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September 21, 2010

Hon. Hilda Solis, Secretary, U.S. Department of Labor
Hon. Kathleen Sebelius, Secretary, U.S. Department of Health and Human Services
Hon. Timothy Geithner, Secretary, U.S. Department of Treasury
Office of Health Plan Standards and Compliance Assistance
U.S. Department of Labor, Employee Benefits Security Administration
200 Constitution Avenue, NW, Room N-5653
Washington, DC 20210

Attention: RIN 1210—AB45

Submitted via the Federal Regulations Web Portal, http://www.regulations.gov

Re: Comments on 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 respond to the request for comments issued by the Department of Labor ("DOL"), Department of Health and Human Services ("HHS"), and the Department of Treasury (collectively, the "Agencies") regarding 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 ("PPACA") (the "IFR" or the "Regulation"), 75 Fed. Reg. 43330 (July 23, 2010).

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 affected by PPACA, Aetna is committed to working with the Agencies in developing reasonable standards for the implementation of PPACA. To that end, we applaud the Agencies for issuing Technical Release 2010-2, which provides enforcement relief for plans and insurers that are working in good faith to comply with the myriad of changes required by the IFR. We note, however, that even with this

temporary enforcement relief, we believe that consumers and other stakeholders would benefit from modifications to the IFR. Accordingly, we are submitting these comments recommending that the IFR be withdrawn and reissued as a proposed regulation, and that the Agencies deem a plan's compliance with the existing DOL claims and appeals regulation as compliant with PHSA § 2719, until such time as a final regulation is issued following the Agencies' consideration of comments received.

Should the Agencies decline to withdraw the IFR, we recommend that the Agencies modify the IFR in certain respects. Among other things, we are concerned that the requirement to include diagnosis codes and their corresponding meaning raises significant privacy issues and could generate a great deal of confusion among members. Additionally, we recommend that the Agencies modify the IFR to adopt a national standard for determining when notices in a non-English language are required. And, we further recommend that the Agencies provide additional time for plans and insurers to exchange information with participants when the plan or insurer receives new or additional evidence or considers a different rationale in connection with a participant's appeal.

Aetna's specific comments on the IFR are set forth below, as are our recommendations for changes to the IFR. To the extent the Agencies decide to modify the IFR rather than withdraw it, we strongly encourage that such modifications be published as soon as possible, given that plan sponsors and plans are already taking steps to assess the impact of the IFR's requirements and means of compliance with its mandates.

1. The Agencies Should Withdraw the IFR

The IFR provides that beginning with the first plan year on or after September 23, 2010, plans and insurers must comply with a host of new requirements that will impose significant financial and administrative burdens on plans, and which realistically cannot be accomplished by July 1, 2011, at which time the Agencies' enforcement grace period will end. Among other things, plans and insurers "must ensure that any notice of adverse benefit determination or final internal adverse benefit determination includes information sufficient to identify the claim involved (including the date of service, the health care provider, the claim amount, if applicable, the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning)." 29 C.F.R. § 2590.715-2719(b)(2)(ii)(E)(1).

Aetna and many other insurers and plans already provide explanation of benefit ("EOB") statements and notices of final internal adverse benefit determinations that include many of the new data elements required by the IFR, including the date of service, the name of the health care provider, the claim amount, and a statement of a participant's appeal rights. However, EOBs and notices of final internal adverse benefit determinations do not include diagnosis or treatment codes as standard data elements, and, as discussed below, requiring their inclusion would impose significant burdens on plans and insurers, and could unintentionally cause confusion and even fear among participants.

In the Preamble to the IFR, the Agencies state that the IFR will not require EOBs or appeal decision notices to include any data that "cannot be automatically populated by plans and insurers[,]" and estimate that insurers as an aggregate would incur $3.5 million in start up costs to add the new data elements required by the IFR, which would be mitigated by the model notices of adverse benefit determinations that the Agencies would issue. 75 Fed. Reg. at 43342. We note, however, that the systems changes needed to include diagnosis and treatment codes (and their corresponding meanings) on EOBs and appeal decision notices would be far more significant than the Agencies estimate. Indeed, there are over 17,000 ICD-9 diagnosis codes, and over 140,000 ICD-10 codes. Likewise, there are thousands of CPT treatment codes, which are continually updated to reflect changes in the health care field. For example, in 2009 alone, 293 new CPT codes were created, 133 codes were revised, and 92 codes were deleted.

