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Via Overnight Mail

September 24, 2010

Hon. Kathleen Sebelius, Secretary, U.S. Department of Health and Human Services
Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Attention: OCIIO-9993-IFC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Hon. Hilda Solis, Secretary, U.S. Department of Labor
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

Hon. Timothy Geithner, Secretary, U.S. Department of Treasury
CC:PA:LPD:PR (REG-125592-10)
Courier's Desk
Internal Revenue Service
1111 Constitution Avenue, NW
Washington, DC 20224

Re: Comments on the Proposed and 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 Secretaries Sebelius, Solis, and Geithner:

The Central States, Southeast and Southwest Areas Health and Welfare Fund ("Central States") is pleased to provide comments to the Departments of Health and Human Services, Labor, and Treasury (the "Departments") regarding the Interim Final Rule and Proposed Regulation (the "Interim Final Rules" or the "Regulations") on the Requirements 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 ("Affordable Care Act") as issued in the Federal Register on July 23, 2010 (75 Fed. Reg. 13329, 75 Fed. Reg. 43109).

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Central States is a multiemployer health and welfare fund. Central States has been providing health and welfare benefits to our members since 1950. Central States is one of the largest single claims processing centers in the United States, handling over 12,000 claims each day for approximately 250,000 participants and dependents. Central States provides approximately $1 billion dollars in benefits annually.

As a key stakeholder in the implementation of the Affordable Care Act, we are filing these comments in response to the Departments' request for comments on the IFR (RIN 1545-BJ63, RIN 1210-AB45, RIN 0991-AB70) and the Proposed Regulation (RIN 1545-BJ62). Our comments include specific suggested changes to the Regulations, as well as requests for clarification on particular areas of the Regulations.

External Review of Multiemployer Plan Decisions

Section 2719 of the Public Health Service Act (PHS Act) provides for federal external review of, among other plans, self-insured plans that are not subject to state insurance regulation. Thus, self-funded multiemployer plans are subject to a federal external review process. PHS Act Section 2719(b)(2) provides for a process "that meets minimum standards established by the Secretary through guidance and that is similar to the process" described for plans subject to state external review. That state external review process is defined in PHS Act 2719(b)(1) as a process "that, as a minimum, includes the consumer protections set forth in the Uniform External Review Model Act promulgated by the National Association of Insurance Commissioners and is binding on such plans."

The Uniform External Review Model Act (UERMA) limits the definition of an "adverse determination" to a determination that a particular claim "does not meet the health carrier's requirements for medical necessity, appropriateness, health care setting, level of care or effectiveness, and the requested service or payment for the service is therefore denied, reduced or terminated." UERMA § 3.A. In other words, external review is limited to those situations where a claim is denied, reduced, or terminated on the basis of a medical judgment. The definition in the UERMA of a "final adverse determination" is simply an adverse determination upheld through the completion of the internal review process. UERMA § 3.V.

Under the Interim Final Rules, specifically 29 C.F.R. § 2590.715-2719(a)(2)(i), an "adverse benefit determination" is defined with reference to the definition contained in 29 C.F.R. § 2560.503-1, and also includes rescissions of coverage. The definition of adverse benefit determination in 29 C.F.R. § 2560.503-1(m)(4) is not limited to adverse determinations based upon medical judgments, but rather includes "any of the following: a denial, reduction, or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit ...." As a result, the Regulations propose to subject any adverse determination (other than adverse determinations based upon eligibility) to external review regardless of whether such determination is based upon a medical judgment.

Although the definition of "adverse benefit determination" makes perfect sense in its original context, namely a definition that applies for purposes of internal review, we suggest that such definition is overbroad in the context of external review. As stated above, the PHS Act indicates that the federal external review process should be similar to the process for state external review. Further, the PHS Act indicates that the process for state external review should be similar to that in the UERMA. However, the Regulations with respect to federal external review depart significantly from both the state external review process and the UERMA with respect to the definition of an adverse determination. For a state external review process, the Interim Final

Rules specify that the state process must provide for external review of adverse benefit determinations "based on the issuer's (or plan's) requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit." 29 C.F.R. § 2590.715-2719(c)(2)(i). Similarly, the UERMA carefully limits the types of determinations that are subject to external review to those determinations involving a medical judgment. In contrast, the Interim Final Rules with respect to federal external review subject any determination to external review, regardless of whether such determination is based upon medical judgment.

