July 25, 2011

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

Secretary Kathleen Sebelius
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Secretary Timothy Geithner
U.S. Department of Treasury
Internal Revenue Service
P.O. Box 7604 Ben Franklin Station
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Submitted via the Federal Regulations Web Portal, http://www.regulations.gov

Re: Comments on the Amendment to the Interim Final Rule Relating to Internal Claims and Appeals and External Review Processes Under the Patient Protection and Affordable Care Act

Dear Secretaries Solis, Sebelius, and Geithner:

Aetna appreciates the opportunity to comment on the Amendment of 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 and Affordable Care Act ("ACA") (the "IFR" or the "Regulation"), issued by the Departments of Labor ("DOL"), Health and Human Services ("HHS"), and Treasury (collectively, the "Agencies"). 76 Fed. Reg. 37208 (June 24, 2011).

Aetna is one of the nation's leading diversified health care benefits companies, providing members with information and resources to help them make better informed decisions about their health care. Our programs and services strive to improve the quality of health care while controlling rising employee benefits costs. Aetna offers a broad

range of traditional and consumer-directed health insurance products and related services, including medical, pharmacy, dental, behavioral health, group life, long-term care and disability plans and medical management capabilities.

As a key stakeholder, Aetna is committed to working with the Agencies in developing reasonable standards for the implementation of the ACA. For that reason, we submitted detailed comments to the Agencies during the IFR's public comment period. We appreciate that the Agencies have adopted many of the recommendations we offered, and we believe that the Amendment to the IFR will benefit consumers and stakeholders by simplifying the IFR and by adopting standards that are more easily administrable. For example, the Amendment eliminates the requirement that diagnosis and treatment codes (and their meanings) be automatically disclosed on any notice of adverse benefit determination, and thereby preserves important privacy protections for participants and their dependents.

Additionally, the Amendment modifies the standard for issuing notices in a non-English language, making it easier for participants to obtain meaningful assistance concerning a denied claim, and standardizing the threshold for plan sponsors as to when such notices must be issued. We also appreciate that the Agencies have requested comments regarding the Amendment itself, and in response, we submit the following comments:

1. The Amendment's Standard Regarding *De Minimis* Violations that Will Not Trigger "Deemed Exhaustion" Should Be Modified

We applaud the Agencies for modifying the "strict adherence" standard set forth in the IFR, which provided that *any* violation of *any* standard set forth in the IFR – even if minor and non-prejudicial – would result in the "deemed denial" of an internal appeal, thus allowing a claimant to immediately pursue either external or judicial review of the claim denial. *See* 29 C.F.R. § 2590.715-2719(b)(2)(F); 45 CFR § 147.136(b)(2)(F); 26 CFR §54-9815-2719T(b)(2)(F). By adopting the Amendment, the Agencies have helpfully modified the IFR's strict adherence standard. Specifically, under the Amendment, a violation of the IFR's rules will not trigger deemed exhaustion if the violation is:

- *De minimis*;
- Non-prejudicial;
- Attributable to good cause or matters beyond the insurer or plan's control;
- In the context of an ongoing, good faith exchange of information between the claimant and the insurer or the plan; *and*
- Not reflective of a pattern or practice of non-compliance by the insurer or plan.

The Amendment also provides that a claimant may request a written explantation of the violation from the insurer or the plan, and that such an explantation must be provided within 10 days, including a statement as to why the violation should not cause the internal appeals process to be deemed exhausted. The Amendment further provides that if an external reviewer or court rejects a claimant's request for immediate review on

the basis that the error was *de minimis*, the claimant has the right to resubmit his or her appeal to the plan. In such circumstances, the insurer or plan must notify the claimant of his or right to resubmit the appeal within 10 days after the external reviewer or court rejects the claimant's attempt at immediate external or judicial review – and the time period for refiling the appeal begins to run upon the claimant's receipt of such notice.

The Amendment's modifications to the strict adherence standard are helpful in allieviating the concerns expressed by many stakeholders regarding this aspect of the IFR. We are concerned, however, that the Amendment's *de minimis* standard is still too restrictive. For example, the Amendment's requirement that an appeal processing error be attributable to "good cause" or a "matter beyond the plan's control" is too narrow, and arguably would preclude many routine processing errors caused by simple human mistake – no matter how minor or non-prejudicial – from avoiding deemed exhaustion. Indeed, the Amendment gives no guidance as to what constitutes "good cause" or a "matter beyond a plan's control," and does not provide guidance as to the level of deference that an external review organization or court – which lack knowledge of a plan or insurer's claims processing practices – should afford to the plan or insurer's explanation of the error.

