General Comment

Please find attached the Parity Implementation Coalition's comments on the Interim Final Rules under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008.

Attachments

EBSA-2009-0010-DRAFT-0660.1: Comment on FR Doc # 2010-2167
Parity Implementation Coalition

April 30, 2010

BY HAND DELIVERY AND ELECTRONIC SUBMISSION

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Room N–5655
U.S. Department of Labor
200 Constitution Avenue, NW.
Washington, DC 20210
Attention: RIN 1210–AB30

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201
File Code: CMS-4140-IFC

CC:PA:LPD:PR (REG–120692–09)
Courier’s Desk
Internal Revenue Service
1111 Constitution Avenue, NW
Washington, DC 20224
REG-120692-09

Re: Interim Final Rules under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008

Dear Secretary Solis, Secretary Sebelius, and Commissioner Shulman:

The Parity Implementation Coalition ("Coalition") is pleased to provide comments on the Interim Final Rules under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 ("Interim Final Rules" or "regulations").¹

The Parity Implementation 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, Bradford Health Services, Faces and Voices of Recovery, Hazelden Foundation, Mental Health America, National Alliance on Mental Illness, National Association of Psychiatric Health Systems, National Council for Community Behavioral Healthcare 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 advocated for more than twelve years in support of parity legislation and are committed to the prompt and effective implementation of the Mental Health Parity and Addiction Equity Act of 2008 ("MHPAEA" or "Act").

The Coalition appreciates the significant work and analysis that has gone into the Interim Final Rules. The Coalition commends the Departments for their efforts to ensure the Act is implemented in a manner that will convey strong parity protections consistent with the intent of Congress. On May 28, 2009, the Coalition submitted comments and a detailed legal analysis to the Departments that outlined the Coalition's views regarding implementation of the Act. We are pleased that the Departments incorporated many of these recommendations into the Interim Final Rules.

The Coalition respectfully submits the following recommendations to further strengthen the Interim Final Rules:

- The Department should make clear that MHPAEA requires parity with respect to scope of services and makes clear that the parity requirements apply to both quantitative and non-quantitative treatment limitations;

- The Departments should clarify that all medical/surgical and MH/SUD benefits must be included within the six classifications created in the Interim Final Rules, and plans must ensure parity both across and within classifications;

- To ensure clarity and consistency with the Act and previous regulations, the Departments should adopt the Interim Final Rules’ definitions of substantially all and predominant in the Final Rules, and maintain the requirement for a single deductible;

- The Departments should clarify that NQTLs are subject to the predominant and substantially all standard and the comparable and no more stringently standards, and ensure that exceptions to these standards are based on independent and objective clinical policies and standards;

- To ensure patients are able to effectively understand and respond to benefit claims denials, the Departments should require plans to disclose the reason for the denial within a specific timeframe;

- The Departments should remain consistent with the statute and prior regulations by using actual costs as the basis for the increased cost exemption;

- The Interim Final Rules’ preemption provisions will normally allow stronger state parity laws to remain in force, and should therefore be included in the Final Rules;

- To ensure effective implementation of the MHPAEA in Medicaid, the Departments should release any additional regulations related to the application of MHPAEA to
Medicaid managed care organizations in a timely manner and should clarify that the IFR applies to Medicaid managed care organizations currently;

- The Departments should establish best practices that plans must use when defining a MH/SUD, including basing such definitions on an independent, national or international standard or state government guideline; and

- To remedy existing inequities and ensure effective implementation of the Act pending issuance of the Final Rules, the Departments should issue timely guidance on issues currently addressed in the regulations.

We appreciate the Departments’ consideration of these recommendations and look forward to working with you to implement these important patient protections.

I. MHPAEA Requires Parity with Respect to Scope of Services and Makes Clear that the Parity Requirements Apply to Both Quantitative and Non-quantitative Treatment Limitations.

The Interim Final Rules state that the “regulations do not address the scope of services issue,” and request comment “on whether and to what extent MHPAEA addresses the scope of services or continuum of care provided by a group health plan or health insurance coverage.”2 The clear language of the MHPAEA requires that the scope of mental health and substance use disorder (MH/SUD) services be no more restrictive than the scope of services for medical surgical.

A. MHPAEA Clearly States that the Parity Requirements Apply to Services.

Mental health benefits are defined in the Act as “benefits with respect to services for mental health conditions.”3 [Emphasis added] In like manner, the Act defines substance use disorder benefits as “benefits with respect to services for substance use disorders.”4 [Emphasis added] The plain language of the Act, with its explicit reference to services in the definitions of mental health and substance use disorder benefits, is strong evidence that Congress intended to include services within the definition of MH/SUD benefits. Under the Mental Health Parity Act of 1996, a similar definition was used for both MH/SUD and medical/surgical benefits.

This interpretation is also confirmed by other sections of the Act. Under the section “Availability of Plan Information,” the Act explains the availability of plan information when “payment for services with respect to mental health or substance use disorder benefits” is denied.5 [Emphasis added] Congress’ explicit use of the term “services” again demonstrates that Congress contemplated some level of services required under the Act.

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4 Id.

5 Id.
Interpreting the Act otherwise would lead to an illogical result that should not be ascribed to Congress. If health plans were allowed to qualify as providing “benefits” while not providing any services, it would severely undermine the statute passed by Congress.

B. The Act Ensures Scope of Services Parity between Medical/Surgical and MH/SUD Benefits by Prohibiting a Plan from Imposing a Limitation on MH/SUD Services that is Either Unknown or Infrequently Used in the Medical/Surgical Benefit.

The logical extension of the analysis above is to determine how many services would suffice to meet MHPAEA’s requirements. Some have argued, for example, that an employer can choose to provide benefits for a mental health condition and then choose to not cover any treatment services specific to that condition (e.g., depression is covered but antidepressant drugs are not covered nor is psychotherapy covered). The question is: Does a plan’s decision not to provide services, or to provide very few services, for a mental health condition violate the treatment limitation section of the Act?

The Act states that no treatment limitation can be more restrictive for a MH/SUD condition than for a medical/surgical condition. This language constrains the ability of plans to impose treatment limitations, but does not preclude them from doing so entirely. The applicable language states only that MH/SUD treatment limitations must be “no more restrictive” than the treatment limitations for medical/surgical benefits. Thus, this language implicitly recognizes that there may be limits in the coverage of medical/surgical benefits. Indeed, the practical reality of insurance coverage demonstrates that these limits exist. Accordingly, some limits on MH/SUD services are authorized.

Any limits applied, however, must be consistent with the text of the Act. The treatment limitation section of the Act states that plans must ensure that treatment limitations applicable to MH/SUD benefits “are no more restrictive than the predominant treatment limitations applied to substantially all medical and surgical benefits covered by the plan (or coverage).” The predominant and substantially all standards, by their very language, are high hurdles that require a plan to apply a treatment limitation to a significant percentage of medical/surgical benefits before it applies a treatment limitation to MH/SUD benefits. If the limitation does not apply to substantially all medical/surgical benefits, or is not a predominant limitation, it cannot be applied to MH/SUD benefits.

This statutory standard requires scope of services parity between medical/surgical and MH/SUD benefits. The statutory language prohibits a plan from imposing a limitation on MH/SUD services that is either unknown or infrequently used in the medical/surgical benefit. In doing so, it ensures a similar scope of services between MH/SUD and medical/surgical benefits. Accordingly, it is unlikely that a plan that limited services to one or no MH/SUD services under a particular diagnosis would meet the requirements of the Act. If a plan chose to severely limit services, it would have to show that the limitation is the most common or frequent (i.e., predominant) type of limit under the plan. In addition, the plan would have to show that it applies similar limits to substantially all medical/surgical benefits under the plan.

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6 § 1185a(a)(3)(A)(i).

7 § 1185a(a)(3)(A)(ii).
Proponents of limiting services may point to the statutory definition of MH/SUD benefits to argue that there is no scope of service parity because a plan has the ability to define the services under the terms of the plan. The statute defines MH/SUD benefits as "benefits with respect to services for mental health conditions, as defined under the terms of the plan and in accordance with applicable Federal and State law." Proponents of limiting services might argue that plans maintain the flexibility to determine which services to provide because the Act specifically allows them to be "defined under the terms of the plan." The Coalition reads this language to mean that it is the mental health conditions and substance use disorders that are "defined under the terms of the plan," not the MH/SUD services. Under this reading, the plan appears to have flexibility as to what mental health conditions and substance use disorders it covers. However, once it decides to cover the condition or disorder, it is subject to the parity requirements governing services that are described below (predominant and substantially all, comparable and no more stringently, all services must be within one of the six classifications, etc).

C. The Scope of Services Parity Requirement Applies to Both Quantitative and Non-quantitative Treatment Limitations.

The Act's broad, inclusive language applies parity requirements to all treatment limitations, both quantitative and non-quantitative. The Act states simply that "treatment limitations" must meet the statute's requirements. It does not differentiate between types of treatment limitations, but rather applies parity requirements to all types of these limitations. The Act provides guidance as to the meaning of the term when it states that "treatment limitation includes limits on the frequency of treatment, the number of visits, days of coverage, or other similar limits on the scope and duration of treatment." [Emphasis added] Use of the word "includes" shows that the list means that the listed treatment limitations are simply examples, not an exhaustive list of the possible treatment limitation subject to parity. In other words, the list is demonstrative rather than comprehensive. If Congress wanted the treatment limitations section to only apply to a subset of treatment limitations, it could have used stronger, more limiting language. That it did not do so demonstrates that Congress envisioned broad application of the treatment limitations parity requirement. The statute supports parity in scope of services by requiring that all treatment limitations—both quantitative and non-quantitative—be no more restrictive in MH/SUD than in medical/surgical.

Since passage of the Act, a number of plans have argued that while parity is required with respect to QTLs, there is no scope of service parity requirement related to NQTLs; therefore, they can use NQTLs to impose more restrictive limits on MH/SUD services than on medical/surgical services. Such an interpretation would lead to an absurd result not in harmony with the intent or letter of the Act. If this argument were accepted, consumers would be protected from higher copayments or arbitrary day limits on services but exposed to 100 percent deletion of essential treatment services through use of a restrictive NQTL. As documented in this submission, many plans have already interpreted the Act in this way and have deleted many well established, evidenced-based treatment levels and categories for both MH and SUD in their 2010 benefits plans.

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8 § 1185a(e)(4), (5).

9 § 1185a(a)(3)(B)(iii).

10 Id.
In the absence of clear regulatory guidance to the contrary, plans may continue this practice going forward.

D. The Act Further Strengthens Scope of Service Parity Requirements by Prohibiting Separate Treatment Limitations.

The Act also ensures scope of service parity by prohibiting separate treatment limitations applied to MH/SUD services that are not applied to medical/surgical services. The treatment limitations section of the Act states that health plans must ensure that “there are no separate treatment limitations that are applicable only with respect to mental health or substance use disorder benefits.”11 This broad language is a further important protection to ensure that there is parity in the scope of services offered.

II. The Departments Should Clarify that All Medical/Surgical and MH/SUD Benefits Must Be Included Within the Six Classifications Created in the Interim Final Rules, and Plans Must Ensure Parity Both Across and Within Classifications.

A. The Interim Final Rules Create Six Classifications Within which All MH/SUD Benefits Must Be Included, and Plans are Prohibited from Creating New Classifications.

The regulations create six classifications of benefits for purposes of applying the parity rules. Some have argued that a plan could create a new classification outside of the six and decide that the classification is not subject to parity requirements. Such an action would be inconsistent with the language of the regulation that limits the classifications to the stated six, contrary to the text of the regulation and the statute, and inconsistent with Congressional intent. We request that the Departments clarify in the Final Rules that all medical/surgical and MH/SUD benefits must be included within one of the six classifications and that additional classifications are not permissible.

The parity regulations create a six-classification scheme to implement the parity requirement.12 The regulations state clearly that these six classifications are the “only” possible classifications for implementing the parity rules.13 Thus, the plain language of the regulations prohibits a plan from creating a new classification of benefits. If a plan cannot create a new classification, it seems clear that all MH/SUD and medical surgical benefits covered by the plan must fit into one of these classes.

