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## EXECUTIVE SUMMARY OF PARITY INTERIM FINAL RULES ANALYSIS

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On February 2, 2010, the U.S. Departments of Labor (“DOL”), Treasury, and Health and Human Services (“HHS”) published interim final rules (“regulations”) implementing the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (“MHPAEA” or “Act”) in the Federal Register.<sup>1</sup> The MHPAEA requires parity between mental health or substance use disorder (MH/SUD) benefits and medical/surgical benefits with respect to financial requirements and treatment limitations under group health plans and health insurance coverage offered in connection with a group health plan.

Patton Boggs, LLP was asked by the Parity Implementation Coalition to analyze a set of questions related to various issues that may arise regarding the interim final rules implementing the *Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008*. This document summarizes the key issues, questions and challenges that may arise as this historic law is implemented by providers, insurers and employers. The analysis was divided into questions regarding scope of service parity and classification of benefits, non-quantitative treatment limitations (NQTLs), and other general questions. Key issues addressed under the analysis fall under each of these major headings.

### **Scope of Service Parity and Classification of Benefits**

#### ***Benefits Must Fit in One of Six Classifications***

- The parity regulations create a six-classification scheme to implement the parity requirement. The regulations state clearly that these six classifications are the “only” possible classifications for implementing the parity rules.<sup>2</sup> Thus, the plain language of the statute 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.

#### ***Moving Services Outside the Six Classifications to Avoid Parity Requirements Violates the Act***

- 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. Moving certain services outside the six classes to avoid the parity requirements would also be a clear violation of Congressional intent. 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 to restrictions on MH/SUD that are more restrictive than those applied to medical/surgical.

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<sup>1</sup> 75 Fed. Reg. 5410

<sup>2</sup> 75 Fed. Reg. 5413

***While the Preamble States the Regulations Do Not Address Scope of Services, the Regulations' Rules Related to Classification, NQTLs and QTLs Confer a Scope of Services***

- Although the preamble to the regulations explicitly states that the regulations do not address scope of services, other parts of the regulation define a scope of service parity requirement both across each of the required six classifications for applying the rule, and within each of the classifications. In addition, the underlying 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.

***A Plan that Covers Few MH/SUD Treatment Services, While Providing Many Medical/Surgical Services, Violates the Act if it Has Applied a Treatment Limitation More Restrictively***

- A plan that offers only one type of MH/SUD treatment service in any of the six required classifications, while at the same time offering many medical/surgical services within the relevant classification is not compliant with the parity regulations if the comparatively low level of MH/SUD services is a result of the application of a treatment limitation to MH/SUD benefits that is more restrictive than the predominant treatment limitation of that type that applies to substantially all medical/surgical benefits in the classification.

***A Plan that Refuses to Cover a MH/SUD Service because there is no Medical/Surgical Analogue Will Violate the Act if it Does Not Refuse to Cover Medical/Surgical Benefits that have no MH/SUD Analogue***

- A plan that refuses to cover a MH/SUD service because there is no medical/surgical analogue violates both the regulations and MHPAEA if the plan 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.

**Non-Quantitative Treatment Limitations (NQTLs)**

- 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.<sup>3</sup> The sole exception to this rule is in cases where “recognized clinically appropriate standards of care...permit a difference.”<sup>4</sup> Under the regulations, one of the two critical factors for determining plan compliance with these requirements is the manner in which the processes, strategies, evidentiary standards, and other factors are used in *applying* the NQTL. 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 second critical prohibition prevents a plan from instituting a NQTL in MH/SUD that is not comparable to an NQTL in the medical/surgical benefit. In such a situation, the question is not whether the same NQTL is applied differently across

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<sup>3</sup> 75 Fed. Reg. 5416

<sup>4</sup> *Id.*

MH/SUD and medical/surgical, but rather whether a NQTL is being applied in MH/SUD that does not exist in medical/surgical.

- There are two standards to which plans must adhere related to NQTLs. 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: (1) not comparable to *or* (2) applied more stringently, than those utilized in the context of medical/surgical benefits. 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 MHPAEA unequivocally applies the “predominant and substantially all” standard to all treatment limitations. Although there is ambiguity in the regulations regarding whether the predominant/substantially all and the “comparable/no more stringently” tests are separate or additive, to remain consistent with the language and intent of the MHPAEA, the regulations should be interpreted to apply both standards to NQTLs. The Act sets forth three inquiries to determine plan compliance with the treatment limitation requirements: (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 statute applies the three-part test to *all* treatment limitations. Because of the difference between QTLs and NQTLs, and the practical difficulties of applying the “no more restrictive” test in the context of NQTLs, the regulations establish a second standard to operationalize the “no more restrictive” statutory test. This second standard is the comparable and no more stringently standard, and it is additive to the predominant and substantially all standard.

#### ***Reimbursement Methods are NQTLs Subject to Parity Requirements***

- 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. Inflation updates, which are tied closely to reimbursement rates and methods for determining charges, would similarly qualify as NQTLs subject to parity requirements. Although inflation updates are not mentioned specifically in the list of NQTL examples, the mention of reimbursement rates would reasonably be interpreted to include such updates.

#### ***Scientific Criteria that Limit or Exclude Benefits on Whether a Treatment is Experimental or Investigative are a Form of a NQTL***

- Scientific criteria that limit or exclude benefits based on whether the treatment is experimental or investigative are a form of NQTL that is subject to the regulations’ predominant and substantially all and comparable and no more stringently standards. Although the regulations do not require identical scientific criteria or standards for determining whether a treatment or diagnostic test is experimental, such criteria must be comparable and be applied no more stringently in MH/SUD than in medical/surgical.

