July 25, 2011

Submitted electronically via http://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: Amendment to 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

Dear Sir or Madam:

We are writing to provide comments on behalf of the American Benefits Council ("Council") regarding the Amendment to 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 ("Amendment" or, taken together with the original interim final rules on this issue, "Amended Interim Final Rules"), which were published by the Departments of Labor, Health and Human Services, and the Treasury ("Agencies") on June 24, 2011 (76 Fed. Reg. 37,208).

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 health and retirement plans that cover more than 100 million Americans.

We appreciate the helpful guidance provided to date by the Agencies with respect to the internal claims and appeals and external review requirements under section 2719 of the Public Health Service Act ("PHSA"), which was added by section 1001 of the Patient
Protection and Affordable Care Act ("PPACA"). We also appreciate the continued efforts of the Agencies to issue important and timely guidance with respect to PPACA generally. Nonetheless, the Council continues to have concerns regarding the internal appeals and external review requirements of the Amended Interim Final Rules and the ability of plans to effectively implement the requirements of the Amended Interim Final Rules.

We appreciate the opportunity to provide comments in connection with the Amendment, and we hope that our comments and recommendations, set forth below, will assist the Agencies in formulating future guidance.

AMENDMENT TO THE INTERIM FINAL RULES

The Amendment addresses numerous concerns raised by employers and plan administrators, particularly related to the timing and likely burdens that would have been imposed by the earlier rules. We appreciate the Agencies’ willingness to consider these views and make several needed improvements.

However, the Council continues to be concerned that many of the provisions contained in the Amended Interim Final Rules appear not to be mandated by PHSA section 2719, but rather were incorporated into the Amended Interim Final Rules at the discretion of the Agencies. Although the Council believes that improvements have been made in the Amended Interim Final Rules to address concerns raised by employers and other interested parties with respect to the original interim final rules, we feel it would be very important, if the Amended Interim Final Rules are further modified in any material manner, that such modifications be made prospectively only and with a sufficient amount of time to implement on a future-plan-year basis, and that employers and all other interested parties be given an opportunity for further comment regarding such modifications.

The Council directs the Agencies to our comments below on the Amended Interim Final Rules. The Council’s comments address those areas which we believe are important to retain in the final internal claims and appeals and external review rules and identifies areas where we recommend that further improvements may be made.

URGENT CARE CLAIMS

The Amendment permits plans to follow the decision-making timeframes in the existing ERISA claims regulations, meaning that decision-making in the context of pre-service urgent care claims must be done as soon as possible consistent with the medical exigencies

References throughout this letter to “plans” should be read to include both group health plans and health insurance issued to group health plans, as appropriate.
involved but in no event later than 72 hours. Furthermore, plans must defer to the attending provider with respect to the decision as to whether a claim constitutes “urgent care.”

We support the approach taken in the Amendment with respect to urgent care claims. We believe that the decision-making timeframes in the existing ERISA claims regulations have appropriately balanced participants’ need for timely administration of urgent care claims with the operational realities of claims administration, particularly considering that the 72-hour review period is an outside timeframe and that speedier review is still required based on medical exigencies. Furthermore, our understanding of current practices is that they have worked well and reflect an appropriate balance between a timeframe which is both administratively workable and which meets the needs of plan participants whose claims may require expedited review due to their particular medical condition.

The Council also believes that deference to the attending provider as to whether a claim constitutes “urgent care” is generally appropriate. We do believe, however, that a very narrow exception to this deference should be created, to encompass situations where a plan has reason to believe that the attending provider’s classification of the claim is willfully or negligently inaccurate (i.e., where a plan has evidence of a consistent pattern of misclassification of claims by a specific provider). We believe that plans should not be compelled to defer to attending providers if the plan has reason to believe that such deference is unwarranted.

We commend the Agencies on the steps taken to date to modify these urgent-care rules, and we believe that, with the small changes discussed above, the final rules on this matter should largely reflect those stated in the Amended Interim Final Rules.