The broad definition of an adverse benefit determination in the Interim Final Rules will lead to several negative consequences. First, the cost to plans will be increased. The broad definition will greatly increase the number of claims that are submitted to external review. The Regulations provide an estimate of 1.3 external appeals for every 10,000 participants. 75 Fed. Reg. 43345. However, the estimate of the number of external reviews contained in the Interim Final Rules understates the number of external reviews that will occur under the broader definition of an adverse benefit determination in the Interim Final Rules. This is because the studies on which the estimate is based examined the number of external reviews occurring under state external review procedures, which more closely approximate the narrow definition of an adverse determination contained in the UERMA (claims involving medical determinations).

Not only will the broader definition of an adverse benefit determination increase the number of external reviews (increasing the cost to the plans), it will also increase the cost of each review. The Regulations estimate a cost of $605 per external review. 75 Fed. Reg. 43345. However, Technical Release 2010-01 issued by the Department of Labor suggests that not only will plans need to fund the cost of medical experts, but must also fund the cost of an Independent Review Organization (IRO) to "utilize legal experts where appropriate to make coverage determinations under the plan." Technical Release 2010-01, § A.3.(a), p.4. Thus, plans will not only be funding the cost of medical experts but the cost of legal experts as well.

Further, many state external review processes require the claimant to pay a nominal fee to initiate external review, which limits the overuse of external review in situations where the claim is likely to be denied. The Interim Final Rules provide that a state external review process may charge up to a $25 filing fee (with an annual maximum of $75). 29 C.F.R. § 2590.715-2719(c)(2)(iv). In contrast, the Regulations do not provide authorization to charge any filing fee for federal external review. Further, the Interim Final Rules provide that a State external review process may not impose a minimum claim threshold. 29 C.F.R. § 2590.715-2719(c)(2)(v). Presumably, no minimum claim threshold will be allowed under federal external review.

As a result of the broad definition of an adverse benefit decision, claims that would otherwise not be eligible for external review under a state process (or under the UERMA) will nonetheless be eligible for federal external review. Many of these claims could involve issues such as the imposition of a $20 co-payment or a $200 deductible. The, the broad definition of an adverse determination, the lack of a fee for federal external review, and the lack of a claim amount threshold, will increase costs for plans with little or no corresponding gains for the participants. Allowing external review which costs an average of $605 on a $20 claim is self-defeating.

The second negative consequence is that external review of claims that are not based upon medical determinations will provide no benefit relative to the cost. Although an IRO may be well-suited to review medical judgments, IROs are not well-suited to make non-medical determinations. Plan interpretation issues are outside the scope of medical expertise, and the solution is not to add the additional cost and delay of having IROs provide legal expertise as

well as medical expertise. Such interpretation issues should not be left to those unfamiliar with the terms of the plan.

The third negative consequence is that IROs are not suited to ensuring the consistency of benefit determinations. Under 29 C.F.R. § 2560.503-1(b)(5), the plan must ensure that determinations "are made in accordance with governing plan documents and that, where appropriate, the plan provisions have been applied consistently with respect to similarly situated claimants." When the fiduciaries of the plan are interpreting the plan and applying its terms, they are familiar with its terms and their prior interpretations. However, IROs are not familiar with the terms of a particular plan or familiar with prior interpretations of the plan. Indeed, given that Technical Release 2010-01 requires assignment of claims to at least three different IROs (who may in turn utilize different reviewers with respect to each separate claim), the possibility of consistent interpretation is greatly diminished, if not eliminated altogether.

In fact, in the special case of multiemployer plans, the benefit of external review of any adverse benefit determination, whether based on medical judgment or otherwise, is minimal or non-existent. The two main goals of external review are to: (1) ensure that medical judgments are made by those with appropriate expertise; and (2) ensure unbiased decision-making. However, the first goal is already adequately addressed by the claims regulations pre-dating the Interim Final Regulations. Further, the second goal is met by the inherent structure of multiemployer plans.