### ***Regulations Should Define “Recognized” Independent Expertise Outside of Plans***

- Although the regulations do not explicitly define “recognized clinically appropriate standards of care,” the regulations and other government coverage policies give guidance that regulators should heed in construing the term. Examples in the regulations demonstrate that “recognized clinically appropriate standards” are those that are based on recommendations made by panels of experts with appropriate training and experience in the fields of medicine involved. In addition, at least one of the agencies that developed the regulations, the Centers for Medicare and Medicaid Services, regularly relies on independent expertise when making its coverage determinations.
- From a policy perspective, a clear definition of “recognized” is critical to ensure the integrity of the Act and to implement the intent of Congress. The only exception to the requirement 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 for when a standard is recognized are not established, 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. Permitting an exception to parity based on a plan’s internal review alone could weaken this intended strength.

### **Other Issues**

#### ***When Defining a MH/SUD Benefit, Plans Terms Must Be Consistent with an Independent or Recognized Standard or State Guideline***

- In defining benefits for MH/SUD conditions, plan terms must be “consistent with generally recognized independent standards of current medical practice.”<sup>5</sup> The regulations do not clearly define what this means, but set forth a list of sources that would meet the “generally recognized” 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. Although these are all “acceptable resources to determine” how benefits are classified, they are not the only sources.

#### ***Plans that State the Plan is Not Offering MH/SUD Benefits are Subject to MHPAEA if the Plan Reimburses for One or More MH/SUD Services***

- Plans that provide MH/SUD treatment services are subject to the parity requirements of MHPAEA. Accordingly, if a plan states it is not providing MH/SUD benefits, but reimburses for specific treatment services for one or more MH/SUD, the plan would be subject to MHPAEA and the regulations. Since a plan in such a situation is offering a MH/SUD benefit, the regulations require the plan to offer services in every benefit classification in which medical/surgical benefits are offered.

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<sup>5</sup> 75 Fed. Reg. 5412

***Medicaid Managed Care Organizations are Subject to the February 2, 2010 Regulations***

- The Medicaid statute requires that Medicaid managed care plans comply with the parity provisions of the Act. Since the regulations implement the Act and do not contain an exemption for Medicaid managed care plans, Medicaid MCOs must comply with the parity requirements as spelled out in the regulations. This conclusion is supported by both the Act and the regulatory history of previous mental health parity laws.

***Participants Can Bring a Private Right of Action Based on Violations of the Statute On or After 10/3/09 but a Claim Based on Improper Implementation of the Regulations May Not be Filed until 7/1/10***

- An aggrieved beneficiary can bring a suit based on alleged violation of the statute that occurred on or after October 3, 2009—the date the Act became effective. However, if the beneficiary’s suit is based on a claim that the plan improperly implemented the *regulations*, the beneficiary would likely have to wait to bring such a suit until July 1, 2010—the date the regulations become effective.

***If Plans Rely on Medical/Surgical Coverage Criteria to Deny MH/SUD Benefits, Plans Must Make these Criteria Available In Some Instances***

- Although there is no general rule requiring plans to disclose the medical/surgical coverage criteria when denying reimbursement or payment for MH/SUD benefits, plans will likely be required to do so in certain instances. The regulations incorporate previous regulatory requirements which state that if an internal guideline, rule, protocol, or other similar factor was relied upon in making an adverse determination, the notification must either include the specific guideline, rule, guideline, 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.<sup>6</sup> If a plan relies upon medical/surgical coverage criteria in denying MH/SUD benefits, this requirement appears to require disclosure of these criteria, either initially or upon request. For example, if payment for a MH/SUD service is denied because no medical/surgical benefits are provided in the corresponding classification, the plan would likely have to include this information.

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<sup>6</sup> DOL Reg. § 2560.503-1 (g)( I)(v)(A).

## MEMORANDUM

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**To:** Parity Implementation Coalition  
**From:** Patton Boggs, LLP  
**Date:** March 26, 2010  
**Subject:** Analysis of Interim Final Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008

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### Summary

On February 2, 2010, the U.S. Departments of Labor (“DOL”), Treasury, and Health and Human Services (“HHS”) published interim final rules (“regulations”) implementing the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (“MHPAEA” or “Act”) in the Federal Register.<sup>1</sup> The MHPAEA requires parity between mental health or substance use disorder (MH/SUD) benefits and medical/surgical benefits with respect to financial requirements and treatment limitations under group health plans and health insurance coverage offered in connection with a group health plan. This analysis focuses on various specific questions related to the regulations and the Act.

### Scope of Service Parity and Classification of Benefits

**Question 1a: Are plans required to include all medical/surgical and MH/SUD benefits in the six classes identified in the regulations or can they create new classes? Does the regulation or the statute provide a basis for challenging an action by a plan to put certain services outside of the six classes, thereby exempting these services from parity requirements?**

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.

**The parity regulations create a six-classification scheme to implement the parity requirement. The regulations state clearly that these six classifications are the “only”**

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<sup>1</sup> 75 Fed. Reg. 5410.

possible classifications for implementing the parity rules.<sup>2</sup> Thus, the plain language of the statute 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 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 new classification applies both on the medical/surgical and on the MH/SUD side. As noted above, **a plan would be 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.”<sup>3</sup> 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.**

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<sup>2</sup> 75 Fed. Reg. 5413.

<sup>3</sup> H.R. REP NO. 110-374, pt. 2, at 12 (2007)(Ways and Means Comm.).

**Question 1b: Do the regulations and the Act define and require parity in scope of services requirement both across each of the required six classifications for applying the rule, and within each of the classifications?**

**Although the preamble to the regulations explicitly states that the regulations do not address scope of services, other parts of the regulation define a scope of service parity requirement.**

Despite this clear statement to the contrary, many other sections of the regulations operate to confer a scope of service parity requirement between MH/SUD benefits and medical/surgical benefits. In the context of this analysis, scope of services is equated with “range of services.”

