

EXECUTIVE SUMMARY

The Parity Implementation Coalition ("the Coalition") is pleased to request the issuance of a final rule clarifying the implementation and enforcement of the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA).

The Parity Implementation Coalition is an alliance of addiction and mental health consumer and provider organizations. Its members include the American Academy of Child and Adolescent Psychiatry, American Psychiatric Association, American Society of Addiction Medicine, Betty Ford Center, Cumberland Heights, Faces and Voices of Recovery, Hazelden Foundation, MedPro Billing, Mental Health America, National Alliance on Mental Illness, National Association of Psychiatric Health Systems, TeenScreen at Columbia University, and The Watershed Addiction Treatment Programs, Inc.

Background

Since the Interim Final Rule (IFR) was issued in 2010, the Coalition has worked closely with the Departments to better understand the IFR, clarify grey areas and educate the consumer and provider communities about rights and benefits in the law. Coalition members have helped individuals and providers file over 150 complaints with state and federal agencies for violations of the law. While sub-regulatory guidance issued by the Departments clarified some of the grey areas and ambiguities in the law, other vital provisions have not been clarified or implemented.

To understand how the law is impacting individuals with mental health conditions and substance use disorders (MH/SUD) over the last year, Coalition members convened a series of 10 parity implementation field hearings around the country with the help of two former Congressmen who championed the law, Patrick Kennedy and Jim Ramstad. From witnesses in cities and towns as varied as Kalamazoo, Michigan to Los Angeles, California we heard common themes: lack of transparency in plan documents, inequality in the continuum of care for behavioral versus medical benefits and medical management techniques applied more stringently on behavioral benefits as compared to medical benefits.

Recommendations

While Coalition members understand there will always be some ambiguities and market forces affecting the delivery of behavioral health benefits, the Coalition's consumer and provider organizations believe that much remains to be clarified in a final rule to operationalize the law. We strongly recommend additional guidance in at least the following five areas:

- 1. Disclosure and transparency
- 2. Scope of service
- 3. Additional classifications of benefits
- 4. Non-quantitative treatment limits (NQTLs) and Recognized Clinically Appropriate Standards of Care
- 5. Medicaid managed care parity

To help the Departments understand the bases for these recommendations, we have provided detailed legal rationale, supporting materials and suggested examples in materials attached to this summary.

1. Disclosure and Transparency

A final rule must clarify:

- Plans must transparently provide an analysis of how medical criteria are applied in making benefit determinations for medical conditions as compared with behavioral conditions for the purpose of parity compliance testing. This is already required today by URAC, a key health plan accrediting body.
- Medical necessity criteria must be made available within 30 days of the request, and not only after a denial is made.
- Medical necessity criteria may not be withheld because they are deemed proprietary.

2. Scope of Services

Coalition members recognize that MHPAEA is not a benefit mandate, but believe that the statute and the regulations' rules related to classifications, NQTLs and quantitative treatment limits, do confer a scope of services requirement (see attached legal analysis and supporting rationale). Absent further guidance with respect to parity in scope of benefits *within* each classification, discriminatory benefit plan design in which a full continuum is provided under the medical benefit, yet mere skeleton benefits are provided under the behavioral benefit, (non-hospital based provider exclusions, key comparable level of care exclusions, etc.) may become ever more pervasive, contrary to the language and intent of the law.

3. Additional Classifications of Benefits.

The Coalition has found that many plans are avoiding covering key essential levels of care and services on the MH/SUD side because the six classifications of benefits are not clear (e.g., non-hospital based facility exclusions, key levels of care exclusions). The inclusion of additional intermediate classifications to the six classification scheme would provide further clarity in this area, i.e., Intermediate inpatient, in-network; intermediate Inpatient, out-of-network; intermediate intensive outpatient, in-network; intermediate intensive outpatient, out-of-network.

4. Nonquantitative Treatment Limits and Clinically Recognized Standards of Care

The IFR provides that an NQTL is a type of treatment limitation and sets forth a test for compliance. This test requires that an NQTL must be applied "comparably and no more stringently" on behavioral conditions versus medical conditions.

The Coalition believes there must be clarity in the following areas to avoid the continued imposition of discriminatory medical management practices on MH/SUD benefits. A final rule must address all of the following issues:

- A threshold proportion to which an NQTL must be applied to a classification of medical/surgical benefits before it can be applied to the same classification of behavioral health benefits. The proportion test would require that any NQTL type or sub-type must be applied to at least 50% of the medical/surgical benefits in each classification of benefits before a comparable NQTL could be applied to the MH/SUD benefits in that classification. Such test could either be applied initially, or as part of the comparability test.
- In addition, comparability, in and of itself, must include a consideration of quantity or magnitude as one of the factors in determining comparability between NQTLs.

- A recognized clinically appropriate standard of care must be defined. The Coalition urges that the following must be included in that definition:
 - An independent standard that is not developed solely by a single health plan or plans
 - Based on input from multiple stakeholders and experts, such as academic researchers, senior practicing clinicians, and consumer leaders with subject matter expertise in addition to a health plan or its advisory panels
 - Recognized or accepted by multiple nationally recognized provider and consumer organizations and/or nationally recognized accrediting organizations that are responsible for developing quality standards
 - Based on objective scientific evidence, such as peer-reviewed publications of control group research trials or expert consensus panels

5. Medicaid Managed Care Parity

A final rule must require Medicaid managed care organizations to comply with MHPAEA regulations. In 2010, when the Departments issued the IFR, CMS announced that separate Medicaid managed care parity regulations would be released. A final rule must provide guidance on how Medicaid managed care organizations must comply with MHPAEA. There is no exception for Medicaid managed care plans in the law and the Departments must issue regulations in addition to their 2009 State Medicaid Director letter and the 2012 informational bulletin clarifying how Medicaid managed care organizations must comply with the law.

DETAILED RECOMMENDATIONS

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1. DISCLOSURE AND TRANSPARENCY

MHPAEA included a provision that requires plans to provide the medical necessity criteria and reason for denial to consumers and providers upon request. At the field hearings around the country, participating organizations learned that there has been limited compliance with these disclosure provisions. Limited sub-regulatory guidance has been provided so that consumers and providers can know what plans are doing to comply with the law. Further, there appears to be very limited enforcement of disclosure violations. Common themes from the field hearings included:

- Plan participants are often not receiving medical necessity criteria in advance of a denial despite the law's requirement that the plan must do so upon request.
- What criteria plans apply in making benefit determinations for medical/surgical services is not made available for parity compliance testing despite numerous requests, and regulatory and accrediting body guidance requiring its availability.
- Plans frequently inform participants that the plan is parity compliant with no explanation or analysis documenting compliance other than "because we say so."