The danger in allowing a new classification is the possibility that, since the classification is not specified in the regulations, it would fall outside the parity protections of the law. The text of the underlying statute demonstrates that creating a classification that is not subject to parity would be impermissible. The Act states that if a plan offers both medical/surgical and MH/SUD benefits, the financial requirements and treatment limitations applicable to MH/SUD benefits may be no

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11 Id.

12 The classifications are: (1) inpatient, in-network; (2) inpatient, out-of-network; (3) outpatient, in-network; (4) outpatient, out-of-network; (5) emergency care; and (6) prescription drugs. 75 Fed. Reg. 5433.

more restrictive than those applicable in the medical/surgical benefit. Unless a plan’s costs increase by a certain threshold, there are no exceptions to this policy. If a plan were to create a new classification and treat MH/SUD benefits more restrictively within that classification than medical/surgical benefits, the plan would violate this clear statutory language.

In addition, the Act prohibits a plan from imposing separate cost-sharing requirements or treatment limitations that are applicable only with respect to MH/SUD benefits. To the extent that a plan creates a separate classification that applies treatment limitations or financial requirements only to the MH/SUD benefits within that classification, the plan would violate the clear meaning of the statute.

It is important to note that the prohibition on the creation of a new classification applies both on the medical/surgical and on the MH/SUD side. A plan is prohibited from moving medical/surgical benefits into a newly created class and denying parity to MH/SUD benefits by claiming that the medical/surgical benefits are part of a new class that is not subject to parity requirements. In similar fashion, a plan could not move MH/SUD benefits into a newly-created class and argue that there are no parity requirements with respect to these MH/SUD benefits.

Moving certain services outside the six classes to avoid the parity requirements would also be a clear violation of Congressional intent. The statute was enacted to remedy “the discrimination that exists under many group health plans with respect to mental health and substance-related disorder benefits.” If a plan were able to move benefits outside the six classes, and thereby evade parity requirements, the Act would be a hollow protection against the discrimination it was enacted to remedy. Congress wanted MH/SUD benefits to be provided no more restrictively than medical/surgical benefits. Allowing plans to create a benefit classification that is not subject to the parity requirements opens the door wide to restrictions on MH/SUD that are more restrictive than those applied to medical/surgical benefits.

B. The Act and the Regulations Define and Require Parity in Scope of Services Across and Within the Required Six Classifications.

Although the preamble to the regulations states that the Interim Final Rules do not address scope of services, the Act and many sections of the regulations confer a scope-of-service parity requirement between MH/SUD benefits and medical/surgical benefits. In light of the language of the Act and the positions already taken by the Departments in the regulations, we request that the Final Rules clarify that benefits for MH/SUD must be comparable in scope to the benefits provided in medical/surgical both across and within each classification.

The Act is clear that limits on the scope and duration of treatment must be applied no more restrictively in the MH/SUD benefit than in the medical/surgical benefit. The statute defines treatment limitations as "limits on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment." [Emphasis added] The statute then prohibits limitations on the scope or duration of treatment under the MH/SUD benefit that are more restrictive than those imposed under the medical/surgical benefit. Thus, the plain language of the statute explicitly discusses scope of services and requires parity in scope.

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The regulations also require parity in the scope of services offered across classifications. The regulations require that when a plan "provides [MH/SUD] benefits in any classification of benefits" described in the rules, MH/SUD benefits "must be provided in every classification in which medical/surgical benefits are provided." This language demonstrates that if a plan is going to offer one MH/SUD service, it must offer a range of these services across classifications.

Similarly, the preamble and the text of the regulations state that "if a plan provides benefits for a mental health condition or substance use disorder in one or more classifications but excludes benefits for that condition or disorder in a classification in which it provides medical/surgical benefits, the exclusion of benefits in that classification for a [MH/SUD] otherwise covered under the plan is a treatment limitation." This statement requires parity across classifications in the scope of services that are offered for a particular condition. For example, imagine a plan that provides benefits for schizophrenia in the outpatient in-network classification but excludes benefits for schizophrenia for the inpatient in-network classification, even though it offers medical/surgical benefits in that classification. This language is a scope of services parity requirement because it precludes the ability of a plan to limit MH/SUD treatment services to less than all of the six classifications.

The regulations' standard governing the application of quantifiable treatment limitations (QTLs) and non-quantifiable treatment limitations (NQTLs) also demonstrates that a range of services must be offered in the MH/SUD benefit if offered in the medical/surgical benefit both across and within the six classifications. The regulations state that QTLs and NQTLs cannot be applied more restrictively or more stringently to MH/SUD benefits than to medical/surgical benefits. This limitation implicitly confers a scope of services in the MH/SUD benefit that is at least similar to the scope of services offered in the medical/surgical benefit. If a treatment limitation cannot be applied more restrictively or more stringently in one benefit than in another, the scope of services offered in each benefit should be largely analogous. For example, consider a plan that uses the NQTL of "medical appropriateness." If a plan restricts medical/surgical benefits to those that are medically appropriate, this NQTL must be comparable and applied no more stringently to MH/SUD benefits. If the NQTL is applied equally stringently to MH/SUD benefits, the scope of these benefits would be similar to those on the medical/surgical side.

The regulations' requirement for scope of services parity within classifications is well demonstrated by an example. Imagine a plan that offers only one type of MH/SUD treatment service in each of the six required classes, while at the same time offering many medical/surgical services within each classification. For example, a plan offers a mental health benefit for depression. Because of this coverage, it is clear from both the Act and the Interim Final Rules that some mental health benefits must be offered in all six classifications in which there is a medical benefit. Without clear guidance about a scope requirement within each benefit class, however, a plan might attempt to offer only outpatient visits to nonpsychiatric physicians for prescription of psychotropic medications and refuse to reimburse for psychotherapy from any specialty mental health provider, such as psychologists and masters-level social workers.

Although the regulations do not require a plan to cover identical MH/SUD and medical surgical services within a classification, they do require that the limitations in each MH/SUD classification be no more restrictive than the limits in the corresponding medical/surgical classification. If limitations were being applied in a no more restrictive manner in the situation above, it is unlikely that only one MH/SUD service would be covered while many medical/surgical
services are covered. Presumably, the plan has developed some reasoning for excluding coverage of other MH/SUD services. If the reason the plan is offering such limited MH/SUD services in a classification is that the plan is applying a treatment limitation to MH/SUD benefits that is more restrictive than the predominant treatment limitation applied to substantially all medical/surgical benefits in the same classification, the plan has violated the requirements of the parity regulations.

Finally, the regulations state that “the parity requirements for financial requirements and treatment limitations are applied on a classification-by-classification basis.” The Departments should clarify that this broad language confers scope-of-services requirements within each classification.

C. The Regulations and the Act Prohibit a Plan from Refusing to Cover a MH/SUD Service with no Medical/Surgical Analogue if it does not Apply a Similar Standard in the Medical/Surgical Benefit.

A plan that refuses to cover a MH/SUD service because there is no medical/surgical analogue violates both the regulations and statute if it does not likewise refuse to cover medical/surgical benefits that have no MH/SUD analogue. In addition, practical and policy concerns weigh against allowing plans to refuse to cover MH/SUD benefits without medical/surgical analogues.

In most cases, a plan that refuses to cover a MH/SUD service because it claims there is no medical/surgical analogue will make this decisions based on a NQTL, as opposed to a numbers-based QTL. Accordingly, this action will be subject to the “comparable” and “no more stringently” standard.

The regulations require NQTLs to be “comparable.” A rule that prohibits coverage for MH/SUD treatments that have no medical/surgical analogue, but does not prohibit coverage for medical/surgical services that have no MH/SUD analogue, is not comparable on its face. In such a situation, the plan would be in violation of the regulations.

This interpretation is also supported by the text of the Act. The treatment limitations section of the Act states that health plans must ensure that “there are no separate treatment limitations that are applicable only with respect to mental health or substance use disorder benefits.” A plan that refuses to cover a MH/SUD service that has no analogue in medical/surgical, but does not apply a similar standard to medical/surgical benefits, violates the

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16 The “comparable” and “no more stringently” standard requires that: “Any processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in a classification must be comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation with respect to medical surgical/benefits in the classification.” 75 Fed. Reg. 5416

17 Id.

18 § 1185a(a)(3)(A)(ii).
parity requirements of the statute because it imposes a treatment limitation “applicable only with respect to” MH/SUD benefits.

As further assistance to the Department, Appendix 1 provides an analysis of how a scope of services parity requirement can be applied in an affordable and equitable manner.

III. To Ensure Clarity and Consistency with the Act and Previous Regulations, the Departments Should Adopt the Interim Final Rules’ Definitions of Substantially All and Predominant in the Final Rules, and Maintain the Requirement for a Single Deductible.

A. The Substantially All and Predominant Definitions in the Regulations are Clear, Logical, and Consistent with the Implementation of Previous Mental Health Parity Laws.

The Coalition supports the Departments’ definitions of substantially all and predominant. They are clear, logical and will help to ensure the strong parity protections envisioned by Congress, and they are consistent with past Agency actions related to mental health parity.

Under the regulations, a financial requirement or treatment limitation applies to substantially all benefits in a classification if it applies to at least two-thirds of the benefits in that classification. If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of the medical/surgical benefits in a classification, that type of requirement or limitation cannot be applied to MH/SUD benefits in that classification. The regulations implementing the Mental Health Parity Act of 1996 (MHPA) used a similar two-thirds test to invoke the parity protections of that law.\(^{19}\) Under the MHPA regulations, if a plan imposes aggregate or lifetime limits on the medical/surgical benefit, the mental health benefit can be no more restrictive than the features which apply to two-thirds of the medical and surgical limits. The two-thirds standard is thus consistent with the position taken by the Departments since the enactment of the MHPA. Additionally, it is a clear and logical standard that providers and plans understand now. The Coalition supports using the same standard in implementing the MHPAEA.

According to the Act, a financial requirement or treatment limit is considered to be predominant if it is the most common or frequent of such type of limit or requirement.\(^{20}\) The regulations interpret this definition to state that if a level of a type of financial requirement or treatment limitation applies to more than one-half of medical/surgical benefits, it is predominant. The Coalition supports this standard as a reasonable interpretation of the statutory language that will help to ensure meaningful parity protection.

B. Combined Deductibles are Consistent with the Goals of the Act.

The Coalition strongly supports the use of combined deductibles as the most effective way to achieve parity within cumulative financial requirements. Under a combined deductible, expenses for both MH/SUD and medical/surgical accumulate together to satisfy a single combined

\(^{19}\) 62 Federal Register 66931, 66933 (Dec. 22, 1997).

deductible before the plan provides either MH/SUD or medical/surgical benefits. The Coalition agrees that this structure is more consistent with the policy goals that led to the enactment of MHPAEA than separately accumulating deductibles. The intent of the Act was to end discriminatory insurance practices with respect to MH/SUD benefits and affirm the necessity and appropriateness of MH/SUD benefits in comprehensive care. Separate deductibles for MH/SUD services would continue the inappropriate distinctions between medical and mental health care services that the Act was enacted to prevent, and could lead to continued higher out-of-pocket spending and discrimination for addiction and mental health consumers. The Coalition strongly urges the Department to include a combined deductible in the Final Rules.

IV. The Departments Should Clarify that NQTls are Subject to the Predominant and Substantially All Standard and the Comparable and No More Stringently Standards, and Ensure that Exceptions to these Standards are Based on Independent and Objective Clinical Policies and Standards.

A. The Regulations Define and Apply NQTls in a Manner Consistent with the Parity Statute.

The regulations’ application of parity requirements to both QTLs and NQTls is consistent with the Act, which allows for broad application of the treatment limitation parity requirements. NQTls applied by plans must be comparable and applied no more stringently to MH/SUD benefits than to medical/surgical benefits.