The regulations’ discussion related to classifications requires 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 rule, 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.**

The preamble and the text of the regulations also 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. In such a case, the language above is a scope of services parity requirement because it precludes the ability of a plan to limit treatment services to less than all of the six classes.

**The rules governing the application of quantitative treatment limitations (QTLs) and nonquantitative treatment limitations (NQTLs) also demonstrate 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, respectively, 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 necessarily be similar to those on the medical/surgical side.

**Even if one believes the regulations are ambiguous with respect to scope of services, the underlying 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 definitions of “mental health benefits” and “substance use disorder benefits” also demonstrate a scope of service parity requirement. The Act’s definition of mental health benefits is “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.”<sup>4</sup> The definition of substance use disorder benefits is “benefits with respect to services for substance use disorders, as defined under the terms of the plan and in accordance with applicable Federal and State law.”<sup>5</sup> A natural reading of these sentences shows 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*. That is, under this language 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 statute’s parity rules that financial requirements and treatment limitations be no more restrictive in MH/SUD than in medical/surgical. If a range of services is provided in the medical/surgical benefit, the range of services in the MH/SUD benefit must be no more restrictive.

**Question 1c: Can a plan only offer one type or level of treatment services for MH/SUD benefits in any of the six required classes even if there are many types and levels of treatment services for medical/surgical within the relevant class? That is, do the Act and the regulations require parity within each classification?**

The regulations clearly state that if a plan provides MH/SUD benefits in any classification, MH/SUD disorder benefits must also be provided in every classification in which medical/surgical benefits are provided. However, can a plan comply with this parity requirement by simply offering 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? **The plan is not compliant with the parity regulations in such a situation if the comparatively low level of MH/SUD services is a result of the application of a treatment limitation to MH/SUD benefits that is**

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<sup>4</sup> *Id.* at § 1185a (e)(4).

<sup>5</sup> *Id.*

**more restrictive than the predominant treatment limitation of that type that applies to substantially all medical/surgical benefits.**

The general parity requirement states that a plan that offers both MH/SUD and medical/surgical benefits may not apply any treatment limitation to MH/SUD benefits in any classification that is more restrictive than the predominant treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification.<sup>6</sup> Although this requirement does not require plans to cover the identical types of treatment services within a class between MH/SUD and medical/surgical benefits, it does prohibit limitations in MH/SUD benefits that are more restrictive than the limitations within the corresponding classification of medical/surgical benefits. In the situation discussed in the question above, one might ask why the plan only offers one type of service in each MH/SUD disorder classification while offering many within each medical/surgical classification. 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 is that the plan is applying a treatment limitation to the MH/SUD benefit 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 regulation.

**Question 1d: How much flexibility does a plan have to define a classification?**

**Under the regulations, a plan has little flexibility in establishing a classification, but significant flexibility in determining the classification in which a particular benefit belongs.**

As noted above, the regulations create six classifications for purposes of applying the parity regulations: (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. The regulations state clearly that these “classifications of benefits are the only classifications used in applying the rules.”<sup>7</sup> Thus, as demonstrated above, plans are not able to “define” or create a new classifications.

**The regulations also define each classification. Although very broad, the fact that the regulations include definitions means that plans will have little flexibility to change these definitions.**

**The area of greatest flexibility for plans with respect to the classifications appears to be in determining the classification in which a particular benefit belongs.** The regulations state only that “in determining the classification in which a particular benefit belongs, a plan...must apply the same standards to medical/surgical benefits and to [MH/SUD] benefits.”<sup>8</sup> Apart from the

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<sup>6</sup> *Id.*

<sup>7</sup> 75 Fed. Reg. 5413.

<sup>8</sup> 75 Fed. Reg. 5433.

definition of each classification, the regulations place no further restrictions on a plan's ability to determine where a particular benefit belongs.

**Question 1e: Can a plan refuse to cover a MH/SUD treatment service because the service has no direct analogue in the treatment of other covered medical or surgical conditions?**

**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.**

The first step in determining the ability of plans to refuse to cover a MH/SUD service without a medical/surgical analogue is to determine what standard applies to such an action. As discussed above, the regulations impose certain standards on treatment limitations and divide treatment limitations between QTLs and NQTLs.<sup>9</sup> QTLs are expressed numerically, while NQTLs are limits that otherwise limit the scope or duration of benefits for treatment under a plan.<sup>10</sup> A decision or standard created by a plan that prohibits coverage of certain benefits "limit[s] the scope" of benefits on its face. Accordingly, such a decision is a NQTL that is subject to the "comparable" and "no more stringently" standard.

As noted above, 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."<sup>11</sup>

If a plan refuses to cover a MH/SUD service because there is no medical/surgical analogue, it would violate the comparable and no more stringently standard if it does not likewise refuse to cover medical/surgical benefits that have no MH/SUD analogue. The regulations require NQTLs to be "comparable."<sup>12</sup> 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

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<sup>9</sup> 75 Fed. Reg. 5412.

<sup>10</sup> *Id.*

<sup>11</sup> 75 Fed. Reg. 5416.

<sup>12</sup> *Id.*

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.”<sup>13</sup> 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 parity requirements of the statute because it imposes a treatment limitation “applicable only with respect to” MH/SUD benefits.**

### Non-Quantitative Treatment Limitations (NQTLs)

**Question 2a: Do the regulations define and apply non-quantitative treatment limits (NQTLs) in a manner consistent with the parity statute? Can plans apply NQTLs more stringently in a MH/SUD classification of benefits than in a medical /surgical classification other than in instances where there is a “recognized clinically appropriate standard of care” that permits a difference?**

The regulators’ choice to apply parity requirements to both QTLs and NQTLs is consistent with the statute 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.”<sup>14</sup> The list in question states that treatment limitation “includes” limits on frequency, number of visits, and days of coverage. 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.<sup>15</sup> 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). Accordingly, the regulators’ decision to include both QTLs and NQTLs as part of the umbrella term “treatment limitation” is consistent with the language of the statute.

