that the Agencies expect to issue future guidance regarding the specific standards for the Federal external review requirement under PHSA section 2719(b)(2) and the Interim Final Rules. The Council requests that any such standards be published in proposed form (versus as interim final rules) to ensure that all interested parties are afforded a meaningful opportunity to comment prior to such standards becoming effective with respect to group health plans. These rules should be published in final form at least six months prior to an effective date which should apply no earlier than plan years beginning on or after January 1, 2012.

Recommendations for Substantive Modifications to Internal Appeals and External Review Requirements

As described above, the Council has significant concerns regarding the new requirements for internal appeals processes in the Interim Final Rules and requests that those provisions be withdrawn and reissued as a proposed rule with a public comment period. If the Agencies do not withdraw and reissue the Interim Final Rules in whole or in part, we request that the Interim Final Rules be modified consistent with the recommendations that follow.

Strict Adherence Standard

The Interim Final Rules provide that if a plan or issuer fails to strictly adhere to all the current and new regulatory requirements for internal claims and appeals processes, then the claimant will be deemed to have exhausted all internal appeals and proceed directly to external review or pursue litigation. This appears to be the case even where the participant has not otherwise been prejudiced in any way. Unlike existing regulatory requirements, this new standard applies regardless of whether the plan or issuer has substantially complied with these requirements or where any error committed was de minimis. Although the enforcement grace period included in Technical Release 2010-02 provides temporary relief from agency enforcement until July 1, 2011, we do not believe it prevents a plan participant from initiating costly external review and/or litigation without first exhausting internal appeals processes.

The new strict adherence standard is highly problematic, particularly given the substantial challenges plans face in implementing the Interim Final Rules. We believe there is a strong likelihood that the strict adherence standard will operate to allow many claimants to

essentially bypass internal appeals processes, which generally provide claimants and plans with an efficient and cost-effective means for timely resolution of disputed benefits claims. Such a rule is undesirable from a policy perspective as it will permit individuals to initiate expensive external review processes[4] or file suit in Federal court, for appeals that could most appropriately be resolved at the internal appeals level in a timely and cost-effective manner. According to the Preamble to the Interim Final Rule, a recent report found that the average cost of an external review was $605. Increased plan costs are ultimately shouldered by participants as well, in the form of higher employee contributions for coverage.

If the Interim Final Rules are not withdrawn and re-proposed, we request that the strict adherence standard be eliminated in any subsequent modified or final regulations.

Requirement to Provide Diagnostic, Treatment and Other Codes in Notices

The Interim Final Rules include new content requirements for notices to participants. These include a requirement that a plan or issuer ensure that any notice of adverse benefit determination or final adverse benefit determination include diagnosis codes (such as an ICD-9 code, ICD-10 code or DSM-IV code), the treatment code (such as a CPT code) and the corresponding meanings of these codes.

This requirement to disclose medical codes raises privacy and other concerns regarding the value of such information to participants for understanding the reasons for a benefit determination. Since the existing ERISA rules broadly define "adverse benefit determination", the result of this new requirement will be to require plans routinely to disclose detailed and highly sensitive information regarding diagnosis and treatment on Explanation of Benefits and similar notices. This new requirement raises significant privacy concerns, particularly for coverage related to mental health and substance use disorders, reproductive health, communicable diseases and other highly sensitive health conditions. These privacy concerns are further heightened where adult children to age 26 are now eligible for coverage under their parents' plans.

While the Council agrees that participants need to have information sufficient to effectively appeal an adverse benefit determination, it is not clear that this new requirement adds to that information in a meaningful way. Given these significant concerns, we recommend that disclosure of diagnostic or similar codes be required only upon request by participants. Furthermore, if mandated disclosure of such codes is retained in any final guidance, we strongly recommend that a period of public comment and consumer testing be conducted similar to that being used by the National Association of Insurance Commissioners ("NAIC") to develop a standard Explanation of Coverage as required by PPACA. Consumer testing would be particularly important for determining the understandability and value of medical code disclosure on EOBs and other notices.