The statute states that the definition of treatment limitations “includes limits on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope of duration and treatment.”21 The list in question states that treatment limitation “includes” limits on frequency, number of visits, and days of coverage. As noted previously, the word “includes” shows that the list is demonstrative rather than comprehensive. In other words, choice of the word “includes” means that the listed treatment limitations are simply examples, not an exhaustive list of the possible treatment limitations subject to parity.22 If Congress had wanted the treatment limitations section to only apply to the listed limits, it could have use stronger, more limiting language. The result of this interpretation is that it is consistent with the language of the Act, for example, to apply the treatment limitation parity requirements to both limits on frequency (one of the listed items) and medical management criteria (not specifically listed) which imposes a limitation on the treatment benefit. Accordingly, the regulations’ inclusion of both QTLs and NQTls as part of the umbrella term “treatment limitation” is consistent with the language of the statute.

The regulations state clearly that any “processes, strategies, evidentiary standards, or other factors” used in applying a NQTl to MH/SUD benefits in a classification must be “comparable to” and be applied “no more stringently” than the processes, evidentiary standards, or other factors used in applying the limitation to medical/surgical benefits in a classification.23 The sole exception to this


22 Id.

rule is in cases where “recognized clinically appropriate standards of care...permit a difference.”

This rule sets forth two critical standards for determining plan compliance with the regulations.

The first standard for determining plan compliance is the manner in which the processes, strategies, evidentiary standards, and other factors are used in applying the NQTL. The regulation states that a plan may not impose a NQTL unless the processes, strategies, evidentiary standard, or other factors “used in applying” the NQTL are comparable to and “applied” no more stringently in medical/surgical than in MH/SUD. Under this construct, plans can have the same NQTL in both MH/SUD and medical/surgical and still violate the parity requirements by applying these NQTLs differently. The regulation states explicitly that the no more stringently standard was “included to ensure that any processes, strategies, evidentiary standards, or other factors that are comparable on their face are applied in the same manner to medical/surgical and to MH/SUD benefits.”

The examples provided in the regulations illustrate this principle clearly. Example 1 of Section (c)(4)(iii) states that a health plan limits benefits to treatment that is medically necessary. The plan requires concurrent review for MH/SUD benefits, and retrospective review for medical/surgical benefits. In such a case, the same NQTL—medical necessity—applies to both MH/SUD and medical surgical benefits. However, the plan violates the parity rules because the process of applying the NQTL is not comparable. Concurrent review is not comparable to retrospective review. Similarly, example 4 presents a situation in which a plan violates the parity requirements by applying the same NQTL in a non-comparable manner. In the example, a plan covers medically appropriate treatments. The plan automatically excludes coverage for antidepressant drugs that are given a black box warning by the Food and Drug Administration, but provides coverage for other black box drugs if the physician obtains authorization from the plan that the drug is medically appropriate for the individual. In this example, the NQTL—medical appropriateness—is applied to both MH/SUD and medical/surgical. However, the unconditional exclusion of antidepressants is not comparable to the conditional exclusion of other drugs with a black box warning. Thus, plans must ensure that the manner a NQTL is applied is comparable and no more stringent in MH/SUD than in medical/surgical, even if the NQTL itself is the same.

The second critical prohibition prevents a plan from instituting a NQTL in MH/SUD that is not comparable to a NQTL in the medical/surgical benefit. In example 5, plan participants are able to access MH/SUD benefits only after exhausting counseling sessions offered under an employee assistance program (EAP). The plan violates the regulations because no similar exhaustion requirement applies with respect to medical/surgical benefits. In such a situation, the question is not whether the same NQTL is applied differently across MH/SUD and medical/surgical, but rather whether a NQTL is being applied in MH/SUD that does not exist in medical/surgical. A

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24 Id.

25 Id.

26 Id.


28 Id.

29 Id.
prohibition on applying a NQTL in MH/SUD while not applying a comparable NQTL in medical/surgical is likewise consistent with the underlying Act.\textsuperscript{30}

\textbf{B. The Regulations Appropriately Require that Plans Meet both the Comparable and the No More Stringently Standards.}

Under the comparable and no more stringently analysis, there are two distinct standards related to NQTLs to which plans must adhere. The processes, strategies, evidentiary standards, or other factors used in applying a NQTL to a MH/SUD benefit must be comparable to and no more stringent than those applied to a medical/surgical benefit. The use of the term “and” clearly demonstrates that plans must meet both requirements. Thus, a plan may violate this section by utilizing processes, strategies, evidentiary standards, or other factors in the context of MH/SUD benefits that are either not comparable to or applied more stringently than those utilized in the context of medical/surgical benefits. The examples in Section (c)(4)(iii) demonstrate this to be the case. Examples 1, 2, 4, and 5 illustrate specific examples in which a plan is either compliant or non-compliant based on whether the NQTL is “comparable” in both the MH/SUD and medical/surgical benefit. Example 3, by contrast, indicates that the MH/SUD NQTL applied in the example is compliant because it is both “comparable to” and “no more stringent” than the medical/surgical NQTL.\textsuperscript{31} This meaningful variation demonstrates that failure to meet either of these standards results in non-compliance with the regulations. The Coalition supports the plain language of the regulations that NQTLs must be both comparable and applied no more stringently in MH/SUD than in medical/surgical.

\textbf{C. The Departments Should Clarify that NQTLs Must Also Satisfy the Predominant and Substantially All Standard.}

The MHPAEA unequivocally applies the predominant and substantially all standard to all treatment limitations.\textsuperscript{32} To remain consistent with the language and intent of the MHPAEA, the Final Rules should make clear that NQTLs must meet both the comparable and no more stringently standard and the no more restrictive standard.

\textsuperscript{30} The treatment limitations section of the Act states that health plans must ensure that “there are no separate treatment limitations that are applicable only with respect to mental health or substance use disorder benefits.” Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, 29 U.S.C.A. § 1185a(a)(3)(A)(ii) (2009). In addition, allowing a NQTL in MH/SUD while not having a similar limitation in medical/surgical would be inconsistent with the purpose of the Act. The purpose of the Act, as stated by each of the five Committees that considered the bill, was to ensure “parity” between MH/SUD benefits and medical/surgical benefits. H.R. REP. NO. 110-374, pt. 1 (2007) (Educ. & Labor Comm.); H.R. REP. NO. 110-374, pt. 2 (2007) (Ways & Means Comm.); H.R. REP. NO. 110-374, pt. 3 (2007) (Energy & Commerce Comm.); S. REP. NO. 110-53, at 3 (2007) (Sen. Comm. on Health, Educ. & Labor, 2007). Parity is “the quality or state of being equal or equivalent.” MERRIAM-WEBSTER, MERRIAM WEBSTER’S COLLEGIATE DICTIONARY 844 (Frederick C. Mish ed., Merriam-Webster) (10th ed. 1992). It seems clear that a plan with an NQTL for MH/SUD but not for medical/surgical is not “equal or equivalent.” In addition, the legislation was enacted to remedy a specific problem, namely, “the discrimination that exists under many group health plans with respect to mental health and substance-related disorder benefits.” H.R. REP. NO. 110-374, pt. 2, at 12 (2007) (Ways & Means Comm.). Interpreting the Act to allow the application of a NQTL in MH/SUD while not applying a comparable or no more restrictive NQTL in medical/surgical would undermine the solution that Congress was attempting to put in place.

\textsuperscript{31} 75 Fed. Reg. 5436.

The Act sets forth a clear three-part test that governs the imposition of treatment limitations to MH/SUD benefits. The treatment limitations applicable to MH/SUD benefits must be “no more restrictive than the predominant treatment limitations applied to substantially all” medical/surgical benefits covered by the plan.33 This phrase contains three discrete tests: (1) is the limitation applied to substantially all medical/surgical benefits; (2) is it the predominant treatment limitation; and (3) is it more restrictive in the MH/SUD benefit than in the medical/surgical benefit? The regulations adopt this test as the “general parity requirement” and use this statutory language repeatedly.34

Importantly, the statute applies the three-part test to all treatment limitations. The statute states that the term “treatment limitations” “...includes limits on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment.”35 This list, while providing examples of treatment limitations, is not comprehensive. The use of the word “includes” in the statute means that the listed treatment limitations are simply examples, not an exhaustive list of all possible treatment limitations subject to parity.36 Thus, the regulations’ inclusion of both QTLs and NQTLs under the definition of treatment limitations is consistent with the statute.37

The regulations also establish a methodology for implementing the predominant and substantially all standard. The first step in the methodology is to determine if the treatment limitation applies to substantially all medical/surgical benefits. Drawing upon the threshold used to implement the 1996 parity statute, the regulations state that a treatment limitation applies to substantially all benefits in a classification if “it applies to at least two-thirds of the benefits in that classification.”38 If the treatment limitation does not meet this test, it cannot be applied in the MH/SUD benefit. The second step involves identifying the predominant treatment limitation. The predominant treatment limitation is the level that applies to more than one-half of medical/surgical benefits subject to treatment limitations in that class.39

Once the predominant treatment limitation that applies to substantially all medical/surgical benefits is identified, a plan is prohibited from implementing a “more restrictive” treatment limitation. As noted in the regulations, QTLs are “expressed numerically.”40 A “more restrictive” QTL is easily identified because of the inherent quantitative nature of QTLs. For example, if a plan

33 Id.
34 75 Fed. Reg. 5412-13, 5419, 5433, 5440, 5446.
35 § 1185a(a)(3)(B)(iii).
36 Id.
38 75 Fed. Reg. 5414.
39 Id.
allows 50 outpatient days per year in the medical/surgical benefit but only 30 outpatient days per year in the MH/SUD benefit, the QTL is clearly more restrictive in the MH/SUD benefit. However, the “more restrictive” test is more difficult to apply to NQTLs. Because NQTLs are not expressed numerically (i.e., are qualitative in nature), the “more restrictive” is not self-proving as it is with quantitative QTLs. Thus, a second standard or test must be established to operationalize the “no more restrictive” statutory test for NQTLs.

For example, imagine a plan that applies precertification for inpatient hospital stays. This NQTL applies to one hundred percent of medical/surgical benefits in the classification so it applies to substantially all medical/surgical benefits, and is also predominant because its applies to more than 50 percent of medical/surgical spending. Accordingly, it can be applied to MH/SUD benefits. However, the third part of the test must now be applied to determine if the precertification for inpatient hospital stays is “more restrictive” in the MH/SUD benefit. A standard is required to make this determination, because it is not evident on its face.

The regulations address this issue by implementing the comparable and no more stringently standard. The regulations state that a plan may not impose a NQTL for MH/SUD benefits unless the processes, strategies, evidentiary standards, or other factors used in applying the NQTL are “comparable to, and are applied no more stringently than” those used in applying the NQTL to medical/surgical benefits. In light of the quantitative/qualitative distinction discussed above, this test is necessary to determine when a NQTL is more restrictive. For example, the precertification described above can be a limited or multifaceted process applied differentially and with very different results. The comparable and applied no more stringently test operationalizes the statute’s no more restrictive standard for NQTLs by ensuring that precertification requirements are demonstrably comparable in operation and application. Under this understanding of the regulations, the comparable and no more stringently standards are additive to the predominant and substantially all standard.

Applying both standards to NQTLs also appears to be supported by the language of the regulations. The regulations state that the “general parity requirement” is the predominant and substantially all standard. The regulations do not expressly exclude NQTLs from the predominant and substantially all standard. Rather, the regulations state that “the test is applied somewhat differently” to NQTLs. As described above, the test is applied somewhat differently out of necessity—QTLs and NQTLs are different; one is quantifiable and the other is not.

If the predominant and substantially all standard were to apply only to QTLs, it could lead to results that are inconsistent with the Act. For example, if the predominant and substantially all test does not apply to NQTLs, a plan could apply a NQTL to a de minimus percentage of medical/surgical benefits and then apply the same NQTL to a greater percentage of benefits on the MH/SUD side. For example, imagine a plan that requires prior authorization (a NQTL) for physical therapy visits in excess of two authorized visits in the medical/surgical benefit. This prior authorization requirement is only applied to physical therapy and other medical/surgical treatments that represent less than 20 percent of medical/surgical spending in that classification of benefits. Without a predominant and substantially all standard, this NQTL could then be applied in the MH/SUD benefit, and possibly to all MH/SUD benefits in the classification. This is inconsistent.