Likewise, the narrowness of the Amendment's current deemed exhaustion language will very likely have the unfortunate and unintended result of further delaying resolution of a claimant's appeal. The reason for this is that the proposed standard creates an incentive for wide-ranging and expansive legal discovery requests concerning matters wholly unrelated to the consumer's appeal, as well as far out of proportion to the significance of the processing error at issue.

For example, plaintiffs' attorneys, in an effort to explore the possibility of a pattern of non-compliance, will have nearly unrestrained free reign to demand that plans produce voluminous documents concerning, among other things: (i) unrelated internal audits of a plan's claims and appeals processing units; (ii) the number – and nature – of other processing errors that may have occured in connection with the processing of unrelated claims appeals; and (iii) other unrelated claim denials for which other claimants sought immediate external or judicial review.

Thus, given that the Amendment's deemed exhaustion standard would unquestionably delay resolution of a claimant's appeal by entangling claimants and plans in unnecessary litigation concerning matters irrelevant to the claim at issue, we urge that the Agencies adopt a standard similar to its previously issued guidance, which held that inadvertant deviations from a plan's appeal processing procedures will not trigger exhaustion of the internal appeals process.

Finally, we note that adoption of such a standard will not harm claimants, given that non-prejudical deviations can be resolved quickly through the plan's internal appeals process, while prejudical errors would still be subject to the deemed exhaustion standard, thus ensuring claimants an opportunity for a full and fair review of an adverse benefit denial.

Recommendation: The Amendment should be revised to provide that inadvertant deviations from a plan's appeal processing procedures that do not harm claimants and which can be meaningfully corrected through internal plan procedures will not cause exhaustion of the plan's internal appeals process – in a manner consistent with the DOL's previously issued view that an inadvertant deviation from a plan's procedures will not trigger deemed exhaustion. See DOL FAQ About the Benefit Claims Procedure Regulation, FAQ F-2, available at http://www.dol.gov/ebsa/faqs/faq_claims_proc_reg.html. Such a standard will much more effectively ensure that claimants are able to have their claims resolved quickly at the administrative level, while simultaneously protecting claimants from errors that are prejudicial.

With respect to a plan or insurer's obligation to notify a claimant of his or right to resubmit an appeal for internal adjudication following an external reviewer or court's denial of a request for immediate external or judicial review, the Amendment provides that the claimant's time for re-filing the appeal begins to run upon his or her "receipt" of such notice. Plans and insurers generally have no way to know when a claimant "receives" a notice, and it is not difficult to imagine situations where claimants will either deny receiving notice, or assert that such notice was received long after it had been mailed by the plan or insurer. We therefore recommend modifying the Amendment to provide that the time period for refiling an appeal begins to run 10 days after the date on which the plan or insurer's notice was mailed. This will afford certainty to plans and claimants as to the date on which the re-filing deadline begins to run.

We also recommend that the Agencies modify the Amendment to provide that any appeal must be re-filed within the timeframe set forth in the plan or policy for the filing of an internal appeal. Such a modification will provide an incentive for claimants to resubmit appeals for internal review quickly, and help minimize the risk that plans and insurers will be forced to adjudicate appeals submitted outside the time frames set forth in their governing plan documents, which are programmed into their claims adjudication systems.

2. The Scope of the Federal External Review Process Should Be Permanently Focused Upon "Medical Judgment" Claims, and Plans Should Determine Whether an Adverse Benefit Determination Involves a Medical Judgment

The IFR established a minimum standard for the Federal external review process that would have allowed virtually all adverse benefit determinations (other than those involving eligibility for group plans) to be subject to external review. *See* 29 C.F.R. § 2590.715-2719(c)(2) (establishing minimum standards for claims subject to State external review) and DOL Technical Release 2010-01 (establishing enforcement safe-harbor for the Federal external review process, requiring that any adverse benefit determination (other than those involving eligibility) be subject to external review).

We appreciate that the Amendment temporarily "suspends" this rule, and instead provides that only claim denials involving medical judgment and rescissions will be

subject to external review during the suspension period. This suspension period will help ensure that claim denials involving non-medical interpretations of plan documents – such as the meaning of a plan's exclusionary or cost-sharing provisions – will not be subject to external review, which should ease the demands placed upon independent review organizations ("IROs"), and will ensure consistency of interpretations within a plan.

