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Comment On: EBSA-2009-0010-0409

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

Document: EBSA-2009-0010-DRAFT-0646

Comment on FR Doc # 2010-2167

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General Comment

"On behalf of NAMI Metropolis / Southernmost Illinois, I am writing to submit comments on the Interim Final Rules under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 and in doing so NAMI Metropolis / Southernmost Illinois endorses the separate comments submitted by the Parity Implementation Coalition and the National Alliance on Mental Illness"

Judy Kruger

President NAMI Metropolis/Southernmost Illinois

See attached file(s)

Attachments

EBSA-2009-0010-DRAFT-0646.1: Comment on FR Doc # 2010-2167

***NAMI MODEL COMMENTS ON THE INTERIM FINAL
REGULATIONS IMPLEMENTING THE MENTAL HEALTH PARITY
AND ADDICTION EQUITY ACT OF 2008***

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration, Room N-5653
U.S. Department of Labor
Attention: RIN 1210-AB30
200 Constitution Avenue, NW.
Washington, DC 20210

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4140-IFC
P.O. Box 8016
Baltimore, MD 21244-1850

CC:PA:LPD:PR (REG-120692-09), Room 5205
Internal Revenue Service
P.O. Box 7604
Ben Franklin Station
Washington, DC 20044

**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:

On behalf of NAMI _____, I am pleased to submit the following 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

NAMI’s consumer and family membership worked hard for more than 17 years to help secure passage of the MHPAEA in Congress. We are anxious to work with DoL, HHS and Treasury to ensure full implementation and equitable coverage for both mental illness and substance use treatment in group health plans. NAMI has also joined separately with the Parity Implementation Coalition and the Mental Health Liaison Group in submitting comments on these regulations.

NAMI is grateful for the significant work and analysis that has gone into the Interim Final Rules and commends the Departments for their efforts to ensure the Act is implemented in a manner that will convey strong parity protections consistent with the

¹ 75 Fed. Reg. 5410 (Feb. 2, 2010).

intent of Congress. On May 28, 2009, NAMI National joined the Parity Implementation Coalition in submitting comments and a detailed legal analysis to the Departments that outlined our views regarding implementation of the Act. NAMI is pleased that the Departments incorporated many of these recommendations into the Interim Final Rules.

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/SU benefits. Under the 1996 mental health parity law, a similar definition was used for both MH/SU 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.

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.

² 75 Fed. Reg. 5416-17.

³ § 1185a(e)(4).

⁴ *Id.*

⁵ *Id.*

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.⁶ 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)."⁷ 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.

⁶ Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act, 29 U.S.C.A. § 1185a(a)(3)(A)(i) (2009).

⁷ § 1185a(a)(3)(A)(ii).

In addition, the plan would have to show that it applies a similar limit to substantially all medical and surgical benefits under the plan.

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."⁸ 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." NAMI joins the Parity Implementation Coalition in reading 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 classes, 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."⁹ [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.¹⁰ In other words, the list is demonstrative rather than comprehensive. If Congress wanted the treatment limitations section to apply only 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 medical/surgical than in MH/SUD.

⁸ § 1185a(e)(4), (5).

⁹ § 1185a(a)(3)(B)(iii).

¹⁰ *Id.*

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 co-payments 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. 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.

¹¹ *Id.*

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 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.”¹⁴ 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

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.

¹³ 75 Fed. Reg. 5413.

¹⁴ H.R. REP NO. 110-374, pt. 2, at 12 (2007)(Ways and Means Comm.).

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, NAMI requests 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.

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 (QTL) 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.”¹⁵ 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 Analog if it does not Apply a Similar Standard in the Medical/Surgical Benefit.

¹⁵ 75 Fed. Reg. 5412.

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

In most cases, a plan that refuses to cover a MH/SUD service because it claims there is no medical/surgical analog 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.¹⁶

The regulations require NQTLs to be “comparable.”¹⁷ A rule that prohibits coverage for MH/SUD treatments that have no medical/surgical analog, but does not prohibit coverage for medical/surgical services that have no MH/SUD analog, 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.”¹⁸ A plan that refuses to cover a MH/SUD service that has no analog in medical/surgical, but does not apply a similar standard to medical/surgical benefits, violates the parity requirements of the statute because it imposes a treatment limitation “applicable only with respect to” MH/SUD benefits.