**Diagnosis and Treatment Codes**

The Amendment changes the requirement in the original interim final rules that all notices of adverse benefit determination and final internal adverse benefit determination must include the diagnosis and treatment codes and their corresponding meanings. Under the Amendment, such notices are not required to automatically include such codes and their corresponding meanings, but must now include a statement that this information is available upon request. If requested, this information must be provided as soon as practicable, and plans may not treat a request for this information, by itself, as a request for an internal appeal or external review.

The routine inclusion, as required by the original interim final rules, of diagnostic and treatment code information on notices of adverse benefit determinations raised several serious administrative, cost and individual privacy concerns. The Council believes that the approach taken in the Amended Interim Final Rules strikes an appropriate balance by making such information available upon request. We believe that the Amended Interim Final Rule will provide this information to those individuals who may seek it in
appropriate circumstances without the unnecessary additional burdens and privacy concerns raised by the original interim final rule on this matter. We urge that the final rule maintain this approach.

**Strict Adherence Standard**

The Amendment provides an exception to the requirement, as stated in the original interim final rule, that allowed claimants to bypass the internal appeals process and go directly to external review or to pursue legal remedies if the health insurance plan did not “strictly adhere” with the standards described in the interim final rule. Under this exception, the “strict adherence” standard will not apply (and thus claimants must first exhaust the internal appeals process) for errors that are minor and that meet a five-part test, under which the violation of the rule by the plan (1) was *de minimis*, (2) was non-prejudicial to the claimant’s right to external review, (3) was attributable to good cause or matters beyond the plan’s or issuer’s control, (4) is not reflective of a pattern or practice of non-compliance by the plan, and (5) was in the context of an ongoing good-faith exchange of information. The Amendment further provides that a claimant may make a written request for an explanation of the plan’s assertion that it meets the *de minimis* exception to the strict adherence standards. Finally, the Amendment provides that if an external reviewer or a court rejects a claimant’s request for immediate review on the basis that the plan has met this exception, the claimant has the right to resubmit and pursue the internal appeal of the claim.

Overall, the Council welcomes the modification of the strict adherence standard in the Amendment. The original rule would have established an unrealistic standard of administrative perfection by permitting claims to be “deemed denied” and moved to external or judicial review if a plan or insurer did not strictly meet the claims-review standards, regardless of how *de minimis* the omission by the plan may have been and even if the claimant was not harmed in any way by the administrative error. The addition under the Amendment of an exception to this strict-adherence standard is appropriate, but the Council notes that this exception itself may prove to be of limited effectiveness, given that it is an inclusive test and therefore all five parts of the test must be met in order for the exception to apply.

By making this exception subject to an inclusive five-part test, the exception is, in fact, open to attacks at each step along the way. As a result, plans may be hesitant to attempt to utilize this exception for truly insubstantial, non-prejudicial errors for fear that some later reviewer may find fault with one or more individual elements of this test. A failure by plans to effectively utilize this exception would 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 result is undesirable from a policy perspective as it will permit individuals to initiate expensive external review processes 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. Increased plan costs are ultimately shouldered by participants as well, in the form of higher employee contributions for coverage. As a result, the Council urges the Agencies to provide, in the final rule as well as in any appropriate interim relief, that this exception will be judged on the totality of the circumstances, with the listed factors each being important, but with no single factor being dispositive. Such flexibility in the application of this exception would provide a greater degree of certainty to plans to judge which claims truly meet this exception.

Furthermore, as noted above, the Amendment allows for a claimant to request a written explanation of both any perceived violation by the plan and the plan’s assertion that it meets the *de minimis* exception to the strict adherence standard. Currently, the Amendment provides that a written response to such requests must be provided within 10 days. The Council believes that this time frame for reply is unrealistic, administratively burdensome and expensive and that such an expedited time frame will provide no real benefit to the participants involved. The Council believes that this time frame should be revised, both in the final rule and in any appropriate interim relief, to provide for at least a 30 day reply period.