Analysis

Without plan administrators and health insurance experts disclosing the medical criteria used and how the criteria are applied to make adverse benefit determinations, plan participants or providers acting on their behalf are unable to determine whether a plan has provided mental health and substance use disorder (MH/SUD) services in the "comparable and no more stringent than" manner required by MHPAEA. The Departments recognized this fact and provided sub-regulatory guidance in December 2010 clarifying that the IFR requires plans to provide the criteria for medical necessity determinations made under a plan or health insurance coverage with respect to MH/SUD benefits to any current or potential participant, beneficiary, contracting provider or authorized representative upon request. The guidance concludes, "Under ERISA, documents with information on the medical necessity criteria for both medical/surgical benefits and mental health/substance use disorder benefits are plan documents, and copies of plan documents must be furnished within 30 days of your request." (Emphasis supplied).

A Department of Labor (DOL) compliance tool that was released to provide more clarity on MHPAEA implementation unfortunately further complicated the disclosure issue. Question 43 of the DOL compliance tool provided that a plan administrator must make medical necessity criteria related to MH/SUD available upon request but precludes medical necessity criteria for medical/surgical benefits from being released until an MH/SUD benefit denial has been made. If criteria used to make medical benefit determinations is withheld from plan participants until there is a denial, beneficiaries are unable to have all necessary information about their benefits to choose a plan that meets their needs.

Despite this sub-regulatory guidance, Coalition members have come to expect non-compliance with disclosure requests by consumers and providers as the norm. Many plan administrators or insurers do not respond to these requests at all. Over 100 cases have been submitted to DOL since December 2010 in which no response to a parity appeal on this basis occurred. Other plan administrators or insurers continue to state that MHPAEA and the IFR do not require disclosure. Others continue to maintain that their criteria are proprietary and cannot be released, despite the legal requirement to do so. In other cases, disclosure is made of the

medical necessity criteria with respect to MH/SUD benefits, but not the comparable criteria used with respect to medical/surgical benefits. Refusals to provide medical/surgical criteria make it impossible for beneficiaries and providers to assess whether medical necessity criteria related to MH/SUD benefits is comparable to the criteria related to medical/surgical benefits and therefore, whether to plan is compliant with the IFR and MHPAEA. Almost every example provided in the IFR gives details of what medical and behavioral criteria are used, and how they are applied as the regulators recognized that this level of detail is needed for any enforcement. These examples are a good template for what information needs to be disclosed by plans in a final rule.

URAC recently released its new <u>standards</u> – Version 7 – for accreditation of health plans. The standards require plans to document that they have disclosed key aspects of the behavioral health benefit to consumers and employers, such as: how compliance with parity is achieved and any restrictions or exclusions on the behavioral health benefit.

In letters dated May 12, 2011 and May 18, 2011, 62 Senators and Members of Congress stated that plans should be required to disclose the criteria and policies used to manage both medical/surgical conditions and MH/SUDs. They emphasized that both sets of criteria and how they are applied are necessary to assess whether cost containment measures are being applied to behavioral health conditions comparably and no more stringently than on other medical conditions.

Recommendations on Transparency and Disclosure of Medical CriteriaA final rule must clarify that:

- Plans must provide medical necessity criteria within 30 days of the request.
- Medical necessity criteria may not be withheld because it is deemed "proprietary."
- Plans must provide an analysis of how medical criteria is applied in making benefit
 determinations for medical conditions as compared with behavioral conditions for the
 purpose of parity compliance testing.

Proposed Examples

Example 1

Facts. A group health plan limits benefits to 100% of inpatient treatment for both medical/surgical conditions and mental health/substance use disorders that is medically necessary. The plan requires precertification and concurrent review for all (100%) inpatient, innetwork mental health and substance use disorder benefits, but only requires precertification and concurrent review for elective admissions for inpatient, in-network medical/surgical benefits. This represents 30% of the inpatient, in-network spending under the medical/surgical benefit.

Disclosure Requirements

The group health plan would need to assess and examine the following "processes, strategies, evidentiary standards, or other factors used in applying the limitation with respect to medical/surgical benefits in the classification." (75 Fed. Reg. 5436). The following illustrates what types of assessments would be needed for an internal analysis by a health plan as well as what types of information may be needed for disclosure. This information would need to be disclosed when requested by a person or entity with appropriate standing.

- 1. Criteria and strategies used to perform precertification and concurrent review for inpatient, in-network medical/surgical admissions.
- 2. Definitions of what is considered an elective vs. an emergency admission for a medical/surgical condition in this classification of benefits.
- 3. What percentage of total admissions in this classification of benefits are defined as elective vs. emergency for both medical/surgical and for MH/SUD.
- 4. An analysis of any differences (between medical/surgical and MH/SUD), if present, of clinical or provider variables that trigger a review. Are best practice guidelines used to support more stringent reviews?
- 5. An analysis of differences between how medical/surgical vs. MH/SUD reviews are conducted, e.g. differences in patient information, who is required to conduct the review on the facility side and the frequency of reviews.

Example 2

Facts. A member is denied benefits for mental health treatment by his plan because the plan determined that the treatment was not medically necessary for inpatient care. The member requested and received a copy of the criteria for medical necessity determinations for mental health and substance use disorder treatment as well as a description of how those criteria are applied to behavioral health, and the reason for denial. The member thinks his plan is applying medical necessity standards more stringently and in a non-comparable manner to benefits for mental health and substance use disorder treatment than for medical/surgical benefits. The member wants to understand how and what relevant parts of the medical necessity criteria used for medical/surgical benefits are applied, and how these criteria and if policies are applied differently to mental health and substance use benefits.

Disclosure Requirements

Under both ERISA and MHPAEA, documents with information on the medical necessity criteria for both medical/surgical benefits and mental health/substance use disorder benefits are plan documents, and copies of plan documents must be furnished within 30 days of the member's request. See ERISA regulations at 29 CFR 2520.104b-1. Additionally, if a provider or other individual is acting as the member's authorized representative in accordance with the Department of Labor's claims procedure regulations at 29 CFR 2560.503-1, the provider or other authorized representative may request these documents. If the member's plan is not subject to ERISA or MHPAEA (for example, a plan maintained by a State or local government), the member should check with their plan administrator.

The plan must disclose all policies, criteria, strategies and documents that are used to apply medical necessity determinations to the inpatient classification of benefits for medical and surgical conditions. This should include what types of medical reviews are being conducted, e.g. concurrent vs. precertification, what proportion of medical admissions are subject to each review type, the factors that determine how and when a medical review is implemented and how they are different from the reviews that are conducted for the inpatient classification of benefits for mental health conditions and substance use disorders, and the rationale for the difference.

Example 3

Facts. A health insurance plan administrator offers both medical/surgical benefits as well as mental health and substance use disorder benefits for most mental health and substance use disorder diagnoses. Their plan includes a number of medical management and cost containment protocols, which are nonquantitative treatment limitations, for both the medical/surgical and the mental health/substance use disorder benefits. The plan contends they are in compliance with MHPAEA even though some of their nonquantitative treatment limitations for behavioral health are different than those for medical/surgical benefits. The plan seeks clarity on what type of internal analysis is required in order to support their conclusion that it is in compliance. Based on this analysis, the plan needs to understand what type of information is required to disclose to a consumer or provider.