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.

NAMI 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.

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 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).

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. NAMI 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. NAMI 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.

NAMI joins the Parity Implementation Coalition in strongly supporting 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 deductible before the plan provides either MH/SUD or medical/surgical benefits. 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

¹⁹ 62 Federal Register 66931, 66933 (December 22, 1997).

²⁰ § 1185a(a)(3)(B)(ii) (2009).

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 used 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 MHSUD 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 rule is in cases where “recognized clinically appropriate standards of care...permit a difference.”²⁴ 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

²¹ § 1185a(a)(3)(B)(iii).

²² *Id.*

²³ 75 Fed. Reg. 5416.

²⁴ *Id.*

“applied” no more stringently in medical/surgical than in MH/SUD.²⁵ 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.”²⁶

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.²⁷ 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.²⁸ 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.²⁹

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 prohibition on applying a NQTL in MH/SUD, while not applying a comparable NQTL in medical/surgical, is likewise consistent with the underlying Act.³⁰

²⁵ *Id.*

²⁶ *Id.*

²⁷ 75 Fed. Reg. 5436.

²⁸ *Id.*

²⁹ *Id.*

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.³¹ This meaningful variation demonstrates that failure to meet either of these standards results in non-compliance with the regulations. NAMI 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.

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.³² To remain consistent with the language and intent of the

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.

³¹ 75 Fed. Reg. 5436.

³² 29 U.S.C. 1185a(a)(3)(A)(ii).

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.

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

³³ *Id.*

³⁴ 75 Fed. Reg. 5412-13, 5419, 5433, 5440, 5446.

³⁵ 29 U.S.C. 1185a(a)(3)(B)(iii).

³⁶ *Id.*

³⁷ 75 Fed. Reg. 5413.

³⁸ 75 Fed. Reg. 5414.

³⁹ *Id.*

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 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.

A precertification requirement for inpatient hospital admission provides an illustrative example of an NQTL. This NQTL applies to 100 percent of medical/surgical benefits in the classification so it applies to substantially all medical/surgical benefits, and is also predominant because it 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.⁴¹ 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 thus 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.⁴² 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.

⁴⁰ 75 Fed. Reg. 5412.

⁴¹ 75 Fed. Reg. 5436.

⁴² 75 Fed. Reg. 5412-13.

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, suppose a plan were to require 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 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.”⁴³ To ensure the strong parity protections envisioned by Congress, the Departments should adopt a definition of

⁴³ 75 Fed. Reg. 5416.

“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.⁴⁴ In the Act, Congress was very clear that treatment limitations should be “no more restrictive” in MH/SUD benefits than in medical/surgical benefits. By expanding previous parity legislation, and using clear language in doing so, Congress expressed a clear 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, recognized treatment guidelines or expert consensus panels.⁴⁵

⁴⁴ 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 Addiction Equity Act. It was in this context that the Act was passed.

⁴⁵ 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.

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 Final Rules should include additional illustrations of common NQTLs, including, but not limited to, the following:

- 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.

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 plain language of the regulations appears to prohibit rate calculation methods that are more stringent for MH/SUD providers than medical/surgical providers. However, NAMI would recommend that the Departments consider strengthening this language, and make clear that inflation updates to provider reimbursement rates are a form of NQTL.

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.

⁴⁶ 75 Fed. Reg. 5416.

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 an 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, NAMI joins the Parity Implementation Coalition in requesting that provider inflation updates be included as an 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

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 an NQTL subject to the parity regulations.

⁴⁷ 75 Fed. Reg. 5443.

⁴⁸ 75 Fed. Reg. 5412.

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.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, a plan enrollee 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.

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.”⁵⁰ 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.⁵¹

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.⁵² If a plan relies upon internal medical necessity criteria in denying MH/SUD benefits, this requirement should require disclosure of these criteria.

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).