41 75 Fed. Reg. 5436.

with the clear language of the statute that addresses limitations that apply to substantially all benefits and those that are predominant. Clear regulatory guidance is essential since plans have already begun interpreting the regulations to permit them to apply any NQTL to MH/SUD benefits even if it only applies to a small percentage of medical/surgical benefits.

Finally, if the substantially all and predominant test is not applied to NQTLs, the percentage of benefits to which a NQTL would have to apply before the comparable and no more stringently standard takes effect is unclear. Is it 100 percent, 80 percent, 50 percent or even lower? Adding to the lack of clarity are the examples in the Interim Final Rules illustrating how NQTLs are to be applied. All of these examples imply that a NQTL must be applied to 100 percent of the medical/surgical spending in a benefit class before that NQTL can be applied to a MH/SUD benefit. Was this the intent of the Regulators?

This lack of clarity could lead to a situation similar to the problem described above, in which a NQTL that applies to only a small percentage of medical/surgical benefits is applied to MH/SUD benefits. Such a result is inconsistent with the language of the statute.

In light of the statutory language and the potential for results inconsistent with Congressional intent, the Final Rules should make clear that NQTLs must meet both the comparable and no more stringently standards and the substantially all, and predominant standard.

D. The Departments Should Clarify that Any Exceptions to the Comparable and No More Stringently Standards Must Be Based on Independent and Objective Clinical Policies and Standards.

The regulations state that NQTLs must be comparable and applied no more stringently to MH/SUD benefits than to medical/surgical benefits. The regulations permit an exception to the comparable and no more stringently standards "to the extent that recognized clinically appropriate standards of care may permit a difference." To ensure the strong parity protections envisioned by Congress, the Departments should adopt a definition of "recognized clinically appropriate standards of care" that is based on independent and objective clinical policies and standards.

Clearly defining "recognized" is critical to ensure the integrity of the Act. As noted, the only exception to the requirements that NQTLs be comparable and applied no more stringently is when "recognized clinically appropriate standards of care" permit a difference. Thus, any attempt to get around the parity requirements will involve finding a "recognized clinically appropriate" standard of care. If adequate requirements are not established to determine when a standard is recognized, the parity requirements may be circumvented. For example, a plan could trigger the exceptions simply because its own employees or hired consultants deem a standard "recognized"—with no outside verification.

Such a result opens a potential loophole that would weaken Congress' intended parity protections. Congress' purpose in passing the Act was to ensure meaningful parity between MH/SUD and medical/surgical benefits by expanding previously-approved mental health parity legislation. In the Act, Congress was very clear that treatment limitations should be "no more

43 75 Fed. Reg. 5416.
restrictive" in MH/SUD benefits than in medical/surgical benefits. By expanding previous parity legislation, and using clear language in doing so, Congress expressed an intent to ensure strong parity protections. Permitting an exception to parity based on a plan’s internal review alone could weaken this intended strength.

To avoid this result, the Departments should clearly define “recognized standards of care.” This definition should state clearly that any “recognized” standard of care for purposes of the NQTL exceptions process must be: (1) an independent standard that is not developed solely by a single health plan or plans; (2) based on input from multiple stakeholders and experts, such as academic researchers, senior practicing clinicians, and consumer and advocacy leaders with subject matter expertise in addition to a health plan or its advisory panels; (3) recognized or accepted by multiple nationally recognized provider and consumer organizations and/or nationally recognized accrediting organizations that are responsible for developing quality standards; and (4) based on objective scientific evidence, such as peer-reviewed publications of control group research trials or expert consensus panels.45

E. The Departments Should Provide Additional Illustrations of NQTLs and More Detailed Discussion of Selected NQTLs of Significance.

NQTLs are used pervasively to manage both medical/surgical and MH/SUD benefits, with great effect on patient access to care. For example, NQTLs such as preauthorization, concurrent review, retrospective review, case management, and utilization review often determine whether a patient receives care or does without. Because of the importance, widespread use, and potential for abuse related to NQTLs, the Departments should provide additional illustrations of NQTLs and highlight selected NQTLs of significance. Such selected NQTLs of significance include: provider reimbursement methods; criteria for determining whether a treatment is experimental; and composition of plan and plan provider panels used for the development of clinical standards.

The Interim Final Rules correctly note that NQTLs and their application are “complex” and varied, and includes several helpful illustrations of common NQTLs.46 The Coalition believes the Final Rules should include additional illustrations of common NQTLs, including, but not limited to, the following:

45 In 1996, Congress passed and the President signed the Mental Health Parity Act (MHPA). The MHPA equates aggregate lifetime limits and annual limits for MH/SUD benefits with aggregate lifetime limits and annual limits for medical/surgical benefits. Thus, the statute gave a measure of protection from the costs of MH/SUD services. Legislation to expand mental health parity was introduced in the House from 1997 until the passage of the Mental Health Parity and Addiciton Equity Act. It was in this context that the Act was passed.

46 These recommendations are consistent with the manner in which numerous government agencies make scientific and clinical judgments. For example, CMS regularly relies on independent expertise when making its coverage determinations. There is clear precedent for CMS to take a rigorous view of the evidentiary basis for Medicare reimbursement of drugs, devices and procedures. In the National Coverage Determination (NCD) process, CMS evaluates all pertinent data, including the scientific data that requesters submit, peer-reviewed medical, technical and scientific literature, and recommendations from expert panels. CMS also can order a health technology assessment to provide an independent analysis of all of the scientific and clinical evidence available on a particular health care technology. The Medicare Coverage Advisory Committee (MCAC) also plays a role in assisting the agency in making sound coverage decisions. MCAC provides independent, expert advice based upon the reasonable application of scientific evidence through members who possess the scientific and technical competence to provide these assessments.

• Prior authorization and concurrent review requirements for outpatient services, in and out-of-network;
• Prior authorization and concurrent review requirements for inpatient services, in and out-of-network;
• Reimbursement rate issues for in and out-of-network;
• Formulary design;
• Service coding;
• Provider network criteria;
• Policy coverage conditions and exclusions; and
• Geographic limitations, in and out-of-network.

Including illustrations such as those above will ensure clarity and optimal implementation of the regulations by plans. Appendix 2 includes types of NQTLs that Coalition members have encountered in the marketplace this year. The Final Rules should also discuss in more detail the following types of NQTLs.

Provider rate calculation methods have the potential to influence physician participation in plan networks and, if set restrictively, could substantially impact patient access to MH/SUD care. The Coalition believes the plain language of the regulations prohibits rate calculation methods that are more stringent for MH/SUD providers than medical/surgical providers. However, the Coalition encourages the Departments to strengthen this language, and make clear that inflation updates to provider reimbursement rates are a form of NQTL.

As noted above, the regulations currently set forth a limited list of NQTLs. One of these NQTLs is “standards for provider admission to participate in a network, including reimbursement rates.”[47] [Emphasis added] The plain language of the regulation, which specifically includes reimbursement rates as an example of a NQTL, demonstrates that provider rate calculation methods are a NQTL subject to the “comparable” and “no more stringently” standards. In addition, the list of NQTL examples lists “plan methods for determining usual, customary, and reasonable charges.” This payment-related NQTL further demonstrates that rate calculation methods are a NQTL subject to parity requirements. Because of the importance of this issue, the Coalition requests that the Departments restate that provider rate calculation methods are subject to the NQTL parity requirements. Additionally, the Coalition requests that provider inflation updates be included as a NQTL. If a plan regularly denies inflation updates to MH/SUD providers while providing them to medical/surgical providers, the result will be that the underlying reimbursement rates become non-comparable. Extending the term “reimbursement rates” to include inflation adjusters is logically consistent and necessary to ensure access to MH/SUD services.

The Final Rules should also make clear that scientific criteria or standards for determining whether a treatment that is experimental must meet the NQTL parity standards. These scientific criteria have the potential to limit or eliminate coverage for treatments or tests that are deemed experimental. Thus, according to the regulations’ own language, such criteria should be viewed as a NQTL that is subject to the NQTL comparable and no more stringently standards.[48]


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Finally, because the composition of plans' provider and consumer expert panels that are used to create and/or validate clinical standards, medical necessity criteria, reimbursement and coverage policies could ultimately limit the scope and duration of benefits for MH/SUD treatment under a plan, the Departments should make clear that the composition of these panels are a form of NQTL subject to the regulations. Among other responsibilities, plan and provider panels help establish standards of care or determine whether a procedure is experimental. Additionally, the panel may attempt to create the "recognized clinically appropriate standard of care" that would permit an exception to the NQTL requirements. The determinations made by the plan, especially if these determinations are related to the standard of care mentioned above, would have an effect on the scope and duration of benefits for treatment under the plan. Accordingly, the composition of plan or provider panels should be a NQTL subject to the parity regulations.

Defining plan or provider panel composition as a NQTL is consistent with the NQTL examples listed in the regulation. For example, the regulation states that standards for provider admission to participate in a network, including reimbursement rates, are a NQTL. Although not a direct effect on beneficiaries, the determination of provider rates has the potential to affect the participation of providers in a plan. If rates are too low, certain providers will not participate in the network. Ultimately, the scope and duration of services to the beneficiary will be impacted when the beneficiary is unable to access services. In a similar fashion, decisions related to plan and provider panels do not impact the beneficiary directly. However, to the extent that such decisions result in MH/SUD benefits being disadvantaged as compared to medical/surgical benefits, the scope and duration of services is ultimately impacted. Accordingly, the Departments should clarify that NQTL parity requirements are applicable to the composition of plan and provider panels.

V. To Ensure Patients are Able to Effectively Understand and Respond to Benefit Claims Denials, the Departments Should Require Plans to Disclose the Reason for the Denial within a Specific Timeframe.

The statute clearly requires that a plan disclose the reason for any denial of reimbursement or payment for services with respect to MH/SUD benefits.\textsuperscript{49} However, patients have faced significant delays in receiving the required disclosure. The Coalition requests that the Departments set a timeframe for plans to provide the reason for the denial. Specifically, when the denial is based on a medical necessity determination, plans should be required to provide the plan's medical necessity criteria to the insured with three business days. Without disclosure of such criteria, the patient has little information to understand what financial exposure he or she is at risk for in undertaking a specific treatment. Summary plan documents are often woefully inadequate with respect to plan payments for MH/SUD. In practice, many patients appeal a denial of care. Without the medical necessity criteria on which the plan based its decision, the patient has little basis for responding to the plan’s denial. It is imperative that this notification be received in a timely manner, so that patients can receive appropriate MH/SUD services.

\textsuperscript{48} 75 Fed. Reg 5412.

\textsuperscript{49} Specifically, the statute states that "the reason for any denial under the plan (or coverage) of reimbursement or payment for services" with respect to MH/SUD benefits "shall, on request or as otherwise required, be made available by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary." 29 U.S.C.A. § 1185a(a)(4).
A requirement to disclose medical necessity criteria is in harmony with the ERISA regulations discussed in the Interim Final Rules. The statute itself states that the notification shall be provided “in accordance with regulations.” For purposes of implementing this requirement, the Interim Final Rules state that if a plan is subject to ERISA, it must provide “the reason for the claim denial in a form and manner consistent with the requirements of 29 CFR 2560.503-1 for group health plans.” Even for non-ERISA plans, “a plan that follows the requirements of 29 CFR 2560.503-1 for group health plans complies with” the requirement to provide a reason for denial.

According to 29 CFR 2560.503-1, if an internal guideline, rule, protocol, or other similar factor was relied upon in making the adverse determination, the notification must either include the specific guideline, rule, protocol, or other similar factor, or the notification must include a statement that such a guideline, rule, protocol, or other similar factor was relied upon in making the adverse determination and that a copy of such rule, guideline, protocol, or other criterion will be provided free of charge to the claimant, upon request. If a plan relies upon internal medical necessity criteria in denying MH/SUD benefits, this requirement should require disclosure of these criteria. A notification of adverse benefit determination must also include reference to the “specific plan provisions on which the determination is based.” Again, if the denial of MH/SUD benefits is based on medical necessity or coverage provisions in the plan, the plan should be required to disclose these “specific” coverage criteria to the beneficiary. Thus, a requirement in the Final Rules that plans provide medical necessity criteria in the case of a denial is consistent with the regulations cited in the Interim Final Rules. For example, if a treatment is denied because it is experimental then the scientific criteria that underlie this denial should be made available to the consumer or provider.