Finally, as noted above, the Amendment currently provides that if an external reviewer or a court rejects a claimant’s request for immediate review on the basis that the plan has met this exception, the claimant has the right to resubmit and pursue the internal appeal of the claim. The Amendment provides that the plan shall provide to the claimant notice of the opportunity to resubmit and pursue the internal appeal of the claim within a reasonable period of time, not to exceed 10 days, after the court or external reviewer rejects the claim for immediate review. The Council notes that there are several problems with this approach. First, a maximum period of 10 days for providing any notice is unreasonably short, especially considering delays that may occur in the transmission of the results of any such court or external review (which may be handled by counsel for the plan, not claims personnel for the plan) to the appropriate claims or appeals personnel for the plan.

The Council believes that a notice of the right to re-submit a claim, given early on in the claims process (such as in any initial claims notice, or at the time of a determination that the violation meets the strict-adherence exception discussed above), would be more appropriate in this circumstance. Requiring the plan to provide, on an unrealistically tight time-frame, notice of the right to resubmit a claim quite simply invites a further “violation” that would then allow the claimant to immediately return to external review and/or court, i.e., although the original “violation” may have fallen within the exception to the strict-adherence standard, a failure by the plan to provide within 10 days the notice of right to resubmit could itself prove to be a “violation” that falls outside of the exception to the strict-adherence standard. Whereas the Amendment appears to create this “trap for the unwary,” the Council believes that a single notice, given earlier in the claims process, would effectively notify claimants of their rights in this situation without causing needless administrative burdens.
Second, the Amendment is unclear regarding the filing deadlines for any claim that is “resubmitted”, stating only that “[t]ime periods for re-filing the claim shall begin to run upon claimant’s receipt of” the notice discussed in the previous paragraph. However, the statutes of limitations for court challenges of claims denials can stretch on for many years, leaving open the possibility that a claimant could challenge a claim denial under the “strict adherence” standard well past the expiration of the applicable internal appeals filing deadlines, receive a court determination that the plan properly applied the exception to the “strict adherence” standard, and then be allowed to “re-start” their internal appeals process. In effect, such “strict adherence” challenges could allow participants to do an “end run” around the existing deadlines for internal claims and appeals. The Council recommends that this rule be clarified, in the final rules as well as in any appropriate interim relief, to make clear that claimants will be provided for any re-submitted claim only such time as might be remaining in any internal claims or appeals deadline (perhaps with a minimum “floor” of 10 days provided in any applicable case), and that any claimant who has surpassed all such applicable internal claims and appeals time frames at the time of the filing of the external review or court challenge will be deemed to have exceeded such time frames immediately upon the start of any “re-submission” period. In essence, the Council believes that the internal claims and appeals “clock” should be frozen where a claimant seeks immediate outside review of a claim under the “strict adherence” standard, meaning that the claimant would not be rewarded for dilatory behavior in seeking such review.

**Culturally and Linguistically Appropriate Notices**

The Amendment changes the provisions in the original interim final rule that required plans to translate notices into languages other than English (i.e., provide such notices in a culturally and linguistically appropriate manner). The Amendment provides that plans can now meet this requirement if they offer language assistance services, translation of notices (upon request), and statements on notices of the availability of language assistance in any “applicable non-English language.” An “applicable non-English language” is defined by reference to the county of residence of the claimant; if English is not spoken (or not spoken well) by 10 percent or more of those individuals (who are literate in the same non-English language) residing in that county, that language will qualify as an “applicable non-English language.” The Amendment also clarifies that language assistance may be provided to these individuals through oral language services, such as a telephone language assistance hotline.

