July 25, 2011

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445–G,
Hubert H. Humphrey Building
200 Independence Avenue, SW.
Washington, DC 20201

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.

CC:PA:LPD:PR
(REG–125592–10)
Courier's Desk
Internal Revenue Service
1111 Constitution Avenue, NW.
Washington, DC 20224.

Re: Group Health Plans and Health Insurance Issuers: Rules Relating to Internal Claims and Appeals and External Review Processes

Dear Sir or Madame:

On behalf of the Parity Implementation Coalition, thank you for the opportunity to comment on the Departments of Treasury, Labor, and Health and Human Services Amendment to Interim Final Rules (IFRs) on the Group Health Plans and Health Insurance Issuers: Rules Relating to Internal Claims and Appeals and External Review Processes.

The Parity Implementation Coalition (Coalition) is a coalition of addiction and mental health consumer and provider organizations. Its members include the American Academy of Child and Adolescent Psychiatry, American Psychiatric Association, American Society of Addiction Medicine, Betty Ford Center, Cumberland Heights, Faces and Voices of Recovery, Hazelden Foundation, MedPro Billing, Mental Health America, National Alliance on Mental Illness, National Association of Psychiatric Health Systems, National Council

for Community Behavioral Healthcare, TeenScreen, and The Watershed Addiction Treatment Programs, Inc. In an effort to end discrimination against individuals and families who seek services for mental health and substance use disorders, these organizations have individually advocated for more than twelve years in support of parity and are committed to the prompt and effective implementation of the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA). We were pleased to see that the nonquantitative treatment limit provisions under MHPAEA and its implementing regulations will be subject to external review.

The Coalition wishes to comment on several modifications contained in the June 24, 2011, Amendment (2011 Amendment) that were made following the Departments' receipt of comments in response to the Interim Final Rule issued on July 23, 2010 (July 2010 regulations). We also provide recommendations below that the Coalition believes will materially improve the process.

Time Period for Notification of Urgent Care Claims

The July 2010 regulations required a plan or issuer to notify a claimant of a benefit determination with respect to a claim involving urgent care, whether adverse or not, as soon as possible, not later than 24 hours after the receipt of the claim by the plan or issuer. The 2011 Amendment to the July 2010 regulations changes the 24-hour requirement to 72 hours.

The Departments attribute the change to comments they received from many plans and issuers that referred to the 24-hour turnaround as a burden. It should be noted that the 2011 Amendment lists consumer advocates, medical associations, and mental health providers as having advocated for maintenance of the July 2010 regulations' 24-hour urgent care plan or issuer notification requirement. The Coalition acknowledges the Departments' point that the 72-hour provision was only intended to serve as a "backstop," since the general rule under the July 2010 regulations and Department of Labor claims procedure mandate a decision as soon as possible "consistent with the medical exigencies involved," thus rendering a change to a 24-hour timeframe irrelevant.

However, the Coalition is concerned that the change to the 72-hour timeframe may result in an unwarranted delay as the patient and the attending provider wait to learn whether or not the plan or issuer denied his or her claim for payment of health care services. Appropriate patient outcomes may be adversely affected. Placing additional stress on patients already confronting the complexities of their acute illnesses is unacceptable by any reasonable standard. Due to the risk of patients experiencing delays as they wait for critical treatment, the Coalition cannot support the 2011 Amendment's substitute of a 72-hour response period for the 24-hour plan and issuer response period. We recommend that the 24-hour response period be reinstated as appropriately set forth in the July 2010 regulations.

State External Review

For a state external review to apply instead of a federal external review, the Affordable Care Act (ACA) provides that the state external review must at a minimum afford the patient consumer the protections of the NAIC Uniform Model Act (NAIC). The July 2010 regulations outline some of the protections required by the NAIC. The Coalition strongly endorses the following requirements:

1) That independent review organizations (IROs) charged with reviewing appeals stemming from health claim denials by health plans be independent from the health plans being reviewed.
2) That an IRO be assigned on a "random basis" or by "another method of assignment" that ensures the independence and impartiality of the assignment process.
3) That the fee an insurance company pays an IRO to review denied health insurance claims not be a function of how many claims decisions the IRO affirms or denies.
4) That the state external review process provide for approval only of IROs that are accredited by a national accrediting organization, and it must be assured
5) That IROs have no conflict of interest that will undermine their independence when adjudicating the merit of health care claims.

The Public Health Services Act (PHSA) provides under § 2179 that if a state external review process does not provide the minimum consumer protections, as mandated by the NAIC, health issuers in the state must implement the federal external review process. The Coalition is concerned about the consumer protections afforded to health care beneficiaries whose claims are externally reviewed under the federal process.

While the July 2010 regulations set forth minimum consumer protections required of IROs participating in a state's external review process, they provide no examples of consumer protections that must be afforded to health care beneficiaries who have their claims reviewed via the federal process. The 2011 Amendment simply explains the criteria for federal external review as 1) claims not meriting a state's external review because of a state's noncompliance with all NAIC consumer protections or 2) patient claims involving medical judgment and/or rescission of health care coverage. The Coalition respectfully requests that the Departments clarify:

- What, if any, consumer protections are guaranteed to health care beneficiaries with claims undergoing federal external review?
- Do the consumer protections available to health care beneficiaries undergoing a federal external review mirror those required of the states' external review processes by the NAIC?

Content Requirements for Notice of Adverse Benefit Determination

The Coalition recommends substituting a requirement that a plan must disclose the denial codes themselves, with an explanation of what those denial codes mean, rather

than notification of opportunity to request codes, in notices of adverse benefit determination. This requirement is supported by the Paperwork Reduction Act. More important, it removes obstacles and reduces the time lag in the appeal process, which is beneficial for all parties concerned.

The July 2010 regulations required plans to provide a description of the plan's or issuer's standard, if any, that was used in denying a claim. For example, a plan must provide a description of a medical necessity standard if the plan applied that standard in denying a claim.

The Coalition respectfully requests that the Departments make clear that, in the event of an adverse benefit determination of a claim for mental health/substance use disorder (MH/SUD) treatment when the claim is going to be externally reviewed, the plan must provide all information necessary for an appropriate analysis under MHPAEA as to whether the test for nonquantitative treatment limitations (NQTLs) is met. This should include any processes, standards or policies as well as how these criteria and policies are applied to the Medical and Surgical conditions comparable to the MH or SU Disorder being denied.

Federal External Review and the Application of Medical Judgment

Non-quantitative Treatment Limitation Provisions in the Mental Health Parity and Addiction Equity Act

It is our view that the 2011 Amendments to the July 2010 regulations include significant provisions and clarifications respecting adverse benefit determinations eligible for external review. Section 2590.715-2719(d)(1)(A) from the 2011 Amendment defines an adverse benefit determination.

> (A) An adverse benefit determination (including a final internal adverse benefit determination) by a plan or issuer that involves medical judgment (including, but not limited to, those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit; or its determination that a treatment is experimental or investigational), as determined by the external reviewer; …

The preamble to the 2011 Amendment to the July 2010 regulations makes it clear that the scope of claims originally proposed as eligible for review under the July 2010 IFR is suspended. This temporarily narrows the scope of claims eligible for external review to those "that involve medical judgment (excluding those that involve only contractual or legal interpretation without any use of medical judgment) as determined by the external reviewer." It is clear, therefore, that external review of claims that are solely legal or contractual matters (i.e., without the involvement of medical judgment) has been temporarily suspended. However, by operation of the 2011 Amendment a legal or contractual matter that by its nature embodies medical judgment (as determined by the reviewer) is eligible for external review.

Illustrations provided in the 2011 Amendment of situations in which a claim is considered to involve medical judgment include adverse benefit determinations based on: "Whether a plan is complying with the nonquantitative treatment limitation [NQTL]

provisions of the Mental Health Parity and Addiction Equity Act [MHPAEA] and its implementing regulations, which generally require, among other things, parity in the application of medical management techniques." These provisions in the 2011 Amendment are highly significant in our view and give rise to various scenarios that, in our view, require further clarification and illustrations as discussed below.

The Coalition believes that these provisions are important because they appropriately establish that adjudication of adverse benefit determinations involving medical judgment and compliance with the NQTL provisions of MHPAEA is, in fact, a two-part test.

Part one of the test is completion of an independent external review of the adverse benefit determination and its basis. The claim denial may be determined to be appropriate based on the applicable stated criteria and/or plan provisions. For example, a health plan denies an admission for inpatient treatment based on its medical necessity criteria and the reviewer, having examined the pertinent patient medical information, concurs with the plan that its medical necessity criteria were not met.

Part two of the test requires that the medical necessity criteria, the plan review processes, evidentiary standards and other requirements must also be deemed "comparable" and applied "no more stringently" for mental health and substance use disorders than those applied to other medical conditions under the nonquantitative treatment limit provisions of MHPAEA. If the review of the plan's criteria and/or processes reveals that they are not in compliance with the NQTL requirements of MHPAEA, then an otherwise "valid" claim denial is invalid because it violates the legal requirements set forth in the NQTL requirements of MHPAEA.

In order for the potential of this NQTL external review process to be realized, the Coalition believes several matters require attention. First, as you know, applying the NQTL test is a complex matter. It would be difficult, at best, for external reviewers to apply the NQTL provisions to the myriad situations that will be forwarded to them for review. We believe it is imperative that appropriate sub-regulatory guidance be issued and that it provide a quantitative test to determine if the plan applied its criteria and standards roughly equally under the behavioral health and medical/surgical benefits. The Coalition recommends that the plan criteria or requirements must be deemed "comparable" and applied to at least 50 percent of medical/surgical conditions to meet the MHPAEA NQTL compliance test.

Second, whether or not an adverse benefit determination involves medical judgment is determined by the external reviewer. We believe that, given the complexity of the NQTL provisions, guidance regarding what constitutes medical judgment in this context will be necessary.

Third, in order to properly 'adjudicate' adverse benefit determinations undergoing external review that have MHPAEA NQTL ramifications, it will be necessary to access health plan information pertaining to the medical management of medical/surgical benefits. The Coalition has communicated to you separately on the importance of

further clarification on plan obligations to disclose necessary information. We again urge you to provide such clarification in the form of sub-regulatory, or final guidance consistent with the Coalition's July 19, 2011, letter. Within the next 10 business days the Coalition will submit specific recommendations as to what specific information plans should be required to disclose in order to enable an NQTL analysis.

In addition, the Coalition believes further guidance is necessary in general on what a "recognized clinically appropriate standard of care" is. With respect to external reviews, we do not see how they can be performed effectively if a reviewer does not have some guidance as to what is acceptable under MHPAEA with respect to this exception to the NQTL requirements. That is, a plan which issues an adverse benefit determination with MHPAEA implications subject to external review, could assert that the comparability test of the NQTL rule does not apply by virtue of the exception clause thereto (i.e., recognized clinically appropriate standards permit a difference). An external reviewer needs some guidance to determine the appropriateness of the basis of the claimed exception.

In this regard, the Coalition believes external review for the NQTL provisions under MHPAEA must clarify the definition of the "clinically recognized standard of care" safe harbor under MHPAEA. The Coalition thinks the standard must be:

1. Independent and not developed solely by the health plan;
2. Based on input from multiple experts and stakeholders, including academic researchers, practicing clinicians, and consumer leasers with subject matter expertise;
3. Recognized or accepted by multiple nationally recognized consumer and provider organizations and/or national accrediting organizations; and
4. Based on objective scientific evidence.

In addition to the above recommendations for sub-regulatory guidance, the Coalition has the following recommendations:

- The language at paragraph (d)(1) of the 2011 Amendment should be amended to:
    1.) Include in the list of illustrations "compliance with MHPAEA and its implementing regulations;"
    2.) Restate the clarifying language included in the preamble discussion that excludes those claims that involve only contractual or legal interpretation without any use of medical judgment; and
    3.) Include within the list of illustrations one or more illustrations that demonstrate MHPAEA and clarify the essential two-part nature of the acceptability test for these claims).

We offer the following illustrations for your consideration for inclusion in the regulation to clarify the application of MHPAEA to external reviews.

Illustration 1

Facts. An inpatient admission for an MH/SUD patient is denied for lack of medical necessity. The plan's criteria stipulate that the patient must have demonstrated failure at a lower level of care prior to inpatient care. The plan's adverse benefit determination is consistent with its stated criteria and the patient's medical history and is valid on its face. However, upon claimant's review it is asserted that the plan's criteria for comparable medical/surgical conditions do not stipulate 'fail first' as an authorization prerequisite for inpatient care.

Conclusion. The application of the plan's criteria in this case involves medical judgment. Given that this situation involves a claim for MH/SUD and that medical management techniques have been applied (which are NQTLs under MHPAEA), the medical management techniques are subject to the MHPAEA test for comparability. This claim is eligible for external review.

The external review analysis confirms that the assertion of the claimant that MHPAEA is implicated is proper and an external review is conducted and a decision is rendered that the fail-first criterion is not compliant with MHPAEA and its implementing regulations. Therefore the medical necessity denial was invalid.

Illustration 2

Facts. An adverse benefit determination is issued for an inpatient admission for a patient with a MH/SUD condition. These admissions must be pre-certified. Inpatient admissions for medical/surgical conditions do not require pre-certification. Hence, the medical management protocols are different.

Conclusion. The plan's determination that the admission is not warranted based on a failure to meet the plan's standard for medical necessity involves medical judgment. The claim is eligible for external review.

The external review raises two or more issues. First, there is the question of the validity of the medical necessity denial on its face. (That is, based on the plan's standards for medical necessity and the medical documentation for the patient.) In addition, there is the matter of 1) whether the plan's standard for medical necessity for MH/SUD is in compliance with the NQTL test; and 2) whether or not the difference in medical management protocols is in compliance with the NQTL test. In this case, the medical necessity denial can be valid on its face and the relevant criteria in compliance with the NQTL rule. However, the differential in the medical management protocols is improper under the NQTL test and therefore the medical necessity denial is invalid.

Illustration 3

Facts. Plan requires pre-authorization for the 12^{th} outpatient visit and beyond. Authorization is denied for visits 13 and beyond.

Conclusion. The plan's determination that the outpatient visits are not warranted is based on a failure to meet the plan's standard for medical necessity and, hence, involves medical judgment. The claim is eligible for external review.

Again, the external review raises two or more issues as in Illustration 2. The two-part test needs to be applied to determine the validity of the denial for the additional outpatient visits.

External Review Expertise

The Coalition is concerned over whether the IROs will have the requisite guidance to appropriately exercise medical judgment needed to accurately use the rules of MHPAEA to adjudicate patients' health care claims, especially where those claims involve mental health and substance use treatment. The Coalition is also concerned the July 2010 regulations do not require those conducting the review and making important claims decisions to have an appropriate degree of medical or clinical education and training in the particular field at issue, or to be currently in active practice and currently credentialed in the particular field at issue, when rendering a decision related to medical necessity or appropriateness. The July 2011amendments do not alter this.

Because of this, the decisions of physicians and other credentialed providers who actually directly treat and personally interact with patients are at risk of being overturned by individuals who lack medical or clinical expertise in the particular field at issue, and/or not currently in practice or credentialed in the field at issue. The final rule should require that reviews and decisions based on medical necessity and appropriateness at both the internal and external levels of appeal, be conducted by an individual with the appropriate medical and clinical education and training that meets or exceeds the education and credentialing of the treating provider in the field at issue, and who is currently in active practice and credentialed in the particular field at issue.

De Novo Review

Regulations issued in July 2010 permitted claimants an immediate review of their claims *de novo* if a plan or issuer failed to "strictly adhere" to all of the regulations' requirements in the initial review of an internal claim. These 2010 regulations clarified that the reviewing tribunal should not give special deference to the plan or issuer's decision but should resolve the dispute *de novo.* Alternatively, the 2011 rule provides an exception to this "strict compliance" standard, allowing the tribunal to avoid reviewing claims *de novo* in five distinct situations the Departments consider to be "for errors that are minor and meet certain other specified conditions." The Coalition asks that the Departments conduct both internal and external reviews applying the "strict compliance" standard outlined in the July 2010 regulations. Errors made by the reviewing tribunal should trigger a *de novo* review of the claimant's claim, whether the claim is undergoing internal or external review. Application of the strict compliance standard, and resulting use of the *de novo* standard in situations in which a plan or issuer fails to 'strictly adhere' to internal and external review requirements, will promote accountability and good faith among insurance review organizations.

Conflict of Interest

In addition, the final rule should include in the current conflict of interest provisions that an individual conducting a review and/or rendering a decision based on medical necessity and appropriateness at both the internal and external levels of appeal, was in no way involved in any previous considerations of the case.

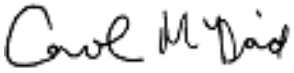
Deemed Exhaustion of Internal Claims and Appeals Processes

The Coalition strongly supports the provision clarifying that if a plan or issuer fails to strictly adhere to all of the requirements of the July 2010 regulations the claimant is deemed to have exhausted the plan or issuer's internal claims or appeals processes, regardless of whether the plan or issuer asserts that is has substantially complied, and the claimant may initiate any available external review process or remedy available under Employee Retirement Income Security Act (ERISA) or state law.

Thank you again for the opportunity to comment. Please do not hesitate to contact Sam Muszynski (703-907-8594; imus@psych.org) or Carol McDaid (202-737-8168; cmcdaid@capitoldecisions.com) with questions or if we may be of assistance.

Sincerely,

Irvin L. Muszynski, JD
Co-Chair
Parity Implementation Coalition



Carol McDaid
Co-Chair
Parity Implementation Coalition