⁵⁰ *Id.*

⁵¹ *Id.*

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

A notification of adverse benefit determination must also include reference to the "specific plan provisions on which the determination is based."⁵³ 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. NAMI joins the Parity Implementation Coalition in requesting 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.⁵⁴ The Act is clear that actual 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."⁵⁵ [Emphasis added] 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.⁵⁶ The Act discusses actuaries, but only to specify

⁵³ DOL Reg. § 2560.503-1(g)(l)(ii); see also *Wheeler v. Aetna Life Ins. Co.*, 2003 WL 21789029, 31 EBC 1782 (N.D. III. 2003) (denial was arbitrary and capricious where letters "utterly fail[ed] to consider the actual language of the plan"); *Ayers v. Maple Press Co.*, 168 F. Supp. 2d 349 (M.D. Pa 2001).

⁵⁴ 29 U.S.C. 1185a(c)(2)(A).

⁵⁵ *Id.*

⁵⁶ 29 U.S.C. 1185a(c)(2)(E)(i)(II), (III).

that their determinations of cost increases should be based on “actual costs.”⁵⁷ 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 1 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.”⁵⁸ As stated by the regulations, the term “incurred expenditures” means “actual claims incurred during the base period.”⁵⁹ Once again, the Departments were clear that the exemption calculation must be based on actual costs. NAMI requests that the Department reject any argument to the contrary.

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 would “prevent the application” of the MHPAEA.”⁶⁰ 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

⁵⁷ 29 U.S.C. 1185a(c)(2)(C).

⁵⁸ 62 Fed. Reg. 66955.

⁵⁹ *Id.*

⁶⁰ 75 Fed. Reg. 5418.

MHPAEA.”⁶¹ 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.⁶² Accordingly, “States have significant latitude to impose requirements on health insurance issuers that are more restrictive than the federal law.”⁶³ NAMI joins the Parity Implementation in strong supports of 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

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.⁶⁴ All states except Alaska, Wyoming, and New Hampshire have at least a portion of their Medicaid population enrolled in managed care.⁶⁵ 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, NAMI requests that 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, NAMI requests that the Departments make clear that Medicaid managed care plans are subject to the requirements of the Act. Both the legislative history of the Act and the regulatory history of previous mental health laws support this conclusion.

As note above, the MHPAEA modified the 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.⁶⁶ The Medicaid managed care statute 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

⁶¹ *Id.*

⁶² 75 Fed. Reg. 5430.

⁶³ *Id.*

⁶⁴ CENTERS FOR MEDICARE AND MEDICAID SERVICES, 2005 MEDICAID MANAGED CARE ENROLLMENT REPORT: SUMMARY OF STATISTICS AS OF JUNE 30, 2006 (2006), http://www.cms.hhs.gov/MedicaidDataSourcesGenInfo/04_MdManCrEnrllRep.asp.

⁶⁵ *Id.*

⁶⁶ 42. U.S.C. 300gg-5(a)(3) (2000).

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.”⁶⁷ The statutory reference in the quote refers to the mental health parity provisions as passed in the 1996 Mental Health Parity Act (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.”⁶⁸ 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.⁶⁹ 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.⁷⁰ The Health Care Financing Administration (HCFA), the predecessor agency to CMS, subsequently released a number of letters to State Medicaid Directors explaining the effect 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 Mental Health Parity Act (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

⁶⁷ 42 U.S.C. 1396u-2(b)(8) (2000).

⁶⁸ S. REP. NO. 110-53, at 5 (2007) (Sen. Comm. on Health, Educ. & Labor, 2007).

⁶⁹ 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.).

⁷⁰ 42 U.S.C. 1396u-2(b)(8) (2000).

⁷¹ Letter from Sally Richardson, Director of the Health Care Financing Administration, to State Medicaid Directors (January 20, 1998), available at: <http://www.cms.hhs.gov/smdl/downloads/SMD012098d.pdf>.

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.

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, NAMI requests that the Departments issue timely regulations related to the application of MHPAEA to Medicaid managed care organizations or explain the delay in promulgating such regulations.

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. NAMI 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.

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.

⁷³ 75 Fed. Reg. 5412.

⁷⁴ *Id.*

The comments included above raise numerous issues that NAMI and the Parity Implementation 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

NAMI is committed to ending discrimination against individuals and families who seek services for MH/SUD. NAMI looks forward to working with the Departments to modify and finalize the Rules so that they promote strong, clear parity protections.

Sincerely,