To comply with this aspect of the IFR, insurers and plans would be forced to reprogram internal system formats, file structures, and processing logic to generate the diagnosis and treatment codes, and would then have to test and debug the reprogrammed systems, and then train employees and contractors as to the reprogrammed system. We estimate that such reprogramming would require as much as a year's time to implement. And, given that Aetna (like many other insurers and plans) is already in the process of upgrading to the X12-5010 version of the HIPAA transaction and code set standards and transitioning its claims systems to the ICD-10 coding system – which are huge and expensive undertakings in and of themselves – the timing required to successfully add diagnosis and treatment codes as standard data elements to EOBs and appeal decision notices could be even longer than a year, and would require even greater expenditures of limited resources.

Coupled with other changes required by the IFR that will have an enormous impact on plan administration, compliance with each aspect of the IFR by the end of the enforcement grace period becomes even more difficult. Among other things, and as discussed more fully below, the following new requirements of the IFR provide examples of why it will be difficult for plans to meet the compliance deadline of July 1, 2011:

- Notices regarding a plan's claims and appeals process must be culturally and linguistically appropriate, as defined by the IFR, which will compel insurers and plans to collect and store language data at the plan level. The required data, however, is not yet available, and will require Aetna and other insurers to collect data from hundreds of thousands of different customer plans. Moreover, in some parts of the country, the number of non-English languages that would meet the IFR's threshold may be significant.

- Plans must respond to "urgent care claims" within no more than 24 hours. This rule does not allow for weekends to be excluded from the calculation, and plans will therefore be required to develop the capability to review claims on a 24-hour basis, seven days a week. This will require that plans hire, equip, and train extra staff to adjudicate claims. Moreover, the IFR does not consider that there are urgent care claims that may take longer than 24 hours to adjudicate. We urge the Agencies to consider what types of claims or circumstances generally require an

urgent care claim to take longer than 24 hours and the feasibility of adjudicating these claims faster than the current standard.

- Plans must "strictly adhere" to the IFR's requirements in every aspect of claims and appeals adjudication. 29 C.F.R. § 2590.715-2719(b)(2)(ii)(F). Under this standard, a simple error in claims processing that does not in any way prejudice a participant would allow a participant to immediately initiate external review or pursue judicial remedies without going through the administrative process, during which the claim dispute may be resolved amicably. Given the myriad of new requirements imposed by the IFR, it is likely that without adequate time to design and implement necessary systems changes, non-prejudicial or *de minimis* mistakes in processing claims will be made, which will produce a rush of claimants bypassing internal appeals and going straight to external or judicial review.

Accordingly, we respectfully request that the Agencies withdraw the IFR and re-issue it in proposed form, and deem a plan's compliance with the existing DOL claims and appeals regulation as compliant with PHSA § 2719, until such time as a final regulation is issued following the Agencies' consideration of comments received concerning the proposed rule. Such deemed compliance would be consistent with PPACA itself, which provides that for purposes of complying with PHSA § 2719(a)(1), a plan and issuer "shall provide an internal claims and appeals process that initially incorporates the claims and appeals procedures (including urgent claims) set forth at [29 C.F.R. § 2590.503-1]" until such time as the Secretary may update such procedures. *See* PHSA § 2719(a)(2). And PHSA § 2719(b) provides that plans and insurers shall provide an external review process that complies with either applicable State external review laws or standards that the Secretary may establish, and specifically authorizes the Secretary to deem external review processes in effect as of the date of PPACA's enactment as compliant with PHSA § 2719(b). Under this provision, the Federal external review process is not even operable until the Secretary issues regulations.

We believe that adoption of this recommendation will allow time for stakeholders and the public to fully consider the implications of the proposed rules, their benefits to plan participants, and their impact on plan administration and operations. This would also afford the Agencies time to evaluate and incorporate the comments as part of the Agencies' final rulemaking process, thus ensuring that the final regulation appropriately considers the positions of various stakeholders.