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<sup>13</sup> 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).

<sup>14</sup> § 1185a(a)(3)(B)(iii).

<sup>15</sup> *Id.*

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.<sup>16</sup> The sole exception to this rule is in cases where “recognized clinically appropriate standards of care...permit a difference.”<sup>17</sup>

**Under the regulations, one of the two critical factors for determining plan compliance with the regulations 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.<sup>18</sup> 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.”<sup>19</sup>

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/SU 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.<sup>20</sup> 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.<sup>21</sup> 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.<sup>22</sup>

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<sup>16</sup> 75 Fed. Reg. 5416.

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> 75 Fed. Reg. 5436.

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

**The second critical prohibition prevents a plan from instituting a NQTL in MH/SUD that is not comparable to an 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.<sup>23</sup>

**It is important to note that there are two standards to which plans must adhere related to NQTLs. 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” demonstrates a desire on the part of regulators to require plans to 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.<sup>24</sup> This meaningful variation demonstrates that failure to meet either of these standards results in non-compliance with the regulations. The plain language of the regulations, combined with the insight provided in the examples, demonstrates a two-part requirement that plans must satisfy.

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<sup>23</sup> 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.

<sup>24</sup> 75 Fed. Reg. 5436.

**Question 2b: Do NQTLs have to meet both the predominant and substantially all *and* the comparable and no more stringently tests of the Interim Final Rule?**

The MHPAEA unequivocally applies the “predominant and substantially all” standard to all treatment limitations.<sup>25</sup> Although there is ambiguity in the regulations regarding whether the predominant/substantially all and the “comparable/no more stringently” tests are separate or additive, to remain consistent with the language and intent of the MHPAEA, the regulations should be interpreted to apply both standards to NQTLs.

The parity 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.<sup>26</sup> 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.<sup>27</sup>

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.”<sup>28</sup> 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.<sup>29</sup> Thus, the regulations’ inclusion of both QTLs and NQTLs under the definition of treatment limitations is consistent with the statute.<sup>30</sup>

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.”<sup>31</sup> If the treatment limitation does not meet this test, it cannot be applied in the MH/SUD benefit. The

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<sup>25</sup> 29 U.S.C. 1185a(a)(3)(A)(ii).

<sup>26</sup> *Id.*

<sup>27</sup> 75 Fed. Reg. 5412-13, 5419, 5433, 5440, 5446.

<sup>28</sup> 29 U.S.C. 1185a(a)(3)(B)(iii).

<sup>29</sup> *Id.*

<sup>30</sup> 75 Fed. Reg. 5413.

<sup>31</sup> 75 Fed. Reg. 5414.

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.<sup>32</sup>

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.”<sup>33</sup> 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.

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 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.<sup>34</sup> 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 interpretation of the regulations, the comparable and no more stringently standards are additive to the predominant and substantially all standard.

Applying both standards to NQTLs appears to be supported by the language of the regulations. The regulations state that the “general parity requirement” is the predominant and substantially all

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<sup>32</sup> *Id.*

<sup>33</sup> 75 Fed. Reg. 5412.

<sup>34</sup> 75 Fed. Reg. 5436.

standard.<sup>35</sup> The regulations never expressly state that the predominant and substantially all standard *should not* be applied to NQTLs. 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.

The above interpretation is not the only interpretation that can be given to the regulations. A strong argument can still be made that the language and structure of the regulations, read separate and apart from the statute itself, demonstrate that two separate standards exist for applying parity to QTLs and NQTLs. Under this interpretation, QTLs are governed by the predominant and substantially all standard, while NQTLs are governed by the comparable and no more stringently standards.

Proponents of this view will note the consistent differentiation in the regulations between QTLs and NQTLs. Beginning with the first mention of treatment limitations in the Preamble, the regulations consistently distinguish between QTLs and NQTLs.<sup>36</sup> The “meaning of terms” section states clearly that “treatment limitations include both quantitative treatment limitations...and nonquantitative treatment limitations.”<sup>37</sup> The structure of the regulation further demonstrates a distinction between QTL and NQTLs. Section (c)(3) of the regulations specifically addresses QTLs while (c)(4) addresses NQTLs.<sup>38</sup>

Importantly, the regulations also differentiate the manner in which the parity regulations are to be applied to QTLs and NQTLs. Section (c)(3) goes into great detail as to how the predominant and substantially all standard is to be applied to QTLs.<sup>39</sup> Nowhere in this detailed discussion do the regulations state that the NQTLs are subject to the predominant and substantially all standard.<sup>40</sup> Indeed, even the very title of section (c)(3), “Financial requirements and quantitative treatment limitations,” demonstrates that the substantially all and predominant standards apply specifically to QTLs.<sup>41</sup> The parity requirements related to NQTLs are included in a separate section, (c)(4). The brief section sets forth the comparable and no more stringently standard, but makes no mention of the predominant and substantially all standard that is extensively discussed in (c)(3). In light of the distinction made in the regulations regarding QTLs and NQTLs and the detailed discussion of how to apply parity requirements in each separate treatment limitation category, a strong argument can be made that the regulatory drafters did not intend the predominant and substantially all standard to apply to NQTLs.

These two conflicting interpretations demonstrate that the regulations are ambiguous as to the proper standard. However, interpreting the regulations to apply separate standards to QTLs and

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<sup>35</sup> 75 Fed. Reg. 5412-13.

<sup>36</sup> 75 Fed. Reg. 5412.

<sup>37</sup> 75 Fed. Reg. 5431.

<sup>38</sup> 75 Fed. Reg. 5433-36.

<sup>39</sup> 75 Fed. Reg. 5433-34.

<sup>40</sup> *Id.*

<sup>41</sup> 75 Fed. Reg. 5446.