As to the goal of ensuring that claims involving medical judgment are reviewed by individuals with sufficient expertise, the existing claim procedures ensure that the goal is met. Under 29 C.F.R. § 2560.503-1(h)(3)(iii), when an internal appeal involves medical judgment, the fiduciary "shall consult with a health care professional who has appropriate training and expertise in the field of medicine involved in the medical judgment." As a result, under the regulations issued prior to the Interim Final Rules, plans are already required to consult medical professionals when a determination is based upon medical judgment.

Further, under 29 C.F.R. § 2560.503-1(h)(3)(v), the health care professional consulted shall not be an individual consulted in connection with the adverse benefit determination on appeal or the subordinate of any such individual. Finally, the Interim Final Rules provide that the plan must ensure that claims and appeals are decided in an independent and impartial manner, and in particular that decisions with respect to an individual such as a medical expert "must not be based upon the likelihood that the individual will support the denial of benefits." 29 C.F.R. § 2590.715-2719(b)(2)(ii)(D). These provisions adequately ensure that adverse benefit determinations involving medical judgments will be reviewed in consultation with unbiased medical professionals. Adding an additional layer of external review will not advance the goal of obtaining unbiased medical judgments but will instead simply increase the cost to a plan.

The other rationale for external review is to ensure that the decision-making is unbiased. As discussed above, the existing regulations regarding internal claim review, coupled with the reinforcement provided in the Regulations, ensure that the plan will receive unbiased medical judgment from a medical professional. Further, as discussed below, the structure of multiemployer plans ensures that the fiduciaries themselves will be unbiased.

In the single-employer plan context, the Supreme Court has held that a conflict of interest may exist where an employer both funds the plan and makes the benefit determinations. *Metro. Life Ins. Co .v. Glenn*, 554 U.S. 105, 128 S. Ct. 2343, 2348 (2008). A similar conflict may exist when an insurer acts as the administrator because the insurer's benefit determinations impact the

bottom-line of both the insurer and the employer. *Metro. Life*, 128 S. Ct. at 2349-50. However, no potential for a conflict of interests exists with respect to a multiemployer plan.

By law, a multiemployer plan must be administered by a board of trustees with an equal number of employer and employee representatives. 29 U.S.C. § 186(c)(5)(B). In the event of a deadlock on a matter, a neutral party is appointed to resolve the dispute. *Id.* As a result, unlike a single-employer plan that is administered solely by the management of a single employer or by an insurer, a multi-employer plan has an equal number of representatives appointed by both management and the union. The structure of multiemployer plans has led numerous federal courts of appeals to conclude that multiemployer plan trustees do not have a conflict of interest when they make benefit determinations. *Anderson v. Suburban Teamsters of N'ern Ill. Pension Fund Board of Trs.*, 588 F.3d 641, 648 (9th Cir. 2009); *Klein v. Cent. States, Se. & Sw. Areas Health & Welfare Plan*, 346 Fed. Appx. 1, 5 (6th Cir. 2009); *Johnson v. Bert Bell/Pete Rozelle NFL Player Ret. Plan*, 468 F.3d 1082, 1086 (8th Cir. 2006); *Otto v. W'ern Pa. Teamsters & Emp'rs Pension Fund*, 127 Fed. Appx. 17, 20 (3rd Cir. 2005); *Manny v. Cent. States, Se. & Sw. Areas Pension & Health & Welfare Funds*, 388 F.3d 241, 242-43 (7th Cir. 2004). *But see Durakovic v. Bldg. Serv. 32 BJ Pension Fund*, 609 F.3d 133, 139 (2nd Cir. 2010) (holding that employer trustees have conflict because employers fund the plan with contributions but placing no discernable weight on the existence of that purported conflict). Because of the balanced nature of the board of trustees, the existence of a potential conflict is minimal at best, particularly in comparison to a single-employer plan.