2. Technical Release 2010-2's Grace Period Should Be Extended Until September 23, 2011, and Expanded to Deem a Plan's Internal and External Appeals Process as Compliant Until Such Date

Should the Agencies decide not to withdraw the IFR, we request that the Agencies modify Technical Release 2010-2 in several respects. Specifically, we request that the grace period be extended from July 1, 2011 until September 23, 2011, to provide plans and insurers the one year that is minimally needed to adopt the full panoply of system and programming changes discussed above. Additionally, we request that the Agencies issue guidance clarifying that a plan or insurer's compliance with Technical Release 2010-2's good faith/substantial compliance policy shall also deem a plan or insurer's internal

claims and appeals process and its external review process as compliant with the IFR's requirements for a transition period that extends until September 23, 2011. Such deemed compliance would be consistent with the Agencies' treatment of State external review processes, which were deemed to be in compliance with the IFR's requirements for a transition period that extends until July 1, 2011. 29 C.F.R. § 2590.715-2719(c)(3).

For self-funded plans that do not currently have external review programs, we recommend that such plans be subject to the external review requirement only when the Federal external review process is developed, so such plans will be governed by uniform federal rules. Such clarification of Technical Release 2010-2 would permit plans and insurers to adopt a phased-in approach to compliance, which is necessary to ensure the smooth implementation of the myriad of new rules imposed by the IFR, and would permit plans to implement the extensive system changes, data collection, and staffing changes with a minimum of disruption to their normal operations.

3. Requiring the Inclusion of Diagnosis Codes on EOBs and Appeal Decision Notices Raises Significant Privacy Concerns

We also are concerned that including diagnosis codes and their corresponding meanings in EOBs and appeal decision notices raises significant privacy issues for plan participants and their dependents, and could unintentionally cause confusion and even fear for our members. We therefore recommend that the Agencies revise the IFR, to remove the requirement for inclusion of diagnosis codes (and their meanings) in EOBs and appeal decision notices.

By definition, EOBs and appeal decision notices contain protected health information ("PHI") that is subject to stringent regulation under the Health Insurance Portability and Accountability Act ("HIPAA"). *See* HIPAA Privacy Regulation, 45 C.F.R. § 164.500 *et. seq.* By requiring the inclusion of diagnosis codes and their corresponding meanings, the Agencies mandate that even more PHI – of an extremely sensitive nature – be included in EOBs and appeal decision notices, rather than limiting the notices to just a description of the medical item or service that was provided, which raises less significant privacy concerns.

For example, consider the privacy issues for a patient who was assigned ICD-9 code 079.53 by his or her health care provider, for which procedure CPT 3552F was performed. Under the IFR, the EOB for that particular service would include the following:

> ICD-9 code and description= 079.53/HUMAN IMMUNODEFICIENCY VIRUS, TYPE 2 [HIV 2];
>
> CPT code and description= 3552F/HGH RISK FOR THROMBOEMBOLISM.

Likewise, a patient assigned ICD-9 code 099.5 and who had procedure CPT 37200 performed would receive an EOB that disclosed the following:

> ICD-9 code and description= 099.5/CHLAMYDIA TRACHOMATIS INFECTION;

CPT code and description= 37200/TRANSCATHETER BIOPSY.

Obviously, the disclosure of the diagnosis code and its meaning could cause considerable concern to the patient, especially if the EOB or appeal decision notice is for a service rendered to a dependent covered by the plan, but is mailed to the plan participant.

Additionally, we are concerned that the inclusion of diagnosis codes will add unnecessary complexity to EOBs and appeal decision notices, and could negatively impact a member's understanding of the notice. This confusion may be enhanced by the fact that diagnosis and procedure codes generally are not included in physician or hospital bills that are sent to members. We also note that diagnosis codes billed by providers are often times incorrect, or include codes for conditions that are later ruled out, and such information could prove upsetting or even alarming to the member. Further, the National Association of Insurance Commissioners (the "NAIC") is working with consumer groups and other stakeholders to test whether the NAIC's proposed standard definitions of terms used on claims and other plan documents are clear and appropriate. Prior to requiring that additional coding information be included on EOBs and appeal decision notices, the Agencies should work collaboratively with consumer groups and plans to determine whether – and the extent to which – coding information assists consumers, and how they would respond to the inclusion of information such as diagnosis codes and their meanings.

We also note that including diagnosis codes with notices may hinder a plan or insurer's ability to offer family EOBs or online access, given the privacy issues that arise from the inclusion of diagnosis codes and their meanings. Accordingly, we recommend that the Agencies remove the requirement to include diagnosis codes and their meanings from EOBs and appeal decision notices.