Disclosure Requirements

The plan should conduct a thorough review of any nonquantitative treatment limitation (for example, application of utilization review criteria and protocols, use of scientific criteria to determine experimental vs. non-experimental status, establishment of fee schedules, provider admission standards) that is applied differently to mental health or substance use disorder treatment services as compared to medical/surgical treatment services in the same classification of benefits. The internal review should measure whether these nonquantitative treatment limitations are applied in a more stringent or non-comparable manner and should include an assessment of what proportion of the medical/surgical benefit the nonquantitative treatment limitation is applied to as compared to what proportion of the mental health/substance use disorder benefit the nonquantitative treatment limitation is applied to within the same classification of benefits (e.g. outpatient, in-network medical to outpatient, in-network behavioral). While the IFR does not set forth a quantitative minimum for the percentage of the benefits in a classification that a nonquantitative treatment limitation must be applied to under the medical/surgical benefit before it can be applied to the mental health or substance use disorder benefit, the plan will need to explain the rationale for any differences in the proportion of benefits in a classification the nonquantitative treatment limitation is applied to. For example, if pre-certification is required for 100% of all mental health or substance abuse inpatient admissions, but is only required for 30 % of medical admissions, this difference will need to be justified and the rationale and support for this difference disclosed.

2. SCOPE OF SERVICES

Background

Members of the Parity Implementation Coalition ("Coalition") submit these recommendations on scope of services based on the difficulties our members are having in accessing equitable addiction and mental health (MH/SUD) services in the post Mental Health Parity and Addiction Equity Act (MHPAEA or statute) marketplace. Coalition members are convinced additional guidance in a final rule on scope of services is necessary before the intent and letter of the law can be realized – eliminating barriers to accessing behavioral health care and ensuring that behavioral health benefits are provided on par with medical/surgical benefits. The Coalition has provided comments on scope of services parity in its paper submitted to the Departments on April 30, 2010, based upon a detailed legal analysis of MHPAEA and the Interim Final Regulations by Patton Boggs (see in particular, pp. 4-9 in attachment 1).

The case that MH/SUD and general health are inseparable was well documented in the 2009 Institute of Medicine report titled, *Preventing Mental, Emotional and Behavioral Disorders Among Young People: Progress and Possibilities.* In fact, a December 2010 Center for

Healthcare Strategies Data Brief titled, *Hospital Readmissions among Medicaid Beneficiaries with Disabilities: Identifying Targets of Opportunity,* states that: "a combination of mental illness and substance abuse is associated with a 4 to 5-fold increase in overall hospital admission rates for chronically ill populations...In particular, this analysis reinforces the impact of behavioral health comorbidities on hospitalization rates. The dramatic increase in readmission risk for individuals with co-occurring schizophrenia and substance abuse highlights the need for improved coordination across physical and behavioral health systems..." Citing, C. Boyd, B. Leff, C. Weiss, J. Wolff, A. Hamblin, and L. Martin. *Clarifying Multimorbidity Patterns to Improve Targeting and Delivery of Clinical Services for Medicaid Populations*. Center for Health Care Strategies, Inc., December 2010.

To achieve the cost savings that are attainable as a result of MHPAEA, the range, scope, levels and settings for MH/SUD benefits must be on par with the range, scope, levels and settings for medical/surgical benefits. Absent additional guidance in a final rule, plans will continue to claim to be compliant with MHPAEA by providing sparse or single levels of inpatient services (e.g., detoxification only for substance use disorders), sparse or very limited levels and types of outpatient services (e.g., outpatient office visits only), and restrictions on prescription drugs (e.g. "fail first" policies) with respect to MH/SUD benefits, while providing a full scope of services and continuum of care with respect to medical/surgical benefits. Plans also claim to be parity compliant while limiting inpatient MH/SUD benefits to hospital-based settings only, thereby excluding accredited and licensed 24-hour inpatient and residential MH/SUD facilities. These are just some examples of outcomes Coalition members are experiencing since the implementation of the Interim Final Rules ("IFR") that were clearly not intended by Congress.

Congressional Intent

Congress has made its position clear over the last three years in repeated correspondence that scope of services parity is an integral part of MHPAEA, including in the following letters:

1) December 14, 2010 House letter to the Departments of Labor, HHS and Treasury (attachment 2) (emphasis supplied)).

"In September 2009 and May 2010, 73 House Members, Chairmen and Subcommittee Chairmen of the three committees of jurisdiction encouraged you [the Departments] to issue regulations clarifying Congressional intent on scope of service, among other issues.

The Congressional intent of this legislation was that patients have access to the full scope of mental health and substance use disorder benefits medically-appropriate for their condition. The basic framework of the law is to equalize mental health and substance use disorder benefits and medical benefits, and end the discrimination that has for so long limited access to mental health and substance use disorder benefits as compared to medical benefits covered by plans. Plan participant and beneficiary access to a similar scope of services and continuum of care on the mental health and substance use disorder side, including both in-network and out-of-network services, as is provided on the medical side, was part of the very impetus of MHPAEA."

2) May 18, 2011 House letter to the Departments of Labor, HHS and Treasury (attachment 3) (emphasis supplied).

"Allowing the law to be implemented without specific guidance on scope of service, disclosure of medical criteria, and non-quantitative treatment limitations increases the likelihood that plans will continue to offer only very limited behavioral health benefits while offering an array of medical benefits and claim compliance with MHPAEA; this was clearly not Congressional intent.

Scope of Services: We continue to believe that without clear guidance on this issue, we will continue to see plans deleting all intermediate levels of behavioral health care, as well as other essential treatment and diagnostic services, while offering a full continuum of treatment levels for medical and surgical conditions.

There are many examples in the market place that document the current practices in place by insurers. For instance, plans are excluding residential treatment for substance use and eating disorders and applying pre-authorization requirements to mental health/addiction benefits that are not applied to medical benefits covered by the plan. We believe these examples illustrate violations of the quantitative and non-quantitative treatment limitation rules as applied to general plan design, and violate scope of services and continuum of care parity as inherently addressed in the statute and defined in the regulations."

3) May 12, 2011 Senate letter to the Departments of Labor, HHS and Treasury (attachment 4) (emphasis supplied).

"With regard to scope of services, ...[t]he regulations themselves confer a scope of service by requiring that plans cover a minimum of six types of services. However, without clear guidance and clarification, health insurance plans are limiting the degree to which intermediate levels of behavioral health services are accessed."

4) October 18, 2012 House letter to the Departments of Labor, HHS and Treasury (attachment 5)

"The Interim Final Rules released in February 2010 requested comments on areas such as "scope of service," thereby leaving these issues unresolved. Specifically, patients and providers consistently report that plans continue to: exclude non-hospital based mental health and addiction facilities from coverage; eliminate vital types and levels of mental health and addiction treatments while covering the full continuum of treatments for medical conditions.."