The Council believes that these changes are significant improvements over the original interim final rule, by relieving plans of the burden of determining all of the possible language needs of the plan participants and routinely providing written notices in each of these non-English languages. We urge that the approach taken in the Amendment be maintained in the final rules so that plans can proceed with implementing these changes without concern that the thresholds will be further modified or that the rule will otherwise be broadened. We believe that this approach is a responsible and reasonable interpretation.
of the statutory requirements and that a broader rule (such as through the establishment of a lower threshold for non-English speaking populations or the availability of language assistance services in any language on request) should only be considered after the implementation and further evaluation of the approach included in the Amendment so that experience can first be gained utilizing this approach and so that plans that do not currently provide such services can first meet a realistic and achievable standard.

**EXTERNAL REVIEW**

*Generally.* Prior to the enactment of PPACA, there was no Federal requirement for ERISA group health plans to provide for external review; existing state external-review requirements applied 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 § 3560.503-1. Given the absence of any Federal-law external-review requirement, many employers who sponsor self-insured ERISA plans have little to no experience administering an external-review process, and have had to start from “scratch” in building their external review processes. It is very likely that notwithstanding their best efforts, many plans may be unable to fully comply with the new Federal external review requirements (either those set out in the Amended Interim Final Rules and its accompanying subregulatory guidance or the federal external review process administered by HHS through an agreement with the Office of Personnel Management) by January 1, 2012. Although the Agencies have provided some interim relief with respect to the implementation and effective dates of this external review, the Council believes that further relief is needed, as explained below.

**Scope of Claims Eligible for External Review.** The Amendment suspends the original interim final rules’ provisions regarding the scope of adverse benefit decisions that may be submitted for external review, and temporarily replaces it with a different scope. The original interim final rule specified that all adverse benefit determination (including rescissions), except for denials based on the claimant’s eligibility to participate in the plan, were subject to external review. Under the Amendment, external review is applicable both for decisions involving a rescission of coverage and for decisions involving medical judgment (excluding decisions that involve only contractual or legal interpretation without any use of medical judgment), including (but not limited to) determinations based on the plan’s requirements for medical necessity, appropriateness, health care setting, the frequency, method, treatment or setting for a recommended preventive service, and

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2 We note that, notwithstanding the enforcement safe harbors established under Technical Releases 2010-01 and 2010-02, plans still face a real likelihood of being subject to ERISA litigation, because these Technical Releases establish a standard of compliance that must be met by plans, and the relief accorded by these Technical Releases extends only to enforcement action by the Agencies, not to any private rights of action. To the extent that a plan fails to comply with the compliance standard as detailed in Technical Releases 2010-01 and 2010-02, a plan 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.
whether a plan is complying with the non-quantitative treatment limitation provisions of the Mental Health Parity and Addiction Equity Act and its implementing regulations. Per the guidance, this more limited scope of review for self-funded group health plans is only effective for claims for which external review has not been initiated before September 20, 2011. The Amendment’s preamble notes that this suspension is expected to be lifted by January 1, 2014.

The Council strongly urges that the final rules maintain a standard that limits claims eligible for external review to claims involving an exercise of medical judgment, not matters where the issue involved is the interpretation of plan terms or an issue of legal interpretation. Not only is this the standard in nearly all cases where states have established external review procedures for insured plans, it also makes practical sense. The resources of Independent Review Organizations (“IROs”) should focus on issues related to reviewing the application of appropriate medical judgment in making coverage determinations, not matters solely determined by plan terms where no medical judgment is involved.

The Council also believes that IRO resources should be focused on claims determinations, not matters that appear to be wholly ancillary to the claims process, such as (as is currently allowed under the Amendment) whether individuals were afforded a “reasonable alternative” program or activity in order to obtain a reward under a wellness program or matters related to the plan or insurer’s compliance with mental health parity requirements. We note that the entire external-review process is predicated upon a claim for benefits that arise through the ERISA claims procedure regime. As such, although the relevant claim must involve “medical judgment” in order to be eligible for external review, the Council believes that an IRO’s authority must be predicated on a fairly simple principle – that there be an actual claim for benefits in the first instance based on the written plan document. The Amendment would stray from this elementary principle by allowing IROs in several instances to make decisions about whether certain benefits are owed to individuals notwithstanding that the plan document itself does not as a matter of contract provide for such benefits. For example, IROs are free to make determinations regarding the complex area of non-quantitative treatment limitations under the mental health parity regulations, an area already rife with confusion and inconsistent application of rules. This represents a very significant and, in our opinion, dangerous departure from the long-standing and well-settled rule that a claim for benefits must be rooted in the plan document itself.