4. The Agencies Should Revise the Non-English Language Threshold

Aetna currently provides its customers and participants with a wide range of language assistance services, including translation and interpretation services. The IFR, however, imposes new rules requiring that notices related to claims and appeals (and customer assistance hotlines) be provided in a "culturally and linguistically appropriate manner." Specifically, the IFR provides that claim and appeal notices and customer assistance hotlines must be provided in non-English languages if the following thresholds apply:

- For plans covering 100 or more participants, the plan or insurer must provide non-English notices upon a participant's request if the lesser of at least (a) 500 participants or (b) 10 percent of plan participants are literate only in same non-English language;

- For plans covering fewer than 100 participants, the plan or insurer must provide non-English notices upon a participant's request if at least 25 percent of plan participants are literate only in same non-English language; and

- For individual coverage, the insurer must provide the notices in a non-English language if at least 10 percent of the population in the claimant's county are literate only in same non-English language.

If a participant makes a request for a notice in an applicable non-English language, the IFR requires that all subsequent notices be provided in that non-English language. 29 C.F.R. § 2590.715-2719(e)(2)(ii). We recommend that rather than requiring all subsequent notices be in the non-English language, only those notices for which the participant specifically requests a non-English notice should be required.

The IFR's requirements relating to notices in a non-English language also requires that insurers collect extensive information from their plan customers (both insured and self-funded) regarding the languages spoken by their respective participants. Given that Aetna alone has over 100,000 customers to which the IFR's requirements may apply, Aetna must expend significant resources to capture extensive data from its customers regarding the languages spoken by their participant populations, and to reprogram Aetna's claims systems and customer assistance hotlines to reflect this new data.

The collection of this information from so many customers by the required compliance date would be daunting enough, but given that many plan sponsors do not have information regarding their participants' literacy in non-English languages – and that participants may not respond to plan surveys regarding non-English language fluency – Aetna's ability to collect and process the required information to comply with the IFR is likely to be hindered.

Moreover, in some parts of the country, the number of non-English languages that meet the IFR's threshold – and the resulting burdens to the plan – could be significant. For example, 92 languages have been specifically identified among students in Los Angeles alone. Additionally, the IFR would require plans and insurers to continually assess the non-English threshold (presumably at least annually), to determine whether there has been any change in participant demographics that may trigger new languages being subject to the IFR's threshold. For example, a plan may have a participant population that requires issuance of notices in Spanish in one year but not the next, resulting in the plan issuing notices in Spanish for only the first year, which could cause dissatisfaction and confusion for Spanish-speaking members who remain participants in the plan.

Rather than basing the non-English language threshold at the plan level, we recommend that the Agencies revise the IFR to use a threshold that is based on a national standard using statistically reliable data, which would require plans and insurers to provide non-English language notices only for a specified number of languages (*e.g.*, top 10 languages represented).

5. The IFR Should be Modified to Allow Plans Additional Time to Exchange New Information Regarding Appeals With Participants

The IFR provides that a plan or insurer must provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by the plan or insurer in connection with the claim. This information must be provided "as soon as

possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required . . . to give the claimant a reasonable opportunity to respond prior to that date." 29 C.F.R. § 2590.715-2719(b)(2)(ii)(C)(1). Similarly, before the plan or issuer can issue a final internal adverse benefit determination based on a new or additional rationale, the claimant must be provided with the new or additional rationale "as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required . . . to give the claimant a reasonable opportunity to respond prior to that date." *Id.* at (C)(2).

These new requirements – which mandate that plans provide these materials during the ongoing appeals process and consider any information that a participant submits in response – essentially creates another level of internal appeal, but the IFR does not provide any guidance as to how this process will work, or how far in advance the plan must provide the new information or rationale, or how quickly a claimant must respond to any new information or rationale. To give the Agencies and plans time to formulate the operational details of this process, we recommend that the Agencies make this aspect of the IFR applicable for plan years beginning on or after July 11, 2011.

We also note that this provision of the IFR creates an ongoing dialogue between the plan and participant, but does not extend the time in which the plan must decide the appeal. If a participant responds to any additional information, evidence, or rationale that the plan provides, the IFR requires the plan to review and consider that information and to respond to it. But this ongoing exchange of information, which is valuable to both the plan and the participant, does not affect the timeframe in which the appeal must be decided.

To ensure that the ongoing dialogue between the plan and a participant concerning new evidence and rationales allows for careful consideration of all information that is submitted, we recommend that the Agencies modify the IFR to allow plans additional time to exchange information with a participant when a member responds to new evidence or rationales. We believe that a reasonable adjustment to the time for deciding a final internal appeal based on the exchange of new information is five days for a non-urgent care appeal, and an additional 48 hours for an urgent-care appeal.