Coalition's Recommendations on Scope of Service and Supporting Rationale

- Scope of service parity does NOT create a mandate Nothing in MHPAEA requires a group health plan to offer coverage for any specific mental health condition or substance use disorder. However, once a plan chooses to provide benefits for a specific mental health condition or substance use disorder, those benefits and the services with respect to those benefits, must be at parity with medical/surgical benefits as provided in subsection (a) of MHPAEA. (MHPAEA clearly defines mental health benefits and substance use disorder benefits as "benefits with respect to services...").
- General parity requirement Must clarify that a group health plan that provides both medical/surgical and MH/SUD benefits, may not apply any financial requirement or treatment limitation, either quantitative or nonquantitative to MH/SUD benefits in any

classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification. Such group health plan may also not apply separate cost sharing requirements or treatment limitations that are applicable only with respect to MH/SUD benefits.

- Treatment limitations Must clarify that the term treatment limitation includes both quantitative and nonquantitative treatment limitations and includes limits on the scope and duration of treatment. Scope is an explicit aspect in the definition of a treatment limitation in the statute. The general parity requirement set forth above must apply to treatment limitations on the scope and range of services and settings covered within any benefit classification. The IFR Preamble sets forth 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 (such as outpatient, innetwork), in which it provides medical/surgical benefits, the exclusion of benefits in that classification for a mental health condition or substance use disorder otherwise covered under the plan is a treatment limitation. It is a limit, at a minimum, on the type of setting or context in which treatment is offered". 75 Fed. Reg. 5413. The definition of scope used by many health care providers applies to levels, categories and types of treatment. The IFR's requirement for scope of service parity among the six classifications is a clear and explicit articulation of scope of service parity. However, the guidance in the IFR as to how to meet scope of service parity is unfinished. As noted above, numerous Senators and House members who were involved in drafting this legislation have recognized the regulations to be incomplete.
- Separate treatment limitations Must clarify that if a plan provides medical/surgical benefits within a classification and imposes any separate more restrictive treatment limitations, including scope of services or continuum of care (for example, level, type or range) on treatment services or settings for MH/SUD benefits within any of the six classifications, then the general parity rules apply separately with respect to that classification for all financial requirements and treatment limitations.
- Scope of service parity does not detract from ability to medically manage care Plans may apply medical management standards in accordance with regulations. A plan, in determining whether or not a nonquantitative treatment limit (NQTL) has been applied more stringently to MH/SUD services within one of the six classifications, may apply medical management standards and other NQTLs, so long as the plan does so in accordance with paragraph (c)(4) of the regulations. This would include the ability of a plan to review and deny any specific MH or SUD treatment type or level if a similar scope of service restriction or NQTL were comparably applied to medical/surgical benefits.
- <u>Geographic restrictions</u> Restricting where covered treatment services may be
 obtained must be added in new guidance to the list of NQTLs. (E.g., plans may not
 exclude out-of-network coverage for MH/SUD benefits provided outside of the local area
 or outside of the state, if out-of-network coverage for medical/surgical benefits extends
 outside of the local area or outside of the state).
- <u>Facility restrictions</u> Restricting the facility-type where covered treatment services
 may be obtained must be added in new guidance to the list of NQTLs. (E.g., plans may
 not exclude accredited, licensed freestanding MH/SUD facilities from coverage under
 MH/SUD benefit if accredited, licensed hospitals and facilities are covered under
 medical/surgical benefit).

- **Formulary design** Under the current list of NQTLs, guidance must clarify that formulary design for prescription drugs includes the scope and range of drugs offered.
- Exclusions and/or limits in general plan design and/or medical standards or criteria based on the justification that diagnostic and treatment services "are not medically analogous" (for example, no coverage of MH/SUD diagnostic or treatment services that are also not indicated for medical/surgical conditions) must be added in new guidance to the list of NOTLs.
- Exclusions and/or limits in general plan design and/or medical standards or criteria limiting the scope, level and range of treatment services or treatment settings within a classification must be added in new guidance to the list of NQTLs.

<u>Reports from Nationally Recognized Experts</u> – these reports provide guidance that it is possible to define, compare, and accredit many common treatment types and levels for both MH/SUDs and medical/surgical conditions in a consistent manner:

- Milliman's December 2010 Report states: "We concluded from this side by side comparison of common medical and behavioral conditions that the levels of care and settings for treatments were similar and analogous. Hospital and Sub-acute inpatient services are typically used by both medical and behavioral patients and intensive outpatient interventions are available as integral services for all of these disease categories. We found that many of the clinical criteria, such as judgments about the acuity and severity of the illness, were similar for both medical and behavioral conditions." The Milliman report also states: "Our analysis shows that these types of outpatient treatment programs are an essential component of an effective continuum of care for both medical and behavioral health disorders. It is unlikely that some patients could be safely and appropriately discharged directly from an Acute or Sub-acute Inpatient facility to Routine Outpatient care without these more intensive outpatient care settings."
- CARF's November 2010 Analysis shows: "Accreditation of behavioral health programs offers an equally appropriate and analogous continuum of services for persons needing treatment for mental illness or substance use disorders. Thus, CARF Behavioral Health accreditation includes both hospital and non-hospital based medical and residential detoxification, both hospital and non-hospital based inpatient treatment, non-hospital based residential treatment, partial hospitalization or day treatment, intensive outpatient, outpatient and community options. Just like a person recuperating from a stroke may first be served in an inpatient setting, followed by ongoing recovery in a residential rehabilitation setting and eventual, periodic follow-up on an outpatient basis, persons needing treatment for substance use disorders may require a period of medical detoxification followed by inpatient or residential treatment and eventual ongoing recovery supports that can appropriately be provided on an outpatient basis. The CARF program descriptions and standards help to consistently define these various levels for substance use disorders nationally and to differentiate these programs and settings. CARF currently accredits 454 Residential Alcohol and Drug Programs and 761 Opioid Treatment Programs nationally. Many national managed behavioral health organizations currently utilize these national accreditation standards for substance use disorder residential treatment facilities in their provider networks."

The Following Proposed Examples Illustrate How Scope of Service Parity Within the Six Classification Scheme Would Be Implemented (Paragraph (c)(2)(ii) *Classifications of benefits used for applying rules* (75. Fed. Reg. 5433)).

Example 1

- (i) Facts. A plan chooses to cover most mental health and substance use disorders. The plan covers a full range of outpatient treatment and diagnostic services for medical/surgical conditions in the outpatient, in-network classification. This coverage includes office visits for both primary care and specialty physicians. This coverage also includes a range of intensive outpatient programs (what the plan may term "intermediate" levels of care), such as cardiac and stroke rehabilitation programs and dialysis centers. With respect to the mental health and substance used disorders, for those diagnoses covered, the plan does not cover partial hospitalization or intensive outpatient services. The plan does cover office visits for primary care physicians, however, not for licensed mental health or substance use disorder specialists.
- (ii) Conclusion. In this Example, the plan has imposed a separate treatment limitation that is applicable only with respect to the mental health and substance use disorder benefit in the outpatient, in-network classification, and that is not applicable to the medical/surgical benefit. The plan has also applied a treatment limitation that is more restrictive as to scope, range and level of treatments than what is applied with respect to the medical/surgical benefit in the outpatient, in-network classification. For both of these reasons, the plan is in violation of this paragraph (c)(2)(ii).