NQTLs would be inconsistent with the statute and could lead to results that are inconsistent with the intent of Congress.

MHPAEA is clear that the predominant and substantially all standard applies to all treatment limitations.<sup>42</sup> An interpretation in which one category of treatment limitations is not subject to the predominant and substantially all standard is inconsistent with a plain reading of the statutory language. Although the comparable and no more stringently standard is not specifically mentioned in statute, one could interpret it as necessary to put into effect, or to operationalize, the statute's no more restrictive standard when applied to NQTLs.

If the predominant and substantially all standard applies 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 (an 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 that are predominant.

Finally, if the substantially all and predominant test is not applied to NQTLs, the percentage of benefits to which an 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? This lack of clarity could lead to a situation similar to the problem described above, in which an NQTL that applies to only a small percentage of medical/surgical benefits is applied to MH/SUD benefits. There is no justification in the statute for implementing a lesser standard than predominant and substantially all. Although the regulators used their discretion to apply the general parity requirement somewhat differently to NQTLs and QTLs, the underlying statute states that predominant and substantially all is the standard that applies to all treatment limitations.

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<sup>42</sup> 29 U.S.C. 1185a(a)(3)(A)(ii).

**Question 2c: Do the regulations prohibit using rate calculation methods for in or out-of-network providers that are more stringent for MH/SUD than medical/surgical providers? Would lack of inflation adjusters for MH/SUD providers vs. medical/surgical providers be considered a NQTL?**

The plain language of the regulations prohibits rate calculation methods that are more stringent for MH/SUD providers than medical/surgical providers.

As noted above, a plan may not impose a NQTL with respect to MH/SUD benefits unless the process, strategies, evidentiary standards, or other factors used in applying the NQTL to MH/SUD benefits are comparable to, or are applied no more stringently than, those with respect to medical/surgical benefits. The regulations define both QTLs and NQTLs. QTLs are defined as limitations which are “expressed numerically,” such as “50 outpatient visits per year.”<sup>43</sup> NQTLs, by contrast, are limitations that are not numeric but that “otherwise limit the scope or duration of benefits for treatment under a plan.”<sup>44</sup> The regulations set forth an illustrative list of NQTLs. One of these NQTLs is “standards for provider admission to participate in a network, *including reimbursement rates*.”<sup>45</sup> (Emphasis added). When the language of a regulation is plain, that language governs. **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 an NQTL subject to parity requirements.

**Inflation updates, which are tied closely to reimbursement rates and methods for determining charges, would similarly qualify as NQTLs subject to parity requirements. Although inflation updates are not mentioned specifically in the list of NQTL examples, the mention of reimbursement rates would reasonably be interpreted to include such updates.** The list of examples is illustrative rather than comprehensive, and can accordingly include other NQTLs. In commenting on the regulations, advocates should note this extension of the term “reimbursement rates” to include inflation adjusters to reimbursement rates. In addition, 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.

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<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

<sup>45</sup> 75 Fed. Reg. 5443.

**Question 2d: Do the regulations require plans to use the same scientific criteria or standards in both medical/surgical and MH/SUD for determining whether a treatment or diagnostic test is experimental?**

Although the regulations do not require identical scientific criteria or standards for determining whether a treatment or diagnostic test is experimental, such criteria must be comparable and be applied no more stringently in MH/SUD than in medical/surgical.

The first step in determining whether plans must use the same scientific criteria or standards for determining whether a treatment is experimental is to determine whether these criteria qualify as a treatment limitation under the regulations. As noted previously, QTLs are limitations which are “expressed numerically,” while NQTLs are limitations that are not numeric but that “otherwise limit the scope or duration of benefits for treatment under a plan.”<sup>46</sup> Since scientific criteria for determining the experimental nature of a treatment or diagnostic test are not expressed numerically, these criteria do not qualify as a QTL. But, since they have the potential to limit or eliminate coverage of a treatment or test that is deemed experimental, these criteria or standards qualify as a NQTL under the regulations. This conclusion is buttressed by the illustrative list of examples provided in the regulations. Example A states that NQTLs include medical management standards limiting or excluding benefits...*based on whether the treatment is experimental or investigative.*<sup>47</sup> From this example, it seems clear that **scientific criteria that limit or exclude benefits based on whether the treatment is experimental or investigative are a form of NQTL that is subject to the regulations’ requirements.**

The NQTL requirements state 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 those applied with respect to medical/surgical standards. These regulations do not require that the exact same processes, strategies, evidentiary standards, or other factors be used, but they must be comparable and applied no more stringently. Thus, for example, if a plan views medical/surgical treatments as non-experimental based on criteria that only use consensus panels, while only recognizing MH/SUD treatments as non-experimental based on controlled clinical trials, the plan has used standards which are not comparable. In such a case, the plan would not be compliant with the parity regulations.

**Question 2e: What is considered a “recognized clinically appropriate standard of care” in the context of a NQTL?**

**Although the regulations do not explicitly define “recognized clinically appropriate standards of care,” the regulations and other government coverage policies give guidance that regulators should heed in construing the term. From a policy perspective, a clear**

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<sup>46</sup> 75 Fed. Reg. 5438.

<sup>47</sup> 75 Fed. Reg. 5443.

**definition of “recognized” is critical to ensure the integrity of the Act and to implement the will of Congress.**

The regulations state that NQTLs must be comparable and applied no more stringently in MH/SUD than in medical/surgical. 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.”<sup>48</sup> The regulations do not provide a clear definition for the term “recognized clinically appropriate standards of care.”