We recommend, however, that the scope of the Federal external review process be permanently focused upon medical judgment claims, rather than just "suspended." Indeed, we submit that there is no reason why the scope of the Federal external review process should be broader than the minimum standards for the State external review process that is generally applicable to insurers and non-ERISA plans. We therefore encourage the Agencies to modify the Amendment to provide that the scope of the Federal external review process shall be no broader than the scope of claims subject to the NAIC's Uniform External Review Model Act. Additionally, to avoid any confusion for claimants as to the type of adverse benefit determinations eligible for external review, we recommend that the Agencies expressly clarify that benefit denials that are based on a plan's exclusionary provisions are not subject to external review.

Some of the Examples in the Amendment indicate that the Agencies intend to interpret the phrase "medical judgment" broadly. For example, the Agencies state that a claim denial based on a preexisting condition exclusion would be eligible for external review. Additionally, in the Preamble the Agencies give an example which provides that determinations as to whether a wellness plan participant is entitled to participate in a "reasonable alternative" activity to obtain a reward under the program will also be subject to external review. We are concerned that such a broad interpretation of "medical judgment" could have unintended adverse consequences for employers and consumers. Employers offering wellness programs are not currently subject to external review in connection with wellness programs. If wellness programs will now be subject to the very expensive external review process, some employers may decline to offer these programs, which will have obvious adverse consequences for employees and which is contrary to the intent of the ACA, which *encourages* employers to offer wellness programs.

Additionally, the Agencies' broad interpretation of “medical judgment” could subject plans to external review even in cases where there is no denied claim for benefits. For example, preexisting condition determinations should not be subject to external review, given that such determinations do not involve a "medical judgment" as defined by the IFR, in that preexisting condition determinations do not involve medical review as to (i) medical necessity, (ii) appropriateness of a procedure or treatment, (iii) health care setting, (iv) level of care, or (v) the effectiveness of a covered benefit. Likewise, the availability a "reasonable alternative" under a wellness program should not be subject to external review, given that the program's decision does not involve a "medical judgment," and there is no claim denial by the plan in connection with its decision, meaning that there is no adverse benefit determination to forward to an external reviewer.

The Amendment also appears to provide that the determination of whether a claim involves "medical judgment" rests with the external reviewer (*i.e.*, the IRO), rather than the plan or insurer. Specifically, the Amendment provides that, during the suspension

period, the scope of the Federal external review process is limited to claims involving rescissions and "medical judgment (including, but not limited to, those based upon a plan's or insurer's requirements for medical necessity, appropriatness, health care setting, level of care, effectiveness of a covered benefit, or determinations as to whether a treatment or procedure is experimental or investigational), *as determined by the external reviewer*." 29 CFR 2590.715(d)(1)(A) (emphasis added), as modified by the Amendment.

Designating an IRO as the entity with decision-making authority as to whether a claim involves a medical judgment is problematic for a number of reasons, and could cause substantial confusion for plan participants. Among other things, if the IRO is the sole entity that decides whether a claim involves a medical judgment, then virtually all notices of adverse benefit determinations will be required to notify claimants of the ability to request an external review – even in cases where it is clear that the denied claim is *not* eligible for Federal external review (such as an adverse benefit determination regarding a claimant's cost-sharing under the plan, or a plan's blanket exclusion of a particular treatment). In such cases, a claimant may request an external review, only to have his or her request denied by the IRO, causing confusion and frustration for the claimant who will not understand why he or she was advised of the possibility of external review, only to have his or her request denied.

Additionally, designating the IRO as the entity responsible for determining whether a claim involves a medical judgment conflicts with the external review process established by Technical Release 2010-01. Under Technical Release 2010-01's safe harbor, all plans subject to the Federal external review process must conduct a "preliminary review" of any request for external review within five days of receiving such request, to determine if the adverse benefit determination at issue falls within the scope of the Federal external review process. If the adverse benefit determination is not eligible for external review, then the plan must so notify the claimant, explaining the reasons for its determination. And in such cases, the claimant may seek judicial review of the plan's claim denial. If, however, the *IRO* is the entity that decides whether a claim involves a medical judgment, then virtually *all* requests for external review (other than those involving eligibility for plan benefits) must be forwarded to the IRO for a threshold decision as to whether the adverse benefit determination is eligible for external review. This would have the effect of nullifying the plan's preliminary review process, and dramatically increasing the IRO's workload – as well as increasing the expenses that must be paid by the plan to the IRO, even for claims that clearly fall outside the scope of the Federal external review process.