Example 2

- (i) Facts. A plan chooses to cover most mental health and substance use disorders. The plan covers a full range of outpatient treatment and diagnostic services for medical/surgical conditions in the outpatient, in-network classification. This coverage includes office visits for both primary care and specialty physicians. With respect to mental health and substance use disorders, for those diagnoses covered, the plan covers partial hospitalization and intensive outpatient services. The plan also covers office visits for primary care physicians and mental health or substance use disorder specialists in this classification. The plan refuses to provide coverage for a specific intensive outpatient program for substance use disorders that is not licensed by the state and/or accredited by a national accrediting organization. The plan provider admission standards require program licensing and/or accreditation for substantially all types of outpatient, in-network programs for medical/surgical conditions.
- (ii) Conclusion. In this Example, the plan may impose this treatment limitation to a specific substance use disorder treatment program in the outpatient, in-network classification of the mental health and substance use disorder benefit because it is no more restrictive than the treatment limitations applied to all medical/surgical benefits in that classification and it does not constitute a separate treatment limitation applied only to the mental health or substance use disorder benefit.

Example 3

- (i) Facts. A plan chooses not to offer coverage for Attention Deficit Hyperactive Disorders (ADHD) under the mental health benefit. The plan does cover general medical physicians (non-psychiatrist physicians) in the outpatient, in-network classification and their prescriptions for stimulant medications (which are listed as approved medications in the prescription drug classification) for the treatment of ADHD. Further, the plan offers benefits for medical/surgical conditions in all classifications of benefits.
- (ii) Conclusion. In this Example, the parity requirements govern the plan's provision of benefits for ADHD because the plan has, in fact, offered benefits for that disorder in two classifications (i.e. outpatient, in-network and prescriptions drugs). The plan is in violation of the

parity requirements because it has limited the benefits for ADHD to two classifications of benefits (i.e., outpatient, in-network and prescriptions drugs), while offering coverage for medical/surgical conditions in all classifications. The plan will be required to meet all requirements of this regulation including no more restrictive standard for financial requirements and treatment limitations.

The Following Proposed Examples Illustrate How Scope of Service Parity Would be Implemented as part of the Rule on NQTLS (Paragraph (c)(4)(ii) *Illustrative list of Nonquantitative treatment limitations* (75 Fed. Reg. 5436)).

Example 1

- (i) Facts. A plan chooses to cover benefits for depressive disorders. The plan also includes a benefit for prescription drugs for both depression and for medical/surgical conditions. However, the plan excludes all categories of drugs for depression other than selective serotonin reuptake inhibitors in the prescription drug classification. The plan covers the full range and types of drugs for substantially all medical/surgical benefits in the prescription drug classification.
- (ii) Conclusion. In this Example, the plan violates the rules of this paragraph (c)(4) by imposing a treatment limitation with respect to the prescription drug classification under the mental health benefit that is not comparable to, and is applied more stringently than, the treatment limitation imposed with respect to the prescription drug classification under the medical/surgical benefit. The plan also violates paragraph (c)(ii)(A) of these regulations by applying a treatment limitation on the scope and range of mental health benefits in the prescription drug classification that is more restrictive than treatment limitations of this type applied to substantially all medical/surgical benefits in this classification. The plan also imposes a separate treatment limitation only with respect to the mental health benefit.

Example 2

- (i) Facts. A plan offers coverage for drug and alcohol use disorders, but limits coverage in the inpatient, out-of-network classification to acute hospital care for detoxification, and limits coverage in the outpatient, out-of-network classification to office visits with primary care physicians for the treatment of drug and alcohol use disorders. The plan does not provide coverage for residential treatment, partial hospitalization, or intensive outpatient programs. With respect to the medical/surgical benefit, the plan covers the full scope and range of inpatient, out-of-network and outpatient, out-of-network treatment services for most medical/surgical treatments in these classifications. For example, under the medical/surgical benefit, the plan covers acute general hospital care, inpatient rehabilitation and skilled nursing facilities in the inpatient, out-of-network classification. The plan also covers intensive outpatient treatments, including stroke and cardiac rehabilitation programs and dialysis centers, specialty diagnostic programs and outpatient surgical facilities in the outpatient, out-of-network classification.
- (ii) Conclusion. In this Example, the plan violates the rules of this paragraph (c)(4) by imposing treatment limitations on the scope and range of treatment in the inpatient and outpatient, out-of-network classifications of the substance use disorder benefit that are not comparable to, and applied more stringently than, the treatment limitations on scope and range of treatments imposed in these classifications with respect to the medical/surgical benefits. The plan also violates the rules of paragraph (c)(ii)(A) of these regulations by applying treatment limitations on the scope and range of treatment covered in the inpatient and outpatient, out-of-network classifications of the substance use disorder benefit that are more restrictive than the treatment limitations applied to most medical/surgical benefits in these classifications. The plan

also imposes a separate treatment limitation with respect only to the substance use disorder benefit.

For example, the plan's coverage of a full range of acute and sub-acute inpatient programs for medical/surgical conditions is not comparable to the plan's exclusion of residential programs for substance use disorders; is more restrictive on scope and range of treatment; and applies a separate treatment limitation only to the substance use disorder benefit. Likewise, the plan's coverage of a full range of outpatient programs for medical/surgical conditions is not comparable to the plan's exclusion of partial hospitalization and intensive outpatient programs for substance use disorders; is more restrictive on scope and range of treatment; and applies a separate treatment limitation only to the substance use disorder benefit.

Example 3

- (i) Facts. A plan offers coverage for alcohol and drug use disorders and includes coverage in the inpatient, in-network classification for acute care services, rehabilitation and residential treatment for substance use disorders. With respect to the medical/surgical benefit, the plan covers acute and general hospital care, inpatient rehabilitation and skilled nursing facility care. A substance use disorder provider has requested reimbursement for a group home, stating that the group home is similar to a residential treatment facility on the behavioral health side, and similar to a skilled nursing facility on the medical side, thereby falling into the required scope of services within the inpatient classification. However this group home program is not state licensed as either a residential treatment program or a skilled nursing facility. Nor is the group home accredited as a residential treatment program by a nationally recognized accrediting organization. Further, the group home provides primarily habilitation services, i.e. room and board, and does not provide on-site intensive treatment or rehabilitation services. The plan refuses to cover this group home program. The plan likewise does not cover group homes for any medical/surgical conditions in the inpatient or outpatient in network classification of benefits. Further, the benefit plan design does not reimburse for habilitation programs whether inpatient or outpatient for any medical/surgical conditions. Is this permissible?
- (ii) Conclusion. Yes. In this Example the plan complies with the general rule on nonquantitative treatment limitations (paragraph (c)(4) of the IFR), because it has imposed a treatment limitation that is comparable to, and applied no more stringently than the treatment limitation imposed with respect to the medical/surgical benefit. Further, the plan complies with the general parity requirement rule (paragraph (c)(2)(ii)(A) of the IFR), because it is applying a treatment limitation to the substance use disorder benefit that is no more restrictive than the treatment limitation applied to all the medical/surgical benefits in the inpatient, in-network classification, and it has not applied a separate treatment limitation only with respect to substance use disorder benefits

Conclusion

The Coalition respectfully urges the Departments to issue clarifying guidance on scope of services parity so that the intent and letter of the statute may be properly implemented and enforced. Without scope of services parity, MHPAEA will fall short of ensuring the equitable coverage for mental health and substance use disorders that the statute was enacted to achieve.