More generally, since all denials of MH/SUD treatments can only be judged as compliant or noncompliant with MHPAEA when compared with the same policies and/or criteria used for medical/surgical treatments, a plan should also be required to make available the corresponding medical coverage criteria or policy that is used for substantially all medical/surgical benefits. For example, if a MH or SUD treatment is considered experimental, the scientific criteria applied to the MH/SUD treatment should be disclosed as well as the scientific criteria used for substantially all medical/surgical treatments. The Coalition requests that the Final Rules state this requirement.

VI. The Departments Should Remain Consistent with the Statute and Prior Regulations by Using Actual Costs as the Basis for the Increased Cost Exemption.

The Act permits an exception to the mental health parity requirements for plans that experience a cost increase of over one percent as a result of the Act. The Act is clear that actual

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50 Id.

51 Id.

52 DOL Reg. § 2560.503-1 (g)(1)(v)(A).


costs incurred, not actuarial cost projections, must form the basis of a cost exemption application. In addition, such an interpretation is consistent with the implementation of the 1996 MHPA. Accordingly, the Departments should reject any argument to allow plans to use actuarial cost projections to establish an exception to the Act.

In establishing the base exception rule, the Act clearly states that the exception will only be triggered if application of the Act results in a one or two percent increase in the “actual total costs of coverage.” This phrasing is repeated throughout the cost exemption portion of the Act, including in the notice section which requires a plan that invokes the exemption to submit “a description of the actual total costs of coverage” to the Secretary. The Act discusses actuaries, but only to specify that their determinations of cost increases should be based on “actual costs.” Under the plain language of the Act, actual costs must be used to calculate the cost exemption, not projected costs.

In implementing the 1996 MHPA, the Departments similarly implemented an exception to parity requirements for plans whose costs increased one percent. The regulations discussed at length the method for calculating the cost increase. The 1996 regulations outline various options for making the calculation, including a purely retrospective approach where increased costs are based on actual experience, and a purely prospective approach where increased costs are based on actuarial projections. The Departments adopted a modified retrospective approach based on actual costs over a certain period of time. The Departments believed that using the costs that the plans actually incurred was important to assure that exceptions were “based on actual experience under the MHPA’s parity requirements and not on projections or estimates of such experience.” In like manner here, the Departments should ensure that actual costs, and not actuarial projections are used to determine eligibility for the exemption.

The 1996 regulations also set out a specific formula for calculating the one percent exception. The formula’s numerator and denominator both relied on a calculation of “incurred expenditures.” As stated by the regulations, the term “incurred expenditures” means “actual claims incurred during the base period.” Once again, the Departments were clear that the exemption calculation must be based on actual costs. We request that the Department reject any argument to the contrary.

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55 Id.

56 § 1185a(c)(2)(E)(ii)(II), (III).

57 § 1185a(c)(2)(C).


59 Id.
VII. The Interim Final Rules' Preemption Provisions will Normally Allow Stronger State Parity Laws to Remain in Force, and Should therefore be Included in the Final Rules.

Since passage of the 1996 MHPA, numerous states have implemented their own mental health parity laws, many of which touch on the same subjects and requirements included in the MHPAEA. The Coalition strongly supports the Interim Final Rules' interpretation that state parity laws with stronger protections than those contained in the MHPAEA will not ordinarily be preempted by the Act.

The operative issue in determining whether a state parity law is preempted is not whether the law is weaker or stronger than MHPAEA, but rather whether the state law acts to "prevent the application" of MHPAEA. The regulations state that MHPAEA requirements are not to be "construed to supersede any provision of State law…except to the extent that such standard or requirement prevents the application of a requirement of MHPAEA." For example, a State law that mandates that an insurer offer a minimum dollar amount of MH/SUD benefits "does not prevent the application of MHPAEA." This is presumably because, even with the minimum dollar amount requirement, the plan could still provide (and would be required to provide) parity between MH/SUD and medical/surgical benefits. The regulations specify that state insurance laws that are stronger than the federal requirements are unlikely to prevent the application of MHPAEA and be preempted. Accordingly, "States have significant latitude to impose requirements on health insurance issuers that are more restrictive than the federal law." The Coalition strongly supports this interpretation of the Act, and requests that it be included in the Final Rules.

VIII. To Ensure Effective Implementation of the MHPAEA in Medicaid, the Departments Should Release any Additional Regulations Related to the Application of MHPAEA to Medicaid Managed Care Organizations in a Timely Manner and Should Clarify that the IFR applies to Medicaid Managed Care Organizations Currently.

Since the 1990s, the Medicaid program has increasingly relied on managed care to deliver services to its Medicaid population. Today, more than 65 percent of the total Medicaid population is served through managed care. All states except Alaska, Wyoming, and New Hampshire have at least a portion of their Medicaid population enrolled in managed care. The Coalition believes that, in light of the Act and regulatory history, the Interim Final Rules apply to Medicaid managed care (MMC) plans. In light of the significant population served under MMC, the Coalition requests that

60 75 Fed. Reg. 5418.

61 Id.


63 Id.


65 Id.
the Final Rules clearly state their applicability to MMC, and that the Departments release any additional regulations related to the application of MHPAEA to MMC plans in a timely manner.

In issuing these guidelines, the Coalition requests that the Departments make clear that Medicaid managed care plans are subject to the requirements of the Act. Through a reference in Social Security Act Section 1932(b)(8), MMC plans are required to comply with parity requirements, and both the legislative history of the Act and the regulatory history of previous mental health laws support this conclusion.

The Act modified the Public Health Service Act (PHSA) to require that if a group health plan offers both medical/surgical benefits and MH/SUD benefits, the financial requirements and treatment limitations for MH/SUD benefits must be no more restrictive than those imposed in the medical/surgical benefit. The Social Security Act refers to this section and mandates that managed care plans "comply" with its provisions. Specifically, the Social Security Act Section 1932(b)(8) specifies that "Each Medicaid managed care organization shall comply with the requirements of subpart 2 of Part A of title XXVII of the Public Health Service Act [42 U.S.C.A. 300gg-5 et seq.] insofar as such requirements apply and are effective with respect to a health insurance issuer that offers group health insurance coverage." The statutory reference in the quote refers to the mental health parity provisions as passed in the 1996 MHPA and as modified by the 2008 Act. Thus, the Medicaid managed care statute requires that MMC plans comply with both the 1996 and the 2008 parity requirements.

This interpretation is consistent with Congressional views on the meaning and application of the Act. The Senate Committee on Health, Education, Labor, and Pensions (HELP) reported its version of the Act out of Committee on April 11, 2007. In the Committee Report accompanying the bill, the Committee stated that "[t]he bill's requirements for issuers of group health insurance would apply to managed care plans in the Medicaid program." Similar language is included in the Congressional Budget Office (CBO) cost estimate included in the Committee Reports from the House Education & Labor, Energy & Commerce, and Ways & Means Committees. Although the committee legislation was not identical to the bill enacted into law, no changes were made to the bill that would alter this analysis.

The view that MMC plans must comply with the parity provisions of the Act is also consistent with past agency interpretation of the 1996 MHPA. The 1997 Balanced Budget Act (BBA) made a number of changes to the Medicaid statute involving managed care, including adding Section 1932(b)(8), the requirement discussed above that MMC plans comply with mental health parity requirements. The Health Care Financing Administration (HCFA), the predecessor agency to CMS, subsequently released a number of letters to State Medicaid Directors explaining the effect

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of the BBA on MMC. In a letter dated January 20, 1998, Sally Richardson, the director of the Center for Medicaid and State Operations, stated that the parity requirements of the 1996 MHPA "apply to Medicaid managed care organizations without exemptions."71 This is so because Section 1932(b)(8) "specifically requires Medicaid managed care organizations to comply with MHPA by treating them, for that purpose, like health insurance issuers offering group health insurance coverage."72 Although this letter was written during implementation of the 1996 Act, its reasoning continues to apply with respect to the 2008 Act. The 2008 Act simply added a section to the original 1996 parity law. This new section falls within the scope of Section 1932(b)(8)'s requirement that managed care organizations must comply with the parity requirements. Accordingly, Section 1932(b)(8) applies equally to the parity requirements in the 2008 Act. This means that MMC plans are subject to the 2008 Act's requirements.

In light of the importance of this issue to the many individuals with mental illness enrolled in MMC plans, the Coalition requests that the Departments issue timely regulations related to the application of MHPAAEA to Medicaid managed care organizations.

IX. The Departments Should Establish Best Practices that Plans Must Use when Defining a MH/SUD, including Basing such Definitions on an Independent, National or International Standard or State Government Guideline.

In defining a MH or SUD condition for the purpose of offering a benefit, a plan's definition of a disorder or condition must be "consistent with generally recognized independent standards of current medical practice."73 For purposes of the regulations, "generally" means that the standard must be "generally accepted in the relevant medical community."74 The regulations set forth a list of sources that would meet the "generally accepted" requirement, including the most current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), the most current version of the International Classification of Diseases (ICD), or a State guideline. The Coalition supports the use of these sources in defining MH/SUD benefits.

The regulations state, however, that these sources are not the only sources that may be used by plans to define a MH or Substance Use Disorder. Thus, although plans have some flexibility in defining a MH/SUD condition, the definitions must be consistent with standards that are generally accepted in the relevant medical community. CMS must ensure that plans are not able to circumvent the parity requirement by establishing plan terms that are not generally recognized independent standards. Such a situation could arise when internal plan panels or consultants determine what is a MH/SUD rather than outside parties. To ensure the integrity of MH/SUD definitions, the Coalition requests that the Departments establish best practices that plans must use when defining a MH/SUD. Such best practices should include basing the definitions on an independent, national or international standard, or state government guideline.


72 This is not to say that MMC plans necessarily meet the requirements of a "group health plan" under the 1996 or 2008 parity acts. However, the statutory language of 42 U.S.C. 1396u-2(b)(8), and the analysis by HCFA demonstrate that MMC plans are treated like group health plans with respect to the parity requirements.


74 Id.
X. To Remedy Existing Inequities and Ensure Effective Implementation of the Act Pending Issuance of the Final Rules, the Departments Should Issue Timely Guidance on Issues Currently Addressed in the Regulations.

The comments above raised numerous issues that the Coalition recommends be added, deleted, or clarified by the Final Rules. However, a timeline for the Final Rules is unclear. Plans have already begun to implement the Act, often with differing interpretations of the statute. In light of ensuring the statute is implemented effectively for the millions of Americans affected by mental illness, the Departments should issue formal guidance related to the issues currently contained in the regulations.

Such guidance is especially important given that the very inequities MHPAEA was enacted to remedy continue to be pervasive. Specifically, the financial restrictions and treatment limitations on access to MH/SUD services continues to be greater than on medical/surgical conditions. This fact has caused great difficulties for individuals and families in need of MH/SUD services.

XI. Conclusion

The Parity Implementation Coalition is committed to ending discrimination against individuals and families who seek services for MH/SUD. The Coalition looks forward to working with the Departments to modify and finalize the Rules so that they promote strong, clear parity protections. Please do not hesitate to contact Carol McDaid, Parity Implementation Coalition Co-Chair, at 202.737.7393 or Sam Muszynski, Parity Implementation Coalition Co-Chair, at 703.907.8594 if you have questions regarding these comments.