Requiring a multiemployer plan to incur the cost of external review is not warranted given the structure of such plans. External review is particularly inappropriate for plan interpretation issues. The terms of a multiemployer group health plan are set by the plan sponsor which is the board of trustees itself. 29 U.S.C. § 1002(16)(B)(iii). Given that the board of trustees creates the terms of the plan, it is proper that the board of trustees interpret the plan, at least where the governing plan documents give the board of trustees such authority. Further, the board of trustees has the experience in interpreting the plan and can do so much more cost effectively than by relying on external review.

For these reasons, we suggest that self-insured multiemployer plans not be subject to federal external review because the cost of such review outweighs the potential benefits given that independent medical review is already required in the internal review process and the structure of multiemployer plans insulates the board of trustees from conflicts of interest. In the alternative, we suggest that federal external review be limited to adverse benefit determinations involving medical judgment and limited in scope to the medical aspects of the determination (as opposed to other determinations such as plan interpretation). Finally, we suggest that consideration be given to establishing a minimum claim threshold and/or allowing the imposition of a nominal fee for external review.

Standard of Review Applied in Federal External Review

In the event that multiemployer plans are subject to federal external review procedures, and in particular if that review encompasses questions other than medical judgment (for example, plan interpretation issues), the IRO should be required to give deference to the decision of the board of trustees if the governing plan documents grant discretion to the board of trustees. This is particularly true with respect to questions of plan interpretation.

Section 2719 of the PHS Act provides that a group health plan shall either comply with the applicable state external review process that at a minimum includes the consumer protections

set forth in the UREMA, or shall comply with an external review process established by the Secretary that is similar to the process under the UREMA. PHS Act Section 2719(b)(1) provides that the external review "is binding on such plans." Similarly, Section 11.A. of the UREMA provides that the external review decision "is binding on the health carrier...."

Notably, although Section 8.D.2. of the UREMA provides that an IRO "is not bound by any decisions or conclusions reached during" internal review, neither the PHS Act nor the UREMA indicates the level of deference to be accorded to the internal review decision. The Interim Final Rules are silent as to the level of deference to be accorded to the decisions made in internal review. However, Technical Release 2010-01 goes beyond the terms of the PHS Act and the UREMA and states that "the assigned IRO will review the claim de novo and not be bound by any decisions or conclusions reached during the plan's internal claims and appeals process...." § 3(e), p.5 of Technical Release 2010-01.

Using a de novo standard of review for external review is not warranted if the plan otherwise gives discretion to a board of trustees. This is particularly true for non-medical issues such as issues involving plan interpretation. The Supreme Court has long held that de novo review is appropriate only when the plan does not give the administrator discretionary authority. *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 115, 109 S. Ct. 948, 956-57 (1989). The Court has described the important interests served by applying a deferential standard of review in situations in which the plan gives discretion to the fiduciaries to make a particular decision:

> *Firestone* deference ... by permitting an employer to grant primary interpretive authority over an ERISA plan to the plan administrator, preserves the "careful balancing" on which ERISA is based. Deference promotes efficiency by encouraging resolution of benefits disputes through internal administrative proceedings rather than costly litigation. It also promotes predictability, as an employer can rely on the expertise of the plan administrator rather than worry about unexpected and inaccurate plan interpretations that might result from *de novo* judicial review. Moreover, *Firestone* deference serves the interest of uniformity, helping to avoid a patchwork of different interpretations of a plan, like the one here, that covers employees in different jurisdictions...."

Conkright v. Frommert, 130 S. Ct. 1640, 1649 (2010).

The PHS Act, like ERISA, is silent as to the appropriate standard of review. The mere reference in PHS Act Section 2719(b)(1) to the fact that external review must be binding does not speak to the question of the standard of review. Rather, it indicates that external review is not mere mediation or non-binding arbitration. Given the long-standing rule that the decisions of fiduciaries are entitled to deference in situations where the plan grants discretion to the fiduciaries, the lack of language addressing the standard of review in the PHS Act indicates that Congress did not intend any change with respect to the standard of review.