3. ADDITIONAL CLASSIFICATIONS OF BENEFITS

The Coalition has found that many plans are avoiding covering key essential levels of care and services on the MH/SUD side because the six classifications of benefits are not clear. The following four additional classifications should be added to the six classification scheme in the IFR:

"Intermediate Inpatient, in-network"

"Intermediate Inpatient, out-of-network"

"Intermediate Intensive Outpatient, in-network"

"Intermediate Intensive Outpatient, out-of-network"

With respect to the medical/surgical benefit, the "intermediate, inpatient" classification of benefits would include, but not be limited to, e.g., skilled nursing facilities, rehabilitation hospitals and/or freestanding rehabilitation facilities.

With respect to the MH/SUD benefit, the "intermediate inpatient" classification of benefits would include, but not be limited to, e.g., clinical residential treatment programs.

With respect to the medical/surgical benefit, the "intermediate intensive outpatient" classification of benefits would include, but not be limited to, e.g., cardiac and stroke rehabilitation programs, dialysis centers, outpatient surgery programs.

With respect to the MH/SUD benefit, the "intermediate intensive outpatient" classification of benefits would include, but not be limited to, e.g., partial hospitalization programs (a/k/a day treatment), intensive outpatient treatment.

These added classifications would help to clarify the key essential levels of care and services that, if provided under the medical/surgical benefit, must be comparably provided under the MH/SUD benefit.

4. NONQUANTITATIVE TREATMENT LIMITS

Background

Members of the Parity Implementation Coalition ("Coalition") submit these recommendations on the general rule for nonquantitative treatment limitations (NQTLs) based on the difficulties our members are having with respect to the imposition of such NQTLs on mental health and substance use disorder (MH/SUD) services in the post Mental Health Parity and Addiction Equity Act (MHPAEA or the "statute") marketplace. The Interim Final Rules (regulations) set forth a "comparable to and applied no more stringently than" test with respect to NQTLs. The regulations set forth that an NQTL is a type of treatment limitation as defined in MHPAEA. However, the regulations were silent as to whether or not an NQTL is required to meet a threshold proportion of application to the medical/surgical benefit before it may be applied to the MH/SUD benefit. While the substantially all and predominant test is required and applied when defining a quantitative treatment limitation, the regulations did not include a threshold test that would be appropriate for NQTLs.

The Coalition provided the Departments with a detailed legal analysis and rationale in its April 30, 2010 comments as to why NQTLs, a type of treatment limitation, were required by the statute, both explicitly and by intent, to require a threshold proportion to which an NQTL must be applied to a classification of medical/surgical benefits before it can be applied to the same classification of behavioral health benefits. (see, in particular, pp. 11-19 of attachment 1). In

addition, since the DOL's issuance of Frequently Asked Questions regarding NQTLS on November 17, 2011, (Question 4 in particular), some insurance issuers and plans believe that simply because medical and behavioral treatment services may have similar characteristics as to cost algorithms, rate of medical inflation, cost variability, unclear outcome measures, etc., an NQTL that is applied to a treatment service in a classification of medical benefits can automatically be applied to an otherwise non-comparable treatment service in the same classification of behavioral benefits based merely on "similar" cost-related characteristics. This insurance industry perception makes a threshold proportion test that much more vital.

Consumers and providers have now had ample experience post MHPAEA IFR with insurers as they apply NQTLs to MH/SUD benefits. The Coalition has seen considerable noncompliance in the application of NQTLs in one or more of four specific areas:

- 1. Nondisclosure of how and to what degree NQTLS are comparably applied to medical/surgical spending;
- 2. Refusal by plans and insurers to respond at all to requests for medical/surgical criteria and/or spending (and on occasion refusal to provide MH/SUD criteria as well);
- 3. Statements by plans and insurers that they may apply an NQTL to any proportion or all of the MH/SUD benefit regardless of what proportion of the medical/surgical benefit that NQTL is applied to; insurers and plans routinely refer to the regulations (as well as to verbal statements made by Departments), as not requiring any threshold proportion of application of an NQTL on the medical/surgical side, before an NQTL may be applied to 100% of the MH/SUD benefit:
- 4. Unilateral statements by plans that an NQTL is justified based on the plans' <u>internally</u> recognized clinically appropriate standards, with no details or support given.

The Coalition, in this document, outlines our recommendations as to how the proportion to which an NQTL must be applied to a classification of medical/surgical benefits before it may be applied to the same classification of MH/SUD benefits may be added to the final regulations, along with a number of examples demonstrating how these recommendations could be implemented, using real life situations that consumers are routinely facing. While the Coalition understands the need for a general rule that is different in analyzing NQTLs than the general rule for financial requirements and quantitative treatment limitations, the Coalition strongly recommends that:

- The general rule for NQTLs must include a threshold proportion to which the application
 of a type or subtype of NQTL must be applied to a classification of the medical/surgical
 benefit before the NQTL can be applied to the same classification of the MH/SUD
 benefit. Two options for how to apply a threshold proportion requirement are provided
 herein;
- Additionally, a number of examples are provided that demonstrate areas in need of further clarification and guidance that are separate from the issue of addressing a proportion requirement; and
- 3) Clarifying guidance must be provided with respect to what constitutes "recognized clinically appropriate standards."

1. <u>A Threshold Proportion Requirement Must be Established under the Medical/Surgical</u> Benefit before NQTLs May be Applied under the MH/SUD Benefit

It is apparent from the general rule on NQTLs and the majority of corresponding examples set forth in the regulations, that the Departments assumed that most NQTLs would be applied to either 100% of the benefits in a class, or not at all. See the facts of *Example 1* - the plan applies medical necessity to 100% of both the medical/surgical and the MH/SUD inpatient, in-network benefit. The plan applies concurrent review to 100% of the inpatient, in-network MH/SUD benefit, but does not apply concurrent review to this class of medical/surgical benefits at all (0%). The plan applies retrospective review to 100% of this class of medical/surgical benefits. In this example, it is determined that the type of medical necessity review processes are not comparable. Therefore, the plan violates the general rule on NQTLs by applying a type of NQTL to 100% of the inpatient, in-network MH/SUD benefit, but not applying it all to the medical/surgical benefit. (The application of a different type of NQTL to medical/surgical benefits, i.e. retrospective review, does not save the plan from non-compliance). *Examples 3, 4* and *5,* likewise assume application of NQTLs to either 100% of the benefit in a classification or not at all (75 Fed. Reg. 5443).

However, the regulations have established that there are varying proportions to which NQTLs are applied. *Example 2* does provide an example in which an NQTL is applied in varying proportions (i.e.: "(i) *Facts...*For mental health and substance use disorder treatments that do not have prior approval, no benefits will be paid; for medical/surgical treatments that do not have prior approval, there will only be a 25 percent reduction in benefits the plan would otherwise pay. (ii) *Conclusion...*the penalty for failure to obtain prior approval for mental health and substance use disorder benefits is *not comparable* to the penalty for failure to obtain prior approval for medical/surgical benefits."(Emphasis supplied)). The Departments use this example to demonstrate how comparability must be applied when different proportions of an NQTL are evaluated for compliance or non-compliance. (Discussed further at page 18 herein).