Sincerely,

Carol McDaid  
Co-Chair  
Parity Implementation Coalition

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

Attachments:
Appendix 1: A Framework for Providing Scope of Service Parity in an Affordable and Equitable Manner
Appendix 2: Non-Quantitative Treatment Limitations Are Applied More Stringently on MH/SUD Benefits
Milliman MHPAEA Scope of Services Research
APPENDIX 1

PARITY IMPLEMENTATION COALITION75
A Framework for Providing Scope of Service Parity in an Affordable and Equitable Manner

This analysis will outline how a full scope of service parity can be achieved in a manner that is consistent with the Mental Health Parity and Addiction Equity Act (MHPAEA). We describe how medical and surgical conditions (medical/surgical) are provided in a wide range of levels and settings and that these are analogous to similar evidence-based levels and settings for mental health and substance use disorders (MH/SUD). We identify how scope of service parity is different from a requirement that a plan cover any MH/SUD benefits and how the lack of full scope of service parity is a form of a non-quantitative treatment limit (NQTL). This is supported by an independent analysis by Milliman (see attached letter from Milliman) of common levels of care and a detailed analysis of how specific medical conditions are treated vs. specific MH/SUD conditions. Finally, we define how plans can provide benefits exclusions and limits on MH/SUD treatment while offering a similar range and continuum of treatments that are reimbursed for medical diseases without resorting to arbitrary benefit exclusions or overly restrictive medical necessity criteria.

The Departments invited comments on whether and to what extent MHPAEA addresses the scope of services or continuum of care provided by group health plans or other health insurance coverage. This analysis will illustrate an approach for how comprehensive “scope of service” parity can be defined and implemented consistent with MHPAEA, both the statute and the regulations. It is our view that a clear approach to defining and implementing scope of service parity is essential to having complete and successful parity coverage for MH/SUD as compared to medical/surgical.

The legal analysis for how and why scope of service parity is required in the statute both in the “letter” of the law as well as in Congressional intent was outlined by Patton Boggs in comments submitted to the regulators in 2009, and reflected in these comments. The Patton Boggs analysis documented how MHPAEA requires "scope of service" parity across all six classifications of benefits and within each benefit classification.

There are two very different perspectives for how to approach this issue and they were summarized in the preamble to the Interim Final Rules (IFR) on Feb. 2. The first position, which was conveyed by the health plan/insurance community, is summarized in the preamble as follows:

Some commenters requested, with respect to a mental health condition or substance use disorder that is otherwise covered, that the regulations clarify that a plan is not required to provide benefits for any particular treatment or treatment setting (such as counseling or non-hospital residential treatment) if benefits for the treatment or treatment setting are not provided for medical/surgical conditions. (Federal Register vol. 75, no. 21, pg. 5416)

The second position, conveyed by the patient/consumer and provider communities, is summarized in the preamble as follows:

Other commenters requested that the regulations clarify that a participant or beneficiary with a mental condition or substance use disorder have coverage for the full scope of medically appropriate services to treat the condition or disorder if the plan covers the full scope of medically appropriate services to treat medical/surgical conditions, even if some treatments or treatment settings are not otherwise covered by the plan. Other commenters requested that MHPAEA be interpreted to require that group health plans provide benefits for any evidence-based treatment. (Federal Register vol. 75, no. 21, pg. 5416)

The first position contends there is no scope of service parity required by MHPAEA and that a plan has the option of reimbursing either a few, none or many treatment services for a MH/SUD. Additionally, proponents of this view argue that there is no connection or comparison between the types or extent of treatments reimbursed for medical/surgical conditions vs. MH/SUD within a classification such as inpatient. Their view is that if only one type of service is provided as a benefit for a specific MH/SUD then that should be considered as compliant with MHPAEA, even if a full range of treatments are provided for most medical/surgical conditions.

If this view were upheld by the regulators, then one could logically conclude that the following scenario would be legal and permissible under MHPAEA. Employer X chooses to offer benefits for depression and then provides reimbursement for only the following treatments in the outpatient benefit classification: psychiatric drugs and visits to a primary care physician. No other specialty treatment is offered: e.g. no office-based psychotherapy. While some would view this scenario as unlikely, the more important issue is that it would be legal under MHPAEA without a specific clarification from the regulators that MHPAEA requires scope of service parity within a benefit classification.

Another unacceptable scenario that applies parity in scope of services inequitably that has been incorporated by some health plans, is limiting coverage in the inpatient classification to licensed acute hospital care only for MH/SUD. These plans have deleted coverage for inpatient residential treatment for MH and SUD as well as partial hospitalization and intensive outpatient treatment programs. Plans have done this because they contend that the statute does not require “scope of services” and they argue that any treatment category that they determine is not comparable can be deleted. Again, this would be legal under MHPAEA without regulations requiring scope of service parity within each of the 6 classifications.

The second position contends that a full scope of all “evidence based treatments” for MH/SUD must be reimbursed if all “evidence based treatments” are funded for medical/surgical conditions. A literal interpretation of this view is that there might be no “floor for coverage of MH/SUD treatments i.e., virtually no permissible exclusions. If this interpretation of MHPAEA were upheld, under the above example if Employer X offered coverage for depression then the plan would have to cover all “evidence-based treatments” including a full range of treatments (all outpatient MH specialist care, partial hospitalization, all levels of inpatient care and secondary services, etc) – assuming a wide range of treatments are provided for medical/surgical. The question would be is there any limit to the MH/SUD treatments that must be funded or would all and every treatment
proposed by a consumer or provider have to be funded? Who would define what is “evidence-based” and under what set of rules?

These are all legitimate concerns; i.e., that health plans not be mandated to provide every specific treatment service and/or provide coverage for the entire universe of services deemed necessary by the community of interests in the mental health and substance use disorder fields.

The other major issue that must be addressed if the “scope of service” matter is to be appropriately resolved concerns the comparability of medical/surgical and MH/SUD levels of care and services. As the preamble to the regulations noted "not all treatments or treatment settings for mental health conditions or substance use disorders correspond to those for medical/surgical conditions."

While some services may not be directly comparable, or exactly equivalent, it does not mean they are not analogous and therefore sufficiently similar to be objectively compared. The Coalition is setting forth the following medical dictionary definition of analogous for discussion: A part or organ having the same function as another, but of a different evolutionary origin. We believe this functional approach is applicable to determining the comparability of the MH/SUD and medical/surgical treatments, given the realities that there is often no strict or precise equivalency between specific treatments for MH/SUD and medical/surgical. There are however, considerable overlap and similarities in treatment settings between medical and mental. For example, almost all medical and mental health conditions occasionally require treatment in inpatient settings and there are many subtypes of inpatient care for both MH/SUD and medical/surgical.

Establishment of a functional basis for comparison of treatments and treatment settings facilitates dealing with the requirement that treatment limitations imposed on MH/SUD may be no more restrictive:

The Departments also recognize that MHPAEA prohibits plans and issuers from imposing treatment limitations on mental health and substance use disorder benefits that are more restrictive than those applied to medical/surgical benefits. (Federal Register vol. 75, no. 21, pg. 5416)

We unequivocally concur with the Departments’ assertion that treatment limitations cannot be more restrictive. The Departments concurred that if a health plan provides a range of services for medical/surgical conditions that factor in patient acuity, severity, determination of the most clinically appropriate cost effective setting, as well as other factors, then to not do the same for MH/SUD conditions is de facto a more stringent non-quantitative treatment limitation, and impermissible under MHPAEA.

This analysis summarizes a method for defining the parity requirement for scope of service within each relevant benefit classification in a manner that:

1. Complies with MHPAEA’s requirements;

2. Does not establish a mandate of coverage for a specific MH or SUD conditions or groups of disorders
3. Provides for a "floor" for benefit limits; and

4. Is consistent with the typical provisions used for medical/surgical coverage as broadly requested by the health plan/insurance community in response to the Departments’ Request for Information (RFI).

This analysis will address the following categorical issues:

- Parity in scope of services vs. a mandate for coverage of specific MH or SUD conditions;
- How most MH/SUD treatment levels are similar or analogous to medical/surgical levels and how most clinical placement criteria for common medical/surgical condition are analogous to clinical guidelines and decisions about MH/SUD disorders;
- How scope of service parity decisions are based on a plan’s medical management and utilization review standards and are, therefore, a type of non-qualitative treatment limitation (NQTL); and
- How a plan uses a variety of benefit exclusions (NQTLs) for limiting medical/surgical treatments and can use those same standards to put a "floor" on MH/SUD treatments.

**Parity in Scope of Services vs. a Mandate for Coverage of Specific MH or SUD Conditions**

The term *scope of services* is defined here to mean the range and types of services that are offered to treat an illness, whether mental or physical. This incorporates the "continuum" of care and levels of care but also includes the types and ranges of treatments within those levels. An example of a continuum of treatment services would be a delineation of the various levels of care from the most intensive and structured to the least intensive and structured. The most common continuum would include acute hospital treatment as most intensive and outpatient care as a mid-range of intensity and home care as typically least intensive or structured.

The six benefit classifications in the regulations define several broad levels of care along a continuum of treatment services. There are many other categories along this continuum that could be created by further sub-divisions such as subacute inpatient, other 24 hour medically-supervised treatment settings, intensive outpatient interventions that are more intensive than office based treatments. These include interventions like cardiac or stroke rehabilitation programs, outpatient surgery, intensive outpatient chemotherapy for common medical disorders and similar programs for treating MH/SUD.

A key concern for public and private payers is: Does a scope of service parity requirement translate into a "mandate" that some or all MH/SUD have to be provided benefits? The Coalition believes the statute is clear on this issue – MHPAEA is not a coverage mandate. MHPAEA is clear that a plan can choose whether or not to provide any coverage for a MH/SUD. The statute is also clear that once a benefit is offered for a specific condition, then those benefits and the services offered in connection with them have to be at "parity" with medical benefits.

After a plan has exercised its statutory authority to "choose" whether or not to offer coverage for a condition then their flexibility is limited in that these covered "benefits" or "treatments" must be
offered in a no more restrictive manner in regards to "financial requirements" and "treatment limitations." Requiring that a similar range and scope of treatments be reimbursed for a specific MH/SUD as compared to medical/surgical refers only to treatment services for that specific MH/SUD. It in no way commits a plan to extend coverage for additional MH/SUDs.

MH/SUD Treatment Levels Are Analogous to Medical/Surgical Levels and Clinical Placement Criteria for Common Medical/Surgical Conditions are Analogous to Patient Placement Criteria for MH/SUD

Consumers with MH/SUD and medical/surgical conditions ideally have access to a wide array of evidence-based treatment levels along a continuum of care. In this section we outline some of the levels for both medical and MH/SUD to show the similarities between the two.

There are multiple levels of care on the medical/surgical continuum. These medical/surgical levels of care have complementary levels of care on the MH/SUD treatment continuum. The complementary treatment levels listed below will range from most intensive to least intensive:

**Acute Hospital:** There are acute general hospitals for medical/surgical treatment as well as free standing specialty hospitals for specific medical conditions. The same is true for MH and SUD: acute treatment services are provided in general hospitals that have specialized units for either SUD or MH disorders. There are stand-alone specialty hospitals for either MH or SUD conditions. Both medical/surgical hospitals and MH/SUD hospitals are usually certified by the Joint Commission.

**Subacute Hospital Care:** It is not uncommon for medical/surgical patients to be transferred to the next level of acuity or intensity when discharged from an acute hospital bed. An example of this is rehabilitation hospitals for physical rehabilitation.

This level of care also exists for the treatment of MH/SUD. These facilities are usually called residential treatment centers (RTCs) for substance use disorders or for psychiatric treatment. These are 24 hour centers (step downs from acute hospital care) and are licensed by state agencies as inpatient or residential treatment facilities and are typically certified by either the Joint Commission or Commission on Accreditation of Rehabilitation Facilities (CARF). These certification agencies usually certify subacute hospitals for medical/surgical patients as well.

**Intermediate Care Facility (ICF):** These inpatient facilities include nursing homes and skilled nursing facilities. The above listed RTCs for SUD and MH can also be compared to this level. However, generally RTCs for MH/SUD provide a more intensive level of care than most ICF's for medical/surgical benefits.

This level of care can also include intensive 24-hour residential rehabilitation services for medical/surgical patients after discharge from either acute or subacute levels of hospital care. These settings can range from supervised living settings like a group home or a small apartment where a range of physical rehabilitation treatments are offered in addition to occupational therapy and community reentry interventions. There are also treatment
settings (group homes and supervised apartments) similar to the medical/surgical supervised living settings for MH/SUD patients.