However, both the regulations and other government medical coverage policies provide useful guidance in defining the term. The regulations provide some indications that the standards must meet a general threshold. Example 3 of Section (c)(4) discusses a plan that uses evidentiary standards in determining whether a treatment is medically appropriate.<sup>49</sup> The standards are developed based on “recommendations made by panels of experts with appropriate training and experience in the fields of medicine involved.”<sup>50</sup> The example notes that the plan complies with parity, in part because “[t]he processes for developing the evidentiary standards” are comparable and applied no more stringently between medical/surgical and MH/SUD benefits.<sup>51</sup> Thus, the example demonstrates that “recognized clinically appropriate standards” are those that are based on recommendations made by panels of experts with appropriate training and experience in the fields of medicine involved.

In addition, other parts of the regulation provide a useful guide for how to determine which standards are “recognized.” The regulations state that plan terms defining benefits for MH/SUD conditions must be consistent with “generally recognized independent standards of current medical practice.”<sup>52</sup> In defining these terms, the regulations state that a plan “may follow 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.”<sup>53</sup> Although this discussion is not repeated in the NQTL section of the regulations, it demonstrates that there are a number of recognized sources for defining which standards are recognized.

CMS also regularly relies on independent expertise when making its coverage determinations. For example, 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

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<sup>48</sup> 75 Fed. Reg. 5416.

<sup>49</sup> 75 Fed. Reg. 5436.

<sup>50</sup> *Id.*

<sup>51</sup> *Id.*

<sup>52</sup> 75 Fed. Reg. 5412.

<sup>53</sup> *Id.*

analysis of all of the scientific and clinical evidence available on a particular health care technology.<sup>54</sup> 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.<sup>55</sup>

From a policy perspective, **clearly defining “recognized” is critical to ensure the integrity of the Act.** The only exception to the requirement 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 for when a standard is recognized are not established, 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.<sup>56</sup> 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 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.

Based on the intent of the Act, other definitions in these regulations and other HHS/CMS practices, the regulators should clearly define “recognized standards of care.” Various best practices exist for developing recognized standards of care, including: (1) gathering input from multiple stakeholders and experts such as academic researchers, senior practicing clinicians, and consumer and advocacy leaders with subject matter expertise; (2) ensuring that the standard has acceptance from multiple provider and national consumer organizations; (3) basing the standard on objective scientific evidence in the field, such as published controlled research trials or expert consensus panels; and (4) approving the standard through accrediting or credentialing organizations.<sup>57</sup> **To ensure the strong parity protections envisioned by Congress, CMS should adopt these or other recognized best practices in defining “recognized clinically appropriate standards of care.”**

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<sup>54</sup> 68 Fed. Reg. 55626-40.

<sup>55</sup> 68 Fed. Reg. 55440.

<sup>56</sup> 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/SU 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/SU 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.

<sup>58</sup> 75 Fed. Reg. 5438.

**Question 2f: Do the forms of NQTLs include the composition of plan and plan provider panels that are advisory to a managed care organization (MCO) or managed behavioral health organization (MBHO) for the development of clinical standards or for determining what is experimental?**

**Because the composition of plan and provider panels could ultimately limit the scope and duration of benefits for MH/SUD treatment under a plan, the composition of these panels would appear to be a form of NQTL subject to the regulations.** The regulatory language and the illustrative list of NQTLs provide some substance to this view.

The regulations define both quantitative treatment limitations (QTLs) and NQTLs. QTLs are defined as limitations which are “expressed numerically.”<sup>58</sup> NQTLs, by contrast, are limitations that are not numeric but that “otherwise limit the scope or duration of benefits for treatment under a plan.”<sup>59</sup> Based on this definition, a limitation that is not numeric, but limits the scope and duration of benefits, is a NQTL. Among other responsibilities, plan and provider panels help establish standards of care or determine whether a procedure is experimental. Indeed, 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 an 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 regulations’ NQTL parity requirements are applicable to the composition of plan and provider panels. In commenting on the regulations, however, this interpretation of the application of NQTLs to plan or provider panel composition should be noted.

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<sup>58</sup> 75 Fed. Reg. 5438.

<sup>59</sup> *Id.*

### Other Questions

**Question 3: Must a plan use an independent, national, or international standard or state government guideline when defining a MH/SUD disorder benefit?**

In defining benefits for MH/SUD conditions, plan terms must be “consistent with generally recognized independent standards of current medical practice.”<sup>60</sup> The regulations do not clearly define what this means, but note specifically that use of the word “generally” is *not* “meant to imply that the standard must be a national standard.”<sup>61</sup> Rather, “generally” simply means that the standard must be “generally accepted in the relevant medical community.”<sup>62</sup> **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. Although these are all “acceptable resources to determine” how benefits are classified, they are not the only sources.** The regulations state that “there are many” sources that could be used. The list above is illustrative, rather than comprehensive, as demonstrated by use of the term “for example” preceding the list. **Accordingly, plans appear to have some flexibility in defining a benefits for MH/SUD conditions. However, the ability of plans to define terms is limited by the fact that 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 actually generally recognized independent standards. Such a situation could arise when internal plan panels or consultants determine plan terms rather than outside parties. As such, the regulations should set forth generally accepted definitions of benefits.

**Question 4: If a plan states it is not providing MH/SUD benefits, but reimburses for specific treatment services for one or more MH/SUD, would the plan be subject to MHPAEA and the regulations?**

**Plans that provide MH/SUD treatment services are subject to the parity requirements of MHPAEA. Since a plan in such a situation is offering a MH/SUD benefit, the regulations require the plan to offer services in every benefit classification in which medical/surgical benefits are offered.**

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<sup>60</sup> 75 Fed. Reg. 5412.

<sup>61</sup> *Id.*

<sup>62</sup> *Id.*

The Act prohibits financial requirements and treatment limitations applicable to MH/SUD “benefits” that are more restrictive than those applied to medical/surgical “benefits.”<sup>63</sup> The Act is clear that MH/SUD benefits include some level of treatment services. Mental health benefits are defined in the Act as “benefits *with respect to services* for mental health conditions.”<sup>64</sup> (Emphasis added). In like manner, the Act defines substance use disorder benefits as “benefits *with respect to services* for substance use disorders.”<sup>65</sup> (Emphasis added). Thus, the plain language of the Act demonstrates that treatment services are included as part of MH/SUD benefits.