Apart from *Example 2*, the NQTL examples overlook the practical use of NQTLs to varying proportions or percentages of the benefits in a classification. In other words, NQTLs are far more typically applied to a certain proportion or percentage of the benefits in a classification, or to certain categories of benefits (e.g., concurrent review for physical therapy visits only¹), as opposed to all or none.² Thus, the general rule on NQTLs with accompanying examples overlooks as a vital preliminary test, the threshold proportion to which an NQTL must be applied with respect to the medical/surgical benefit, before the remaining analysis of comparability and stringency can be made. Without this preliminary test, plans can and do apply an NQTL to a *de minimus* percentage of a classification of medical/surgical benefits and then apply the same NQTL to a far greater percentage, or all of the same classification of MH/SUD benefits.³

A chief reason that led to the passage of MHPAEA was the common practice of insurers applying an accumulation of the most restrictive financial requirements and treatment limitations

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¹ These categories could be quantified based on what proportion of the spending they represent in a class of benefits, similar to the use of claim amounts for the substantially all and predominant tests.

²If it was the regulators intention to require a 100% application of an NQTL under the medical/surgical benefit in order for it to be applied under the MH/SUD benefit, that is more restrictive than what the statutory language provides and on a plan's ability to effectively manage benefits for purposes of cost containment.

³ It is important to note that in all of the examples in which NQTLs are applied non-comparably or more stringently and that lead to a denial of care for MH or SUD benefits, a key consequence is either a higher out-of-pocket expense for the consumer or no access to care.

(both QTLs and NQTLs) to 100% of the MH/SUD benefit, while only applying these separate restrictions to small percentages of the medical/surgical benefit. An example of a common MH/SUD pre-parity benefit is the following: 30 day inpatient limit, 20 outpatient visit limit, higher co-pay and deductibles, more restrictive out-of-network benefits, 100% precertification of both inpatient and outpatient care with routine concurrent reviews, a denial rate often double or triple that of medical/surgical and routine fail-first requirements for SUD inpatient care. Given the relative low unit costs for these services compared to medical/surgical care, this level of management was often unnecessary and, of course, is now discriminatory. It has been recognized by a number of health policy researchers that the application of intensive, nonquantitative cost containment interventions can be more restrictive than arbitrary quantitative limits. Based on a recent study performed by Milliman, Inc. for the Coalition, the average daily allowed charge for a typical medical/surgical inpatient day is up to 6 times greater than the average daily allowed charge for a typical MH/SUD inpatient day. While inpatient medical/surgical days typically require more use of expensive technology and other ancillary services than MH/SUD inpatient days, the difference in allowed charge levels is significant. Based on data supplied to the Coalition, the average outpatient cost for MH/SUD services ranges from \$80 to \$100 per visit and the average of number of visits approved during preauthorization is around five to six. The continued application of non-parity compliant NQTLs post parity to a relatively small portion of the total medical/surgical benefit, yet to a far greater portion of the MH/SUD benefit remains a great concern for both providers and consumers.

For purposes of financial requirements and quantitative treatment limitations, it is clear that the first step of the regulations in applying the general parity requirement is that they must apply to "substantially all," defined as "at least two-thirds" of the medical/ surgical benefits in a classification before they can be applied at all to MH/SUD benefits in that classification. Thus, if a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of the medical/surgical benefits in a classification, that type of financial requirement or quantitative treatment limitation cannot be applied to MH/SUD benefits in that classification.

A. Option 1 for Applying a Threshold Proportion Test to NQTLs The Threshold Proportion test is applied First – followed by Comparable and No More Stringent

For purposes of NQTLs, there must also be a threshold proportion to which a type or subtype of NQTL must be applied with respect to a classification of the medical/surgical benefit before it can be applied at all to MH/SUD benefits in the same classification. The Coalition proposes that a merged hybrid of the "substantially all/predominant" requirement be applied to NQTLs. The regulations, in describing NQTLs with examples, introduced the concept of subtypes of NQTLs. There are many broad categories of NQTLs, e.g. the application of medical appropriateness; but, these can be applied in different ways (via subtypes or categories), such as concurrent review and retrospective review. Based on our experience with insurance plans post-MHPAEA, it is likely that certain broad categories of NQTLs such as application of medical appropriateness, fee schedules, provider admission standards, etc. will typically be applied to more than two-thirds of the medical/surgical benefit. However, the subtypes of these general categories may only be applied to a smaller percentage of the medical/surgical benefits. The Coalition recognizes that it is important that MH/SUD benefits are able to be "managed" similarly to medical/surgical benefits, and that the measurement of NQTLs be reasonably efficient. Given the nature of the different subtypes of NQTLs and how widely and differently they may be applied to medical/surgical benefits (which has many different sub-specialty areas), the Coalition recommends that the threshold proportion for a merged hybrid substantially all/predominant test be "at least 50 percent" for any specific type or subtype of NQTL.

The substantially all and predominant tests as applied to financial requirements and quantitative treatment limitations have been defined in the regulations in terms of type (substantially all) and levels (predominant). However, many subtypes of NQTLs are not susceptible to a quantitative "level" analysis, or have only one quantitative level. For example, a type of financial requirement such as a co-payment may be applied to 70% of the medical/surgical benefits in a classification, at a level of \$30. Whereas concurrent review (or a comparable technique) may be applied to 70% of the medical/surgical benefit, but not have quantitative levels to speak of. Thus, the Coalition recommends a merged test that consists of one threshold of proportion on a classification of the medical/surgical benefit of "at least 50 percent" before that NQTL can be applied to the same classification of MH/SUD benefits. Then, the frequency with which NQTLS are applied, the magnitude of penalties imposed, etc. would follow as part of the comparable and no more stringent tests.

Further rationale for a threshold proportionality test is that it adds efficiency and reduces the administrative burden on plans as they only have to provide evidence of one level of spending for each type or subtype of NQTL. As outlined above, most broad types of NQTLs are going to easily meet the "at least 50 percent" test as most of them are applied to more than two-thirds or even 100% of the medical/surgical benefits. Thus, there should be little administrative work needed to establish their eligibility to be applied to MH/SUD benefits.

We believe that, in addition to reducing administrative complexity, establishing the required proportion to which an NQTL must be applied with respect to the medical/surgical benefit before it can be applied to the MH/SUD benefit will reduce the number of appeals and legal challenges to the application of NQTLs. Based on the regulations, plans already do need to consider the proportion to which they are applying NQTLs with respect to the medical/surgical benefit in order to meet the comparable to and applied no more stringently than test. However, without threshold test as to proportion, it is likely that plans will be challenged on any NQTL that appears to be applied to a small proportion of the medical/surgical benefit. This test of "at least 50%" for NQTLs should be added to the general rule for NQTLs. Once this test is met, the remainder of the NQTL general rule, "comparable to" and "applied no more stringently than" can be applied. The below crosswalks demonstrate the application of the respective general rules:

Tests for Meeting Quantitative and Nonguantitative Requirements

Financial Requirements and Quantitative Treatment Limitations

- 1. Substantially all (type) At least 2/3
- 2. Predominant (level) More than 50%
- 3. No more restrictive than

Once a financial requirement or quantitative treatment limitation meets the substantially all test of at least two-thirds on the medical/surgical side, it can then be applied on MH/SUD benefits; however, it may be applied no more restrictively than the predominant level applied on the medical/surgical side.

Nonquantitative Treatment Limitations

- 1. Proportion test (type/subtype) At least 50%
- 2. Comparable to (type/subtype)

(NOTE: Comparability is often defined as having at least two aspects: 1) determining similarity of type or nature, and; 2) a magnitude dimension. In fact, the regulations use comparability in both of these ways in their examples).

3. No more stringently than

Once an NQTL meets the proportion test of "at least 50%" on the medical/surgical side, a comparable NQTL may then be applied on the MH/SUD side; however, it may only be applied no more stringently than as applied on the medical/surgical side. Therefore, the test for NQTLs must include the following steps:

- 1) A type or subtype of NQTL must be applied to at least 50% of the medical/surgical benefits in a classification in order to be applied to the same classification of benefits on the MH/SUD side;
- 2) Such type or subtype of NQTL that has met the at least 50% proportion test, must then be comparable to a type or subtype of NQTL applied to the MH/SUD benefit and must be applied in a comparable manner as to magnitude;
- 3) The comparable type of NQTL must be applied no more stringently to a classification of MH/SUD benefits than it is applied to the same classification of medical/surgical benefits.

Without applying a proportion test as the first step of the comparability analysis of NQTLs, the general rule for NQTLs falls short of effectuating parity and is inconsistent with the clear language of the statute. The statute has only one definition for a treatment limitation and that definition includes a quantitative test. This quantitative test was essential and therefore specifically added to MHPA in 1996 and to MHPAEA in 2008 as Congress recognized the large loop hole that would be created in the absence of such a test. With the regulations in effect for nearly three years, many plans have imposed discriminatory NQTLs on MH/SUD benefits and have specifically relied upon the regulations to support such practices. For example, one large employer group plan has applied utilization review restrictions to 100% of the plan's behavioral health benefits, while applying the same restrictions to only physical and occupational therapy services on the medical/surgical side - a nominal proportion or percentage of the plan's medical/surgical benefits. This was clearly was not the intent of either Congress or the Departments.

Examples of NQTLs in which the Proportion test is Applied, followed by Comparable and No More Stringent tests

Example 1

(i) Facts. A group health plan limits benefits to 100 % of inpatient treatment for both medical/surgical and mental health/substance use disorder that is medically necessary. The plan requires concurrent review for all (100%) inpatient, in-network mental health and substance use disorder benefits but only requires concurrent review for elective admissions for inpatient,

in-network medical/surgical benefits. This represents 30% of the inpatient, in-network spending for the medical/surgical benefit. The plan has a requirement that retrospective reviews for inpatient, in-network medical/surgical benefits can be applied to 55% of medical/surgical inpatient spending.

(ii) Conclusion. In this Example 1, the plan violates some of the general rules governing NQTLs. The same nonquantitative treatment limitation-medical necessity-applies to 100% of both medical/surgical and to mental health and substance use disorder benefits for inpatient, in-network services. Therefore, the NQTL of applying medical necessity meets the NQTL proportion test and can be applied to MH/SUD inpatient, in-network benefits. However, the concurrent review process which is a subtype of a medical necessity treatment limitation only applies to 30% of the medical/surgical inpatient, in-network benefits so it does not meet the proportion test of more than 50 percent. Therefore, the concurrent review process cannot be applied to the mental health and substance use disorder inpatient, in-network benefit. While such a difference might be permissible in certain individual cases based on recognized clinically appropriate standards of care, in the absence of such a clinically recognized standard exception, it is not permissible to apply this NQTL, i.e., concurrent review, to MH/SUD inpatient, in-network benefits. However, the retrospective review process does meet the proportion test of more than 50% and therefore can be applied to MH/SUD benefits. Further, retrospective reviews conducted with respect to the inpatient, in-network medical/surgical benefit are considered comparable in nature to retrospective reviews conducted with respect to the MH/SUD inpatient, in-network benefit.

Example 2

- (i) <u>Facts</u>. Same facts as Example 1 above, except that the plan in implementing the retrospective review process only reviews a sample of 10% of the inpatient, in-network medical/surgical charts while reviewing 100% of the mental health and substance use disorder inpatient, in-network charts.
- (ii) Conclusion. In this Example 2, the plan is applying the retrospective review process in a non-comparable (as to magnitude) and a more stringent manner with respect to the mental health and substance use disorder benefit than how the plan applies retrospective review with respect to the medical/surgical benefit in this classification, and is therefore not compliant with the general rules governing NQTLs.

Example 3

- (i) Facts. A plan generally covers medically appropriate treatments. In determining whether prescription drugs are medically appropriate, the plan automatically excludes coverage for any mental health or substance use disorder drugs that are given a black box warning label by the Food and Drug Administration (indicating that the drug carries a significant risk of serious adverse effects). For most other drugs with a black box warning for medical/surgical conditions, i.e. 60% of the medical/surgical pharmacy spending for black box warning drugs, the plan will provide coverage if the prescribing physician obtains authorization from the plan that the drug is medically appropriate for the individual, based on clinically appropriate standards of care. For the other 40% of medical/surgical drugs that carry a black box warning the plan automatically excludes coverage.
- (ii) Conclusion. In this Example 3, the plan violates the general rules governing NQTLs. Although the same nonquantitative treatment limitation--medical appropriateness--is applied to 100 % of both MH/SUD benefits and medical/surgical benefits, the plan imposes a subtype of medical appropriateness limitation which is the blanket exclusion of mental health and substance use disorder prescription drugs given a black box warning. This subtype of an NQTL does not meet the required proportion test with respect to the medical/surgical benefit as the exclusion for prescription drugs with a black box warning only applies to 40% of the

medical/surgical pharmacy spending. In the case of multi-tiered prescription drug benefits, the proportion test of more than 50% applies tier by tier.

Example 4

- (i) Facts. A plan reviews all treatments as to whether they are experimental or non-experimental. The plan uses the same scientific criteria for determining when a mental health/substance use disorder or medical/surgical treatment is determined to be experimental. Therefore, the plan has a comparable NQTL which is applied to all of medical/surgical and MH/SUD benefits and this meets the proportion test. The plan, however, has allowed for reimbursement for over 70% of the medical/ surgical spending in the outpatient, in-network classification of benefits, having deemed these treatments as non-experimental even though these treatments have only met basic levels of scientific evidence (e.g. only one controlled research study, and instead merely case studies combined with a recommendation by a Consensus Panel from a Specialty Professional Association). Meanwhile, mental health