**Intensive Outpatient Care:** This level of care includes treatment interventions that are less intensive than acute, subacute or ICF levels but are more intensive than office based physician/clinician treatment settings. Common examples of this for medical/surgical patients include: outpatient rehabilitation services and office-based chemotherapy for cancer patients. Examples of intensive outpatient care for medical/surgical patients are outpatient surgical centers for a variety of surgical procedures as well as intensive diagnostic procedures like colonoscopy that require a multidisciplinary team of physicians and nurses. These services can also be delivered via intensive home care interventions (home infusion therapies or pulmonary treatments).

Intensive outpatient treatments for MH and SUD are quite common and, like medical/surgical care, are provided via a step-down level of care from inpatient care. Examples include intensive outpatient programs for SUD which can be delivered several times a week for several weeks and have a multi disciplinary team, and may be in specialized treatment settings. Day treatment or partial hospitalization programs for psychiatric patients with a variety of diagnoses are another typical example of this level of care.

**Office based Treatment:** This is the most common treatment setting for both medical/surgical and MH/SUD patients. A variety of interventions are delivered in these settings including pharmacotherapies. Often numerous diagnostic tests are reimbursed for medical/surgical patients in this setting. Typically most diagnostic tests are reimbursed for medical/surgical patients while there continue to be limitations on common MH/SUD diagnostic test like administering a range of psychological tests and reimbursement for diagnostic standardized tests like the PHQ 9 for depression.

**A Description of How Scope of Service Parity Decisions are Based on Plan’s Medical Management and Utilization Review Standards and are therefore, a Type of a Non-Qualitative Treatment Limitation**

The issue at hand here concerns the proper boundaries of how plans place treatment limitations on MH/SUD services in a manner that is no more restrictive than those applied to medical/surgical.

This discussion recognizes that plans de facto have a “coverage determination construct” (CDC) that incorporates criteria and/or rationales to decide the types and levels of treatment benefits a plan decides to provide for medical/surgical benefits. This CDC is a NQTL as defined in the regulations (and varies from plan to plan) and therefore must be applied comparably to what types and level of treatment will be covered for mental health/substance use disorders.

Health plan benefits for inpatient care provide an illustration. A health plan, by its coverage terms, provides a wide range of benefits for various types/levels of inpatient care for medical/surgical benefits (e.g., hospital, sub-acute hospital, ICF, SNF, etc). There are a number of generally-recognized independent industry standards that would recommend these levels/types of care for reasons of clinical appropriateness and cost effectiveness. Most medical/surgical benefit packages offer reimbursement for this full range of inpatient levels and types. The American Society of Addiction Medicine has a set of clinical guidelines used to place patients in the appropriate level of
care for addictive disorders. The American Psychiatric Association has treatment guidelines for virtually all prevalent mental illness conditions.

However, the fact that coverage is offered does not guarantee an insurer's obligation to pay for any specific patient for every inpatient level or type. A positive reimbursement determination by a health plan for a defined benefit is dependent on a finding of "medically necessity" under the plans benefit contract.

Considerations that guide medically necessary coverage determinations for benefits typically include (but are not necessarily limited to):

1. Do contractual limitations apply? Is care consistent with professional standards of practice?

2. What is the patient's condition/acute and severity e.g., is treatment delivered in a safe and effective manner?

3. What is the cost? Is there an equally effective and safe but less costly alternative? Is the level of care/service intensity appropriate to the patient's condition?

(Note: The factors operative in any particular health plan may vary, but almost always can be gleaned from plan documents.)

In essence, health plans provide a coverage determination process whereby a patient's clinical need is balanced against the plan's coverage and terms, cost effectiveness and standards of care to provide optimal health services. As noted by Towers Perrin in its May 28, 2009 response to the RFI, "Treatment at the least intensive level of care suited to the patient's needs is a basic tenet of the definition of medical necessity for MH/SUD and medical/surgical services.

However, with respect to mental health/substance use disorder coverage, if the plan severely limits the scope/coverage of services within the inpatient classification it is not acting consistently with independent and generally-recognized care guidelines and/or comparable to the level of care options provided by the medical/surgical benefit. It thereby precludes the application of similar factors for medically necessary coverage determinations for MH/SUD treatments. This in effect bars access to comparable types of care, and the limited coverage benefit is by operation of the coverage determination process, an NQTL of the type prohibited by the parity Act.

Completely eliminating reimbursement for categories and levels of care precludes access to the most clinically appropriate, least restrictive, safest and most effective, cost-efficient treatment option. Stated differently, where the decision matrix (i.e., the NQTL) that produces a broad scope of stated covered benefits on the medical/surgical side is not applied comparably to the MH/SUD benefits, a prohibited mental health treatment limitation is in operation.

Applying this CDC comparability requirement in defining a scope of benefits does not establish a specific benefit mandate per se. It does require a plan that chooses to provide coverage to establish benefits for MH/SUD using the same criteria it uses for medical/surgical and apply similar factors in making coverage determinations.
Moreover, providing for comparable coverage establishment and determination processes does not enfranchise all available treatments and providers in the mental health/substance use disorder delivery system(s). Health plan policy conditions and exclusions can contractually limit coverage so long as comparable factors are applied to medical/surgical, a point which is more fully addressed below.

**How a Plan Uses Benefit Exclusions for Limiting Medical/Surgical Treatment and Can Use those Same Standards to Put a “Floor” on MH/SUD Treatments**

Plans have a variety of medical policy and benefits exclusions that are applied to medical/surgical treatments and these are typically applied to most or all of the medical/surgical benefit. These medical policies would fit the definition of a NQTL as defined in the MHPAEA regulations as they both define and limit the medical benefit. If they are applied to all medical and surgical treatments and they are applied in a comparable and no more restrictive manner then these same benefit exclusions can be applied to MH/SUD treatments. Given the broad definitions of these exclusions, plans have significant latitude in deciding which MH or SUD treatments can be excluded. However, the regulations clearly requires a comparable and no more stringent application.

The most common types of benefit exclusions are non reimbursement for: 1) custodial care; 2) services that are primarily educational in nature; 3) habilitation services; and 4) experimental treatments. While there is no universal definition of these terms across health plans, we believe the following definitions are reasonably representative.

**Custodial care:** Non-skilled, personal care provided to help a person in the activities of daily living, such as bathing, dressing, eating, transferring (for example, from a bed to a chair) and toiletry. It may also include care that most people do for themselves such as food preparation, diabetes monitoring and/or taking medications.

When these activities occur when a person is in a 24-hour treatment facility, such as a hospital they are reimbursed as a part of a “package” of medically supervised services, but when they are offered outside of a treatment setting they are typically not covered.

**Education:** Education, special education, or job training, especially if these educational activities occur outside of a health care treatment program. Services, treatment, education testing or training related to learning disabilities or developmental delays. Charges for any services or supplies related to education, training or retraining services, including, for example: testing, special education, remedial education, job training and job hardening programs.

**Habilitation:** Services that are primarily related to normal living expenses, such as food and housing costs. Again while these services are reimbursed while a person is in a hospital or other 24-hour treatment setting, they are typically not covered when a person is residing outside of those care settings even if they are receiving intensive or regular outpatient treatments.

**Experimental:** Refers to paying for treatments that are not “proven” based on scientific evidence such as controlled research studies or expert consensus panels. If
the treatment is a drug or device that requires FDA review then the FDA’s approval can provide the necessary review that the treatment is both safe and effective.

Concerns have been raised that if a comprehensive “scope of service “parity is required that a plan will have to reimburse all requested treatments for MH/SUD including: experimental and untested treatments; services that are primarily educational in nature and are not part of a recognized treatment or rehabilitation program; and long term custodial care where the patient is receiving supportive services but active treatment interventions are not needed or are deemed unnecessary. However, if these exclusions are applied to medical/surgical, then they can be applied to MH/SUD and will allow a plan to set a floor on “Scope.”

Some examples help illustrate this point. If a plan has a set of scientific criteria that are used to determine what medical treatments are considered evidence-based or non-experimental then (assuming these standards are applied to substantially all medical/surgical treatments in a benefit class) these same sets of standards can be applied to MH/SUD treatments and will serve to limit these treatments to those that are evidence-based or non-experimental.

If a plan refuses to reimburse for habilitation services such as housing and food costs for a cancer patient that is receiving outpatient treatment such as chemotherapy in a physician’s office, then they can apply this same benefit restriction to mental health support services or paying for living expenses or food and housing for a depressed patient that is receiving outpatient pharmacotherapy and psychotherapy.

Many plans do not reimburse for “custodial care “for medical/surgical. Most plans define this as not reimbursing for interventions that are not going to result in any clinical improvement and are also primarily for services that are not medical in nature such as assistance with bathing, eating, etc.. Again, these same standards can be applied to interventions for MH/SUD assuming they are applied in a no more stringent manner and are applied to substantially all medical/surgical spending.

**Chronic Care vs. Acute Care:** There is confusion about whether and when payers generally cover treatment services for chronic medical/surgical conditions and when they cover them in a long term care setting. It is important to define these terms so that a coverage determination NQTL can be applied equitably. The issue is whether reimbursing for services in a long term care setting is the same as paying for treatment of chronic disease over a long period of time. It is very different.

Most commercial and Medicaid Managed Care Organization (MCOs) spend the majority of their resources on chronic conditions and do so over the long term. It is well documented that chronic conditions, such as diabetes, heart disease, most forms of cancer, and chronic respiratory conditions, represent the majority of costs in a typical health plan’s medical expenditures. Beneficiaries with these chronic illnesses will be reimbursed for their care in both inpatient and outpatient settings over many years and possibly for the duration of the patient’s life. If this is a plan’s standard medical policy for medical/surgical conditions, then it will need to be the same for MH/SUD benefits.

Part of the confusion in this area is the lack of a standard definition of what is considered “long term care” or care in a long-term care setting and the difficulty in separating that
definition from what is typically reimbursed by most health plans. For example, one common definition of long term care is:

    Facility charges for care services or supplies provided in: rest homes, assisted living facilities, group homes or similar institutions serving as an individual's primary residence or providing primarily custodial or rest care.

This definition, if applied consistently between medical and behavioral, would allow a plan to reasonably determine what treatments and settings are reimbursable for MH/SUD.

Conclusion

We believe MHPAEA requires parity across and within each of the six benefit classifications. As illustrated, it is imminently feasible to define and apply this requirement within each of the six classifications without imposing benefit mandates, precluding coverage limitations. The coverage determination process discussed herein is an NQTL as defined by the regulations. Hence, the parity stipulation between benefits offered for MH/SUD and medical/surgical requires that a process to determine them be comparable.
APPENDIX 2

PARITY IMPLEMENTATION COALITION

Non-Quantitative Treatment Limitations Are Applied More Stringently on MH/SUD Benefits

Most individuals covered by health insurance believe that if they or their covered family member require treatment, they will be covered. Even when their policy covers them, millions of Americans with mental health/substance use disorder (MH/SUD) conditions frequently encounter, even since MHPAEA was enacted, non-quantitative treatment limits (NQTLs) imposed by plans that present significant barriers to accessing MH/SUD services.

Non-Quantitative Treatment Limitations Rooted in Substantial MHPAEA Legislative History

Consumer and provider testimony expressing frustration and confusion while attempting to navigate ambiguous policies was an important part of the legislative history of MHPAEA leading to the inclusion of language defining treatment limitations "as limitations including limits on frequency of treatment, the number of visits, days of coverage or other similar limits on the scope or duration of treatment." This broad definition reflected the nationwide call for transparency in plan decision-making that was recommended at nearly every hearing held on parity legislation.

The Interim Final Regulations (regulations) recognize the importance of addressing NQTLs to achieve the promise of health care equality for millions of Americans with MH/SUD conditions. Without a policy that applies parity requirements to NQTLs, the promise of parity will never be realized.

Coalition Survey of Health Plan Policies and Practices

The Parity Implementation Coalition (Coalition) conducted a survey of health plan policies and practices since MHPAEA was enacted. Policies issued in over 25 states by nearly every large managed care plan, many of the managed behavioral health organizations, several large self-insured employers and many Blue Cross/Blue Shield plans were analyzed. These results are just a sample of the inconsistencies, questionable interpretations or clear violations of the law we found as the Coalition members sought to provide or access benefits in the 2010 behavioral health marketplace.