[4] According to the Preamble to the Interim Final Rule, a recent report finds that the average cost of an external review was $605.

New 24-Hour Rule for Urgent Care Claims

The Interim Final Rules would decrease the maximum amount of time that a plan has to respond to an urgent care claim from 72 to 24 hours. Such a change will increase a plan's costs of reviewing claims significantly, due to the fact that claims would need to be processed seven days a week. Furthermore, the change is unnecessary as plans are already required to review urgent care claims as soon as possible, unless it is otherwise impossible to do so.

The current ERISA regulation regarding claims procedures requires a plan to inform a claimant of an urgent care benefits determination "as soon as possible…but not later than 72 hours".[5] Therefore, plans are already required to respond as quickly as possible. In other words, the plan cannot wait 72 hours or even 24 hours before informing the claimant of the plan's determination if the plan can inform the claimant sooner. Only where it is otherwise *impossible* for a plan to respond as soon as possible is a plan afforded additional time, up to a total of 72 hours, to evaluate the claim. Thus, imposing a maximum 24-hour limit is, at a minimum, wholly unnecessary and, at worst, setting up plans and issuers for noncompliance.

We agree that urgent care claims should be handled as quickly as possible. We believe, however, that the decision making timeframes in the existing ERISA claims regulations appropriately balanced participants' need for timely administration of urgent care claims with the operational realities of claims administration. In light of the foregoing, we request that the Interim Final Rules be modified to either retain the 72-hour rule provided for under existing ERISA rules, or, at a minimum, allow plans one full business day to evaluate a claim.

"Testimony" for Purposes of Internal Claims and Appeals Processes

The Interim Final Rules require that a plan or issuer allow a claimant to present "testimony as part of the internal claims and appeals process."[6] We request confirmation that a plan may require that such testimony be provided in written form, as opposed to oral testimony. If a plan or issuer were required to provide a venue for, and hold hearings to accept, oral testimony, this would significantly increase administrative cost and burden for the appeals process and ultimately the plan and participants. We believe written testimony would satisfy the statutory requirements, sufficiently protect the interests of the claimant and avoid unnecessary costs.

Provision of Notices in a "Culturally and Linguistically Appropriate" Manner

The Interim Final Rules require that notices pertaining to available internal claims and appeals and external review processes be provided in a "culturally and linguistically

[5] 29 C.F.R. §2520.503-1(f)(2)(i).
[6] Temp. Treas. Reg. § 54.9815-2719T(b)(2)(ii)(C); 29 C.F.R. § 2590.715-2719(b)(2)(ii)(C); 45 C.F.R. §147.136(b)(2)(ii)(C).

appropriate" manner. The Interim Final Rules require that notices be provided in a non-English language if a certain number of individuals are literate in the same non-English language. Specifically, the Interim Final Rules provide that:

- If a group health plan covers fewer than 100 participants at the beginning of a plan year, assistance is required if 25 percent or more of all plan participants are literate only in the same non-English language.

- If a group health plan covers 100 or more participants at the beginning of a plan year, assistance is required if the lesser or 500 or more participants, or 10 percent or more of all plan participants, are literate only in the same non-English language.

- If coverage is provided in the individual insurance market, assistance is required if 10 percent or more of the population residing in the claimant's county are literate only in the same non-English language.

To the extent that any of the preceding thresholds are met, a plan must: (i) include a statement in the English version of all notices, prominently displayed in the non-English language, offering the provision of such notices in the non-English language; (ii) if a request is made by a claimant, provide all subsequent notices in the same non-English language; and (iii) ensure that customer assistance processes provide assistance in the appropriate non-English language.

The thresholds used for purposes of the Interim Final Rules are those that currently apply under ERISA with respect to Summary Plan Descriptions ("SPDs") for group health plans. Significantly, however, the Interim Final Rules require plans to provide, upon request, written notices in the non-English language of the individual who makes such a request. The requirement that plans translate written notices into one or more non-English languages represents a significant deviation from existing ERISA rules, which do not require that notices be provided in languages other than English. The ERISA regulations for SPDs expressly state that any assistance provided "need not involve written materials".[7] The regulations provide only that the requisite assistance must be (i) provided in the non-English language common to participants, and (ii) calculated to provide them with a reasonable opportunity to become informed as to their rights and obligations under the plan.