6. The IFR's "Deemed Exhaustion" Standard Should Be Modified to Apply Only to Errors that Are Prejudicial to Participants

The IFR provides that if a plan fails to "strictly adhere" to all of the new requirements set forth in the IFR, the participant will be deemed to have exhausted the plan's internal claims and appeals process, and, consequently, may immediately pursue either external or judicial review of the claim denial. 29 C.F.R. § 2590.715-2719(b)(2)(F). This deemed denial applies regardless of whether the plan substantially complied with the IFR, or if the error was *de minimis. Id.*

We appreciate that the Agencies have adopted an enforcement grace period with respect to this new standard through the issuance of Technical Release 2010-2. However, we note that this aspect of the IFR is a significant departure from the DOL's long-held position that *de minimis* errors in plan administration that had no prejudicial effect on a participant would not trigger a "deemed exhaustion" of remedies or constitute a failure to

provide a full and fair review of the claim. DOL FAQ About the Benefit Claims Procedure Regulation, FAQ F-2, available at http://www.dol.gov/ebsa/faqs/faq_claims_proc_reg.html. Neither the IFR nor the Preamble provides any explanation for this fundamental policy shift by the DOL, and we respectfully submit that simple errors in claims processing that are not meaningful to the outcome of the claim or appeal decision and which do not prejudice the participant should not cause a deemed exhaustion of the plan's internal claims and appeals process. Accordingly, we urge the Agencies to modify this aspect of the IFR, to provide that *de minimis* errors which do not prejudice a participant will not result in a deemed exhaustion.

7. Only Benefit Denials Relating to the Exercise of Medical Judgment Should Be Subject to External Review

The IFR establishes minimum standards for the State and Federal external review processes that would allow almost 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). Under the IFR, adverse benefit determinations that involve matters such as a plan exclusion or cost-sharing requirements would be subject to external review, notwithstanding the fact that such claims can be resolved by simple reference to the plan document, and do not raise issues of medical judgment.

To avoid overburdening the external review process and to appropriately defray the expenses that plans must pay for external reviews – which average $605 per review – we recommend that the Agencies modify the IFR to provide that only claims that involve the exercise of clinical or medical judgment – such as medical necessity, experimental/investigational, medical appropriateness, health care setting, level of care, or effectiveness of a covered benefit – will be subject to the external review process.

8. There Should Be a Minimum Dollar Threshold for External Reviews

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 addressed in the Agencies' recent guidance concerning the non-enforcement safe harbor for group health plans subject to the Federal external review process (DOL Technical Release 2010-01), 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. The average cost for an external review is currently $605. 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 participants 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, which the plan must pay even if it prevails.

9. To the Extent Diagnosis and Treatment Codes Are Required for Claim Decision Notices, Only Primary Codes Should Be Included

Should the Agencies retain the IFR's requirement that EOBs and appeal decision notices include diagnosis and treatment codes, we request that the Agencies issue guidance clarifying that only the primary code must be included, rather than each series of codes that may be reflected in the claim.

10. Plans Should Be Allowed to Deny Urgent Care Claims When a Facility Does Not Provide Required Information Within Required Timeframes

The IFR reduces the time in which plans and insurers must decide benefit claims involving urgent care, from 72 hours to 24 hours. 29 C.F.R. § 2590.715-2719(b)(ii)(B). We note, however, that facilities and provider offices may submit an urgent care claim on a Friday or just before a holiday, but may not be fully staffed over the weekend or during the holiday, and therefore do not respond to a plan's request for additional information regarding the claim. In such circumstances, the plan may be forced to deny the claim based on the lack of information. The Agencies should confirm prior guidance that if a facility or provider fails to provide the information reasonably requested by the plan within the time available to the plan for deciding the claim, the plan may deny the claim based on the information that is available to it. *See* DOL Frequently Asked Question C-21, available at http://www.dol.gov/ebsa/faqs/faq_claims_proc_reg.html.

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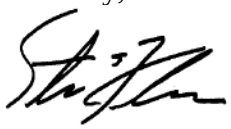
Aetna is pleased to have the opportunity to provide comments regarding the claims and appeals IFR, and we thank you for consideration of our comments. Should you have any questions, please feel free to contact me.

Sincerely,



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