To put an IRO in the role of essentially making legal interpretations with respect to a specific plan is beyond the well-settled role of an IRO as a claims reviewer. Doing so raises a host of related issues, such as the effect of an IRO’s decision where it is inconsistent and/or in conflict with existing federal regulations or other IRO interpretations with respect to the same plan. Allowing this much-expanded role for IROs would unnecessarily muddy the waters of already confusing areas of legal interpretation. Moreover, expanding the scope of matters subject to external review to include both “medical judgment” issues and “mixed” questions of medical judgment and legal judgment is unnecessary and likely will serve only to increase plan costs and administrative burdens. Lastly, to the extent that
relevant agencies are of the view that existing legal remedies are insufficient with respect to existing federal laws, this is a matter for Congress and should not be addressed in the form of an overly broad “claims” review rule. Accordingly, the Council urges the Agencies to alter the final rule, and provide any appropriate interim relief, to make clear that external reviews are limited to review of claims for benefits arising through the existing claims and appeals procedures, and that review of legal and/or plan interpretation issues is outside the scope of the IRO’s review.

**Inclusion of Preventive-Care Coverage Among Scope of Matters Eligible for External Review.** As mentioned above, the Amendment specifically provides that, among the situations that will be found to involve “medical judgment” and thus be eligible for external review are “[t]he frequency, method, treatment, or setting for a recommended preventive service, to the extent not specified.” The Council notes that this flies in the face of the availability of the use of reasonable medical management techniques to determine any coverage limitations, as permitted under the interim final regulations related to coverage of preventive services under PPACA. Whereas the preventive-care interim final rules permit plans to use such medical management techniques where permissible, the Amendment appears to limit the effectiveness of such medical management, by allowing IROs to second-guess any such decisions reached by a plan. The Council urges the Agencies to clarify that any external review of such preventive care choices will not subject the medical-management decisions of the plan to such varied (and potentially inconsistent) external review.

**“Suspension” of Original Interim Final Rules.** As noted above, the Amendment provides that the scope of claims subject to external review, as described in the original interim final rules, will be “suspended” and temporarily replaced with the more limited scope discussed in the Amendment, with this more limited scope of review for self-funded group health plans only effective for claims for which external review has not been initiated before September 20, 2011. The Amendment’s preamble notes that this suspension is expected to be lifted by January 1, 2014. The Council is encouraged by the limitations in the scope of external review as presented in the Amendment, but urges the Agencies to lift this suspension (subject, of course, to appropriate modifications in the interim to this scope-of-review language under this suspension provision) only upon the implementation of final rules that limit the scope of external review to claims involving an exercise of medical judgment, as recommended above.

**Rescissions.** As noted above, the Amendment includes rescissions of coverage among the scope of issues that are reviewable by IROs. The original interim final rule provided that external review would apply to any adverse benefit determination, but noted that any adverse benefit determination (which appears to include a denial, reduction, termination, or a failure to provide payment for a benefit) which is based on a determination that

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1 75 Fed. Reg. 41,726 (July 19, 2010).
someone fails to meet the requirements for eligibility under the terms the plan is not eligible for such external review.

The Council notes that the original interim final rule is reasonably read as exempting nearly all rescissions from external review, because nearly all rescissions would involve a determination regarding an individual’s eligibility for coverage. Although rescissions are generally included among the categories of decisions that are eligible for external review, this must be read in concert with the rule noted above, which makes clear that eligibility-related determinations are not within the scope of external review. Hence, the Council believes that, based on well-established canons of construction, many (if not most) rescissions would be exempted from external review based upon the original interim final rule.