Conversely, a plan that offers treatment services for a MH/SUD offers a MH/SUD benefit. Because MH/SUD “benefits” are regulated by the Act, a plan in such a situation would be subject to the Act’s parity requirements.

The regulations implement the Act’s parity requirements by dividing the various types of benefits into six classifications.<sup>66</sup> The regulations require that when a plan “provides [MH/SUD] benefits in any classification of benefits” described in the rule, MH/SUD benefits “must be provided in every classification in which medical/surgical benefits are provided.”<sup>67</sup> 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. Accordingly, when a plan offers a MH/SUD treatment service, it must then provide MH/SUD benefits in any classification in which medical/surgical benefits are provided.

An example may help illustrate the operation of these requirements. Imagine a plan that indicates it does not provide MH/SUD benefits, but that reimburses for psychotropic drug treatment for depression. In light of current treatment practices in both the MH/SUD and medical/surgical areas, it seems clear that both medications and the prescription of these medications can be equated with services. Since the plan is providing MH/SUD services, it can be said to be providing MH/SUD benefits. Thus, the plan is subject to parity requirements. “Prescription drugs” is one of the benefit classifications identified in the regulations. Since the plan is offering this classification of benefits, the plan must also provide MH/SUD benefits in every classification in which it provides medical/surgical benefits.

**Question 5: Must cumulative financial requirements be combined and not applied separately?**

**By the clear terms of the regulation, cumulative financial requirements must be combined and not applied separately between medical/surgical and MH/SUD benefits. The**

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<sup>63</sup> Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act, 29 U.S.C.A. § 1185a(a)(3)(A) (2009).

<sup>64</sup> § 1185a(e)(4).

<sup>65</sup> *Id.*

<sup>66</sup> The classifications include: (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.

<sup>67</sup> *Id.*

regulations state that “a plan may not apply cumulative financial requirements or cumulative quantitative treatment limitations to mental health or substance use disorder benefits in a classification that accumulate separately from any such cumulative financial requirements or cumulative treatment limitations established for medical/surgical benefits in the same classification.”<sup>68</sup> **Although the Departments considered allowing separate deductibles, they concluded that “prohibiting separately accumulating financial restrictions and quantitative treatment limitations is more consistent with the policy goals that led to the enactment of MHPAEA.”**<sup>69</sup>

**Question 6: Do the parity regulations provide preemption of weaker state parity laws but not stronger state parity laws?**

**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.**<sup>70</sup> The regulations state that MHPAEA requirements are not to be “construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement...except to the extent that such standard or requirement prevents the application of a requirement of MHPAEA.”<sup>71</sup> 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.**<sup>72</sup> Accordingly, “States have significant latitude to impose requirements on health insurance issuers that are more restrictive than the federal law.”<sup>73</sup>

**Question 7: Must Medicaid managed care organizations (MCOs) comply with these regulations, or is CMS permitted to issue separate regulations for these organizations?**

**The Medicaid statute requires that Medicaid managed care plans comply with the parity provisions of the Act. Since the regulations implement the Act and do not contain an exemption for Medicaid managed care plans, Medicaid MCOs must comply with the parity requirements as spelled out in the regulations. This conclusion is supported by both the Act, and the regulatory history of previous mental health parity laws.**

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<sup>68</sup> 75 Fed. Reg. 5415-16.

<sup>69</sup> *Id.*

<sup>70</sup> 75 Fed. Reg. 5418.

<sup>71</sup> *Id.*

<sup>72</sup> 75 Fed. Reg. 5430.

<sup>73</sup> *Id.*

The Act modified the Public Health Service Act (PHSA) to require that if a group health plan offers both medical/surgical benefits and MH/SU benefits, the financial requirements and treatment limitations for MH/SU benefits must be no more restrictive than those imposed in the medical/surgical benefit.<sup>74</sup> The Medicaid managed care statute refers to this section and mandates that managed care plans “comply” with its provisions. Specifically, 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.”<sup>75</sup> 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 Medicaid MCO 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.”<sup>76</sup> 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.<sup>77</sup> Although the Committee-passed 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 Medicaid MCO plans must comply with the parity provisions of the Act is also consistent with past agency interpretation of MHPA.** The 1997 Balanced Budget Act (BBA) made a number of changes involving managed care to the Medicaid statute, including adding Section 1932(b)(8), the requirement discussed above that MCO plans comply with mental health parity requirements.<sup>78</sup> 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 Medicaid managed care organizations. 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.”<sup>79</sup> 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

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<sup>74</sup> 42 U.S.C. 300gg-5(a)(3) (2000).

<sup>75</sup> 42 U.S.C. 1396u-2(b)(8) (2000).

<sup>76</sup> S. REP. NO. 110-53, at 5 (2007) (Sen. Comm. on Health, Educ. & Labor, 2007).

<sup>77</sup> 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.).

<sup>78</sup> 42 U.S.C. 1396u-2(b)(8) (2000).