Recommendation: We recommend that the Agencies modify the Amendment to:

- Permanently focus the scope of the Federal external process on claims involving medical judgment and rescissions, by providing that the scope of the Federal process shall be no broader than the scope of claims subject to the NAIC's Uniform External Review Model Act;

- Clarify that adverse benefit determinations that are based on plan exclusionary provisions (such as no coverage for a particular procedure or condition) are not eligible for external review;

- Delete the Examples in the Amendment and its Preamble which state that preexisting condition determinations and determinations as to reasonable alternatives under a wellness program are subject to Federal external review; and

- Delete the phrase "as determined by the external reviewer" in connection with the determination of whether a claim involves a medical judgment. Instead, the Amendment should provide that a plan must determine whether an adverse benefit determination involves a "medical judgment," as defined by the Amendment. If so, the plan must forward the request for external review to an IRO for decision. If the adverse benefit determination does not, however, involve a "medical judgment," the plan must provide written notice to the claimant advising as to the reasons why the claim is not eligible for external review, and advising the claimant of his or her right to seek judicial review of the plan's adverse benefit determination.

3. <u>There Should Be a Minimum Dollar Threshold for External Reviews</u>

The IFR provides that a qualifying State external review process "may not impose a restriction on the minimum dollar amount of a claim for it to be eligible for external review." 29 C.F.R. §2590.715-2719(c)(2)(v). And although it is not specifically addressed in the Amendment or in the Agencies' Technical Releases, we assume that a minimum claim threshold would be prohibited for the Federal external review process as well, given that the Preamble to the IFR states that the Federal process "will be similar to a State external review process that complies with the standards in these regulations." 75 Fed. Reg. at 43336.

We recommend that the Agencies revise the IFR to permit a reasonable minimum dollar threshold for an adverse benefit determination to qualify for external review. Currently, at least 15 states have minimum dollar thresholds (often $500) for their external review processes, and although such thresholds are scheduled to be phased out effective January 1, 2012, we submit that they are necessary to avoid low-dollar claims. Currently, the average cost for an external review is $650, and in many cases, the cost of the external review vastly exceeds the dollar value of the benefit at issue. For example, we recently had an external review as to whether an $18.70 out-of-pocket expense should be applied to a claimant's deductible, which cost $450 to adjudicate. And we expect the cost of external reviews to increase if a host of decisions that do not involve "medical judgments" – such as those related to preexisting condition exclusions and wellness programs – will now be subject to external review.

Lack of a dollar threshold, allowing an individual to appeal claims of any dollar amount to external review, can lead to unintended consequences. Among other things,

lack of minimum dollar threshold can result in increased costs for all plan beneficiaries and the different treatment of similarly situated plan beneficiaries.

For example, if a plan excludes a service and the charge for the service is $20.00 and the adverse determination is submitted for external review, a logical response of the plan or the carrier is to simply pay the $20 dollar item to avoid hundreds of dollars in external review costs. This however, has negative consequences for the plan as a whole, since some plan beneficiaries may receive benefits that others do not, and over time, will force plan benefit changes that result in higher costs for all plan beneficiaries (and employer plan sponsors).

Put simply, the absence of a minimum dollar threshold on the value of an adverse benefit determination creates an extraordinary cost, which is borne solely by the plan, for an appeal that involves a low dollar value. And, it creates an incentive for claimants to seek external review of even the smallest dollar claims where there is no merit to the appeal, in the hope that the plan will simply pay the claim rather than incur the even higher costs of an external review.

Recommendation: The Agencies should adopt a $500 threshold for the external review process.

4. The Agencies Should Publish the List of States That Satisfy the External Review Process During the Transition Period As Soon As Possible, And Clarify that If a State Does Not Appear on the List, Insurers *Must* Follow the Federal External Review Process

In the Preamble to the IFR, the Agencies indicate that by October 2011, they will publish a list of states with external review processes that satisfy the Amendment's minimum requirements during the pre-2014 transition period.

We respectfully request that the Agencies publish such a list as soon as possible, to provide insurers with sufficient lead time to follow the Federal external review process with respect to those states that do not appear on the Agencies' list, and to ensure that plan documents are appropriately updated to reflect state law for policies issued in those states that do appear on the list.

Recommendation: We request that the Agencies expressly provide that, with respect to states that do not appear on the Agencies' list (*i.e.*, those states which do not have external review processes that satisfy the minimum standards required during the pre-2014 transition period), insurers operating in such states *must* satisfy the Federal external review process, rather than any state external review process.

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Aetna is pleased to have the opportunity to provide comments regarding the Amendment to the claims and appeals IFR, and we thank you for consideration of our comments. Should you have any questions, please feel free to contact me.

Sincerely,

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