The Amendment first retains the original rule in the regulations, but then temporarily suspends the application of the original rule in favor of what is described in the preamble to the Amendment as a "narrower" rule. This "narrower" rule, in turn, states that external review applies to, inter alia, "[a] rescission of coverage (whether or not the rescission has any effect on any particular benefit at that time)." As noted above, this “narrower” rule will apply for claims for which external review has not been initiated before September 20, 2011, and will no longer apply upon the lifting of this “suspension” (which the preamble notes is expected to occur by January 1, 2014). Upon the lifting of this “suspension,” the original interim final rule will apparently take effect again. The policy justifications for this initial suspension extend beyond the close of the 2013 calendar year. Additionally, the timing construct set forth in the Amendment means that plans will be subject to an array of rules with regard to potential external review of rescissions, with many such rescissions falling outside the scope of external review before September 20, 2011, then falling within the scope of such review until approximately January 1, 2014, at which point they will again fall outside the scope of such review. Such a construct obviously leads to increased expense and administrative burden as well as confusion by participants regarding their rights as to external review. As a result, the Council urges the Agencies to make clear, in both final rules and interim guidance, that external review of rescissions is subject to the guidelines laid out in the original interim final regulations, including the exception for eligibility determinations.

Self-Funded Plans Contracting with Three IROs by July 1, 2012. Under the technical guidance released by HHS and DOL in conjunction with the Amendment (Technical Release 2011-02 for both agencies), self-funded group health plans (other than non-Federal governmental plans) are provided additional time to contract with IROs to handle external

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1 See, e.g., Negonsott v. Samuels, 507 U.S. 99 (1993) (a court must, if possible, give effect to every clause and word of a statute); Morales v. Trans World Airlines, Inc., 504 U.S. 374 (1992) (it is a commonplace of statutory construction that the specific governs the general); General Motors Acceptance Corp. v. Whisman, 387 F.2d 774 (5th Cir. 1968). Although these canons of construction make reference to statutory construction, such canons are frequently applied in the context of regulatory construction and there is no reason why they should not be applied in this context.
review, with such plans being required to contract with at least two IROs by January 1, 2012, and with at least three IROs by July 1, 2012. In addition, plans are required to rotate assignments among the IROs on a random basis.

The Council continues to have concerns about the ability or necessity for self-insured plans to satisfy the requirement under the Amended Interim Final Rules to contract with three IROs by July 1, 2012. 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 for such external review with three different IROs will substantially add to the time and costs associated with complying with the new Federal external review requirement.

The Council recommends that a safe harbor be established to provide that plans will be deemed to comply with the retention-of-IROs requirements so long as these plans contact with at least two IROs and claims are randomly assigned between these entities. We see no additional advantage to contracting with three or more IROs in order to safeguard against bias in decision-making. We recommend that the agencies also conduct an evaluation of the outcome of decisions made under a two-IRO safe harbor rule (where claims are assigned randomly) and determine whether these determinations vary in a material way from those made when plans or insurers have contracted with three or more IROs and claims are assigned randomly. A change in the safe harbor rule should only be considered if there is evidence of a material difference in the outcome of IRO determinations when plans or insurers contract with more than two IROs. We also urge that the final rules clarify that a self-insured plan may meet these requirements through the contracts established by its third-party administrator and any IROs retained by the third-party administrator.

Finally, the Council urges the Agencies to address whether IROs 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.” Given that any decision made by an IRO with respect to an external appeal must be binding on the plan, 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 seek additional public comment on this issue prior to issuing any final regulations or other guidance.

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5 ERISA § 3(21)(A).
Thank you for the opportunity to comment on the Amendment and for considering our recommendations. We look forward to working with you on these important issues. If you have any questions or would like to discuss these comments further, please contact the undersigned at (202) 289-6700.

Sincerely,

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Senior Vice President,  
Health Care Reform

Kathryn Wilber  
Senior Counsel,  
Health Policy