<sup>79</sup> 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>.

health insurance issuers offering group health insurance coverage.”<sup>80</sup> 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 Medicaid MCO plans are subject to the 2008 Act’s requirements.**

The statute, legislative history, and regulatory history demonstrate that the Act applies to Medicaid MCO plans. The regulations state that they are “implementing” the Act. **The regulations do not contain an exemption for MCOs from compliance with the requirements therein. Since the Act’s requirements apply to Medicaid MCOs, and since the regulations that implement the Act give no indication that separate rules apply to MCO plans, MCOs must comply with these regulations.**

**Question 8: What date did MHPAEA become effective? What date do the regulations take effect? An aggrieved beneficiary can bring a suit based on violations of the statute that occurred on or after what date?**

The changes made by the Act are “generally effective for plan years beginning after October 3, 2009.”<sup>81</sup> The regulations are generally applicable for plan years beginning on or after July 1, 2010.<sup>82</sup> Because the requirements of the Act had already entered into force by the time the regulations were released, the Departments implemented a “good faith compliance period from Departmental enforcement until plans have time to implement changes consistent with the regulations.”<sup>83</sup> For purposes of this compliance period, the Departments will take into account “good-faith efforts” to comply with a reasonable interpretation of the statutory MHPAEA requirements with respect to a violation that occurs before the applicability date of the regulations.<sup>84</sup>

The good faith compliance period above applies to Departmental enforcement. It does not, however, “prevent participants or beneficiaries from bringing a private action.”<sup>85</sup> **Accordingly, an aggrieved beneficiary can bring a suit based on alleged violation of the statute that occurred on or after October 3, 2009—the date the Act became effective. However, if the beneficiary’s suit is based on a claim that the plan improperly implemented the *regulations*, the**

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<sup>80</sup> 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.

<sup>81</sup> 75 Fed. Reg. 5411.

<sup>82</sup> *Id.*

<sup>83</sup> 75 Fed. Reg. 5419.

<sup>84</sup> *Id.*

<sup>85</sup> *Id.*

beneficiary would likely have to wait to bring such a suit until July 1, 2010—the date the regulations become effective.

**Question 9: When a plan denies reimbursement or payment for MH/SUD benefits, must it disclose to the beneficiary the rationale for the denial *and* the corresponding coverage criteria in medical/surgical?**

**Although there is no general rule requiring plans to disclose the medical/surgical coverage criteria when denying reimbursement or payment for MH/SUD benefits, plans will likely be required to do so in certain instances. Specifically, when the plan relies upon the medical/surgical coverage criteria in its denial of MH/SUD benefits, the plan will likely be required to disclose this information to the plan beneficiary.**

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. 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.”<sup>86</sup> However, the statute does not specify what form this notification should take. Rather, the statute states that the notification shall be provided “in accordance with regulations.”

The regulations promulgated to implement MHPAEA state that “the reason for any denial under a group health plan of reimbursement or payment for services with respect to mental health or substance use disorder benefits...must be made available by the plan administrator to the participant or beneficiary.”<sup>87</sup> For purposes of implementing this requirement, 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.”<sup>88</sup> 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.<sup>89</sup> The regulations in 29 CFR 2560.503-1 contain numerous content and time requirements related to “adverse benefit determinations” for all initial claims denials. The analysis below focuses on the areas that appear to have the most relevance to a denial of MH/SUD benefits.<sup>90</sup>

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<sup>86</sup> 29 U.S.C.A. 1185a(a)(4).

<sup>87</sup> 75 Fed. Reg. 5437.

<sup>88</sup> *Id.*

<sup>89</sup> *Id.*

<sup>90</sup> DOL Reg. § 2560.503-1 includes a host of requirements related to notification that are not a focus of this analysis. For example, to be adequate, a notification of adverse benefit determination must be written in a “manner calculated to be understood by the claimant.” Neither the DOL or case law provides much guidance on what format or language would comply with this requirement. However, it seems reasonably clear that plain language would meet this standard, while technical or legal jargon may not. DOL Reg. § 2560.503-1(g)(l). Additionally, a notification must also

The adverse benefit determination regulations state that 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, guideline, 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.<sup>91</sup> Note that under the second option, the plan is not required to specifically identify the guideline, rule, guidance, or protocol in the notification itself, but rather to provide the option for the beneficiary to receive this information upon request.<sup>92</sup> If a plan relies upon medical./surgical coverage criteria in denying MH/SUD benefits, this requirement appears to require disclosure of these criteria, either initially or upon request. For example, if payment for a MH/SUD service is denied because no medical/surgical benefits are provided in the corresponding classification, the plan would likely have to include this information.

A notification of adverse benefit determination must also include reference to the "specific plan provisions on which the determination is based."<sup>93</sup> Again, if the denial of MH/SUD benefits is based on the coverage criteria (or lack of coverage) in medical/surgical, the plan would likely be required to disclose these "specific" coverage criteria to the beneficiary.

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state the "specific reasons" for the adverse determination. Courts have found that conclusory statements in support of a benefits denial, without more, are insufficient. DOL Reg. § 2560.503-1(g)(I)(i). *See also Helms v. Gen. Dynamics Corp.*, 222 Fed. Appx. 821 (11th Cir. 2007) (use of terse, boilerplate denial letters, in addition to other flaws, led to reversal of denial); *HCA Health Servs. of Ga., Inc. v. Employers Health Ins. Co.*, 240 F.3d 982 (11th Cir. 2001); *White v. Aetna Life Ins. Co.*, 210 F.3d 412 (D.C. Cir. 2000); *Anderson v. Nationwide Mut. Ins. Co.*, 592 F. Supp. 2d 1113 (S.D. Iowa 2009) (conclusory statements without specific details not sufficient; court concluded that denial letter failed to list relevant facts of claim and failed to provide a rationale of how two cited documents supported its decision to terminate benefits in light of relevant facts); *Richardson V. Cent. Suites, Se. & Sw. Areas Pension Fund*, 645 F.2d 660, 2 EBC 1477 (8th Cir. 1981) (decided under old claims regulations, which contained the same requirement, and holding that decisions were "wholly conclusory" and failed to recite facts of case or rationale supporting judgment).

<sup>91</sup> DOL Reg. § 2560.503-1 (g)(I)(v)(A).

<sup>92</sup> Frequently Asked Questions and Answers on Benefit Claims. *QIA-C 16* (Dec. 17, 2001).

<sup>93</sup> DOL Reg. § 2560.503-1(g)(I)(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).