Nor are there good policy reasons to change the rule. Indeed, policy reasons counsel against mandating de novo review. All of the factors supporting deferential judicial review listed in *Conkright* support deferential external review. First, efficiency is served because the plan is already required to obtain unbiased medical expertise in deciding internal appeals, and requiring an additional layer of external review simply increases costs to the plan. Second, deferential review promotes predictability because the board of trustees has experience is interpreting the plan. Third, deferential review promotes uniformity because the board of trustees in interpreting

the plan is a consistent manner rather than relying on different interpretations provided by multiple IROs.

Deferential review is particularly appropriate when a multiemployer plan provides for deferential review. Because the board of trustees consists of an equal number of employer and employee representatives, the terms of the plan represent the considered balanced judgment of those representatives. Similarly, the interpretation of the plan represents an experienced, balanced judgment taking into account the interests of all of the plan's participants and beneficiaries. This is unlike the single-employer plan context in which the typical plan has fiduciaries that are appointed solely by the employer, and who are typically employed by that particular employer.

For these reasons, we suggest that the IRO should apply a deferential standard of review in those situations where the plan gives discretion to the board of trustees to make such a decision.

Reversal of Adverse Benefit Determination

Although not explicitly addressed in the Interim Final Rules, Technical Release 2010-01 provides that in the event of a reversal of an adverse benefit determination, "the plan immediately must provide coverage or payment (including immediately authorizing or immediately paying benefits) for the claim." Technical Release, § A.4., p. 6. Such a rule is unwarranted because it deprives the plan of meaningful judicial review of an external review decision.

Nothing in the PHS Act alters the right of a participant or beneficiary to seek judicial relief of an adverse benefit determination under 29 U.S.C. § 1132(a)(1)(B) (although exhaustion of administrative remedies is required). Thus, a participant or beneficiary dissatisfied with the result of external review may go to Court to seek relief from that decision.

Similarly, nothing in the PHS Act alters the right of a fiduciary to seek judicial relief from an adverse external review decision under 29 U.S.C. § 1132(a)(3). However, 29 U.S.C. § 1132(a)(3) contains the significant limitation that the relief sought must be equitable. *See Great-West Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 212-14, 122 S. Ct. 708, 714-15 (2002) (equitable restitution allows recovery of money only where specific funds can be identified that have not been dissipated); *Sereboff v. Mid Atlantic Medical Servs., Inc.*, 547 U.S. 356, 362-63, 126 S. Ct. 1869, 1873-74 (2006). No issues are raised if the plan is not required to immediately pay a claim after the external review process is complete. However, the equitable relief limitation might eliminate the plan's ability to recover the payment through judicial review because the precise proceeds of the claim payment may no longer be available for recovery or specifically identifiable. As a result, the requirement of immediate payment is tantamount to denying the plan the right to obtain meaningful judicial review because even if the Court rules in favor of the plan, the plan will not be able to obtain a remedy.

The immediate payment rule causes particular difficulty if the external review is to be conducted under a de novo standard of review because the decision of the IRO will not be that the adverse benefit determination was arbitrary and capricious (as under deferential review). If the IRO is required to apply a deferential standard of review, and the IRO nevertheless reverses the adverse benefit determination, there is a high likelihood that the IRO's decision will be upheld in judicial review since the adverse benefit decision was found to be not only wrong, but completely unreasonable.

In contrast, under de novo review, the IRO might disagree with the adverse benefit determination but the question may be a close one upon which reasonable minds could differ. In that circumstance, there is a greater likelihood of reversal of the IRO's decision upon judicial review. However, the lack of a meaningful remedy results in the plan covering the cost of the claim even if the court ultimately agrees with the plan.
For these reasons, we suggest that the plan not be required to make immediate payment if the plan seeks judicial review within 30 days of the IRO's decision.

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Central States is pleased to have the opportunity to provide comments on the Proposed and Interim Final Regulations relating to Internal Claims and Appeals and External Review Processes. Thank you for considering our comments. Should you have any questions, please feel free to contact me.

Very truly yours,

Thomas C. Nyhan
Executive Director