Requiring that plans translate each notice of an adverse benefit determination or appeal into another language will be administratively burdensome. In contrast, plans and issuers are familiar with the current ERISA rules and have established systems in place to comply with such rules. We believe the existing rules under ERISA are sufficient to ensure that all participants have appropriate access to essential information with respect to their claims and appeals rights and obligations under ERISA. For these reasons, we request that the Interim Final Rules be modified to adopt the ERISA standards set forth in the DOL

[7] 29 C.F.R §2520.102-2(c).

regulations previously cited for purposes of providing notices in a "culturally and linguistically appropriate" manner.

External Review Requirements Related to Independent Review Organizations (IROs)

As discussed above, the Interim Final Rules require that if a plan or issuer is not subject to an applicable State external review process, such plan or issuer must comply with a Federal external review process. The Agencies subsequently established an interim enforcement safe harbor and guidance for self-insured group health plans as set out in Technical Release 2010-01.

One of the requirements of Technical Release 2010-01, is that a plan or issuer must use the services of an IRO to conduct the external review. The plan or issuer must contract with at least three IROs for such purpose under the plan. We believe this requirement is unnecessarily burdensome, given that the IROs are required to be accredited by the Utilization Review Accreditation Commission ("URAC") or a similar nationally-recognized accrediting organization and such accreditation standards assure that the IROs are free from conflict of interest. Given such accreditation, it is unclear how contracting with three IROs would increase the degree of independence with which a claim is reviewed. In fact, the duplication of negotiating, contracting, and coordinating all of the requirements in the safe harbor with three different IROs will substantially add to the time and costs associated with complying with the new Federal external review requirement.

Another issue related to IROs is whether such organizations will be considered fiduciaries for purposes of ERISA. Under current ERISA rules, a plan fiduciary is determined through a functional test and encompasses those entities that "exercise[] any authority or control respecting management or disposition of [the plan's] assets".[8] Given that any decision made by an IRO with respect to an external appeal must be binding on the plan[9], questions arise as to whether the benefits decision causes the IRO to become a plan fiduciary, regardless of whether the IRO wants and/or contractually assents to assume ERISA fiduciary status. Given the importance of this issue to plan sponsors and other involved parties, the Council recommends that the Agencies provide opportunity for additional public comment prior to issuing any final regulations.

External Review Should Not Be Applied to Coverage Determinations

If a plan is not located in a State that requires an external review process that meets minimum standards, or if the plan is self-funded, the plan must implement a Federal external review process enumerated in the Interim Final Rules and elaborated upon in Technical Release 2010-01. The Interim Final Rules require external review not only for denials based on medical necessity, experimental or investigational treatments, or

[8] ERISA §3(21)(A).
[9] Temp. Treas. Reg. § 54.9815-2719T(d)(2)(iv); 29 C.F.R. § 2590.715-2719(d)(2)(iv); 45 C.F.R. §147.136(d)(2)(iv), Technical Release 2010-01, page 6.

appropriateness of care or settings of care ("medical review denials"), but also any claims regarding whether a service is covered under the terms of the plan.

For example, if a plan provides for no more than 20 visits with regards to a non-essential benefit and a participant files a claim with respect to a 21st visit, under previous law this claim would be subject to internal review, but not any additional appeals process. Under the Interim Final Rules, however, it appears that this claim is subject to external review.

As the foregoing example illustrates, expanding the scope of claims subject to external appeal to include coverage determinations that are best suited for resolution at the plan level is completely unnecessary and likely will serve only into increase plan costs and administrative burdens. We therefore request that the Interim Final Rules be amended to clarify that coverage determinations not be subject to external review.

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Thank you for the opportunity to comment on the Interim Final Regulations and for considering our recommendations. Please contact me at 202-289-6700 with any questions or if we can be of further assistance.

Sincerely,

Kathryn Wilber
Senior Counsel, Health Policy
American Benefits Council