NQTLs are Applied on Out-of-Network MH/SUD Coverage without Corresponding Requirements on Medical/Surgical Coverage

A key provision in MHPAEA requires plans that provide both medical/surgical benefits for out-of-network coverage to provide out-of-network coverage for mental health/substance use disorders, consistent with the financial and treatment limitation requirements of the Act.

Various NQTLs are being applied exclusively to out-of-network MH/SUD benefits and are determinative of whether, when, and where plan participants may be able to access coverage. These

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treatment limitations for MH/SUD out-of-network care can have several detrimental consequences for consumers. For example, out-of-network limitations have included requiring 100 percent out-of-pocket expenditures for any denied care in an out-of-state treatment program and denials for reimbursement for out-of-network providers that often lead to limited or no availability of care at all. MH/SUD consumers face these consequences despite the fact that out-of-network care would have been approved for medical conditions.

We know that access to out-of-network care for MH/SUD patients is often the difference between accessing care or going untreated. The access problem is particularly dire for individuals needing MH/SUD services living in rural America – for example, the American Academy of Child and Adolescent Psychiatry has only two members in the entire state of Wyoming.

Examples of 2010 plan terms currently in operation include the following:

- Various Large Health Insurers
  - Out-of-network MH/SUD services not located in the state where the policy is written are not covered.

- Large Managed Behavioral Health Organizations (MBHO)
  - Persons accessing out-of-network providers for MH/SUD can be stabilized only, and must be transferred to an in-network provider in order for coverage to be in effect. No similar provision for out-of-network medical/surgical.
  - Precertification and concurrent review protocols for all out-of-network mental health/substance use disorder care; no corresponding precertification or concurrent review protocols for out-of-network medical/surgical care.

- Various Blue Cross/Blue Shield Plans
  - Will not make medical necessity criteria available upon request to patients who are seeking MH/SUD out-of-network services, as required under MHPAEA. Will only make medical necessity criteria available after an out-of-network coverage determination is made.

**Benefit Limitations or Policy Exclusions that Restrict Coverage for MH/SUD More Stringently than Medical/Surgical Conditions are NQTLs**

The Coalition survey found continuations of current contractual benefit limitations as well as some disturbing new limitations. One limitation noted with increasing regularity was the practice of the plan becoming the “mental health/substance abuse designee.” Plan participants are prohibited from seeking treatment without permission from the designee – and the designee can terminate the MH/SUD treatment at any time regardless of the views of the treating provider or participant. Not only is there not a similar designee for medical/surgical services, but participants may be discouraged from seeking services for MH/SUD conditions at all because the designee totally controls all of the following and the participant appears to have no ability to choose how their MH/SUD health care dollar is spent:

- Access to care;
- Choice of provider;
- Treating clinician’s qualifications;
• Duration of treatment; and
• Type of treatment.

Many of the treatment limitations have the impact of severely reducing access to services for people with MH/SUD. The impact can be more severe than a financial requirement or a quantitative treatment limitation because it can result in the consumer having no treatment access at all or having to bear 100 percent of the cost out-of-pocket.

For example, in one of the exclusions listed below only short-term crisis care will be reimbursed for MH/SUD. This treatment limitation is not applied to medical services and, if applied to MH/SUD, would lead to very limited reimbursements of most MH/SUD treatments whether occurring in outpatient or inpatient settings. A significant portion and variety of services which are not short term crisis medical/surgical care are reimbursed for people with chronic and often relapsing diseases, such as diabetes, heart disease, renal disease, and most forms of cancer. While most health plans pay for the treatment of these diseases over a period of years, some plans propose to pay for MH/SUD solely on a crisis basis. Plans contend this type of NQTL is legal and appropriate under MHPAEA.

Listed below are a number of these restrictive policies that have been implemented in 2010 that health plans view as compliant with MHPAEA.

Major Multi-state Employer Benefit Plan:
EXCLUSIONS
Mental Health/Substance Abuse
• Services that extend beyond the period necessary for short-term evaluation, diagnosis, treatment, or crisis intervention.

• Treatment of conduct and impulse control disorders, personality disorders, paraphilias and other mental illnesses that will not substantially improve beyond the current level of functioning, or that are not subject to favorable modification or management according to prevailing national standards of clinical practice, as reasonably determined by the Mental Health/Substance Abuse Designee.

• Treatment provided in connection with or to comply with involuntary commitments, police detentions and other similar arrangements, unless authorized by the Mental Health/Substance Abuse Designee (the employer/health plan).

• Services or supplies that in the reasonable judgment of the mental health/substance abuse designee are not, for example, consistent with certain national standards or professional research.

Several Blue Cross/Blue Shield Plans and Self-Insured Employers:
EXCLUSIONS
• All substance abuse services (even though the plan offers a full array of mental health benefits).

• Treatment for illicit drugs.
Coverage Exclusions for Types and Levels of MH/SUD Treatment

While some barriers to care unearthed in the Coalition survey extend beyond those written directly into policies, others are directly transparent and directly exclude entire levels of care – although the basis for the exclusions vary. These exclusions apply only to MH/SUD services/levels of care and not for common medical/surgical services.

Contractual exclusions/limitations have been added that render certain levels of care excluded as a matter of contract without any consideration of whether the care is medically necessary, effective, or essential to successful treatment for MH/SUD. Due to these restrictive policies that are not applied to medical treatments for common medical conditions, access to care for MH/SUD is often severely restricted and all necessary care provided to an individual must be borne out-of-pocket. Moreover, out-of-pocket expenses for ‘non covered’ care may not accumulate toward the health plan’s deductible requirements for other health care sought by the individual.

Examples of contractual exclusions or limitations that apply exclusively to MH/SUD but not to medical/surgical include:

- **Multiple Blue Cross/Blue Shield plans exclude:**
  - MH/SUD residential treatment services
  - SUD partial hospitalization
  - SUD intensive outpatient programs

- **Multi-state Employer Plans/Several Blues Plans/MBHOs**
  - Admission criteria for inpatient MH/SUD services that require patients to be homicidal or suicidal before being eligible for coverage while there is no similar restriction on medical benefits.

- **Major Managed Care Organizations/Blue Plans/MBHOs**
  - Plans are covering mental health benefits and dropping substance use disorder benefits altogether claiming that MHPAEA (even after a plan decides to offer MH/SUD coverage) requires them to cover either MH or SUD at parity with medical/surgical, but not both.

- **Major managed care organizations**
  - MH/SUD services that extend beyond the period necessary for short-term evaluation, diagnosis, treatment, or crisis intervention.
  - Residential treatment services.
  - Treatment provided in connection with or to comply with involuntary commitments, police detentions and other similar arrangements, unless authorized by the Mental Health/Substance Abuse Designee.

**Conclusion**

NQTLs pose significant barriers to accessing care for those with MH/SUD conditions. There is a strong statutory basis for NQTLs under MHPAEA and there is a strong need for clarifying regulations since plans are interpreting the regulations in a way that continues to limit access to equitable MH/SUD care. The survey conducted by the Coalition documents the need for additional
examples of NQTLs in the final regulations, and special attention should focus on out-of-network parity NQTLs where access is particularly constrained. Elimination of entire levels of care essential to the range and scope of services for effective MH/SUD care must not be permitted under the final rules when there is a comparable range and scope of medical/surgical services.

Only as we end the discriminatory insurance practices between MH/SUD and medical/surgical conditions will we begin to see the artificial distinctions between treatments for the mind and body begin to disappear.
April 30, 2010

Carol McDaid
Principal
Capital Decisions, Inc.
101 Constitution Avenue, NW
Washington, DC 20001

Re: MHPAEA Scope of Services Research

Dear Carol:

We have completed our research on Milliman Care Guidelines for illustrative medical and behavioral conditions and disorders, including the scope of services across several different treatment modalities along their care continuums. This letter presents the results of these research efforts.

Results

We reviewed Milliman Care Guidelines for three different medical conditions and three different behavioral disorders and compared the recommendations for treatment across the spectrum of care alternatives that vary by treatment intensity. We compared treatments for a myocardial infarction to major depression, diabetes to alcohol dependence disorder, and seizures with schizophrenia. In each comparison of medical and behavioral conditions, we found that a broad spectrum of treatments in various settings are recommended, based on the severity of the condition and the recovery of the patient. These treatments included inpatient hospital care (including various care intensity alternatives), subacute hospital care (including rehabilitation hospitals, skilled nursing facilities and other sub-acute facilities), intensive outpatient services, home health services, and routine outpatient care.

We concluded from this side by side comparison of common medical and behavioral conditions that the levels of care and settings for treatments were similar and analogous. Hospital and subacute inpatient services are typically used by both medical and behavioral patients, and intensive outpatient interventions are available as integral services for all of these disease categories. We found that many of the clinical criteria, such as judgments about the acuity and severity of the illness, were similar for both medical and behavioral conditions. However when we look at the specific treatments (type of medication) given in these settings, they are unique to the illness or disorder. This is true for all illness category comparisons, not just medical and behavioral.

Our findings support that a full spectrum of evidence-based treatment alternatives are necessary to provide optimal and efficient care, and to obtain clinically-effective outcomes. We do not recommend differences in the availability of a continuum of care alternatives between common medical and common behavioral conditions. While some healthcare services vary considerably between medical and behavioral conditions due to the underlying nature of the disorders, access
to a complete continuum of evidence-based care alternatives is vital for achieving best practices in care delivery.

We also believe that physical and behavioral disorders are inter-related. Comorbidities between physical disorders and behavioral disorders are very common and we support the treatment of the mind and body in an integrated approach. As the Surgeon General reported in 1999 on the subject of mental health, "everyday language tends to encourage a misperception that mental health or mental illness is unrelated to physical health or physical illness; in fact, the two are inseparable".

Our Approach

We reviewed detailed Care Guidelines that are researched, developed and annually updated by Milliman clinicians and consultants based on current best evidence. These Guidelines are the results of a substantial amount of research into best practices that are documented in medical and scientific literature. The Care Guidelines presuppose access to all levels of care, including the full continuum of care and support services, and some alignment of philosophy or incentives among the members of the healthcare team. If preferred alternative levels of care are not available, continued acute care may be required.

We included reviews of several elements of the Care Guidelines in our comparisons of medical and behavioral disorders:

- Recommended treatment options along care continuum
- Indications for admission to various treatment options
- Interventions within treatment options
- Medications for each condition
- Goal lengths-of-treatment
- Extended stay/treatment indications
- Discharge criteria

The editors, contributors, and reviewers have created the Care Guidelines to achieve the following goals:

- Assist clinicians in making informed decisions in many healthcare settings including hospital, acute and subacute medical and rehabilitation, skilled nursing, home healthcare, and ambulatory facilities. When the continuum of care is used, more intensive levels of care are reserved for patients who cannot be managed safely and effectively at lower levels.

- Communicate a range of demonstrated best practices, not average or minimally acceptable practices.

- Display quality measures from US national organization quality initiatives such as the Centers for Medicare and Medicaid Services Hospital Quality Alliance initiative, the National Committee for Quality Assurance HEDIS® measures, and the Joint Commission's National Patient Safety Goals.
• Provide information to reduce unnecessary variation in healthcare practice because substantial unnecessary variation still pervades medicine.

• Display the current best evidence used in developing the Care Guidelines to encourage clinician participation in the practice of evidence-based medicine. Key points are enhanced with footnotes, explanations, annotations, or references to describe the evidence base for each guideline conclusion.

• Encourage patient education and patient choice. Informed patients can cooperate with caregivers to achieve better outcomes and can make better choices about their healthcare.

• Use a concise, accessible format to support rapid assimilation of information.

Caveats

This report is intended for the exclusive use of the Parity Implementation Coalition in developing your response to the Interim Final Rules (IFR) regarding the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA). Other uses may be inappropriate. If this report is submitted as part of your response to the IFR, it should only be attached in its entirety. It should not be released to parties outside of the Coalition other than the Department of the Treasury, the Department of Health and Human Services, and the Department of Labor without the expressed written consent of Milliman.

Please let us know if you have any questions regarding this report or any of the tables of results.

Best regards,

Stephen P. Melek, FSA, MAAA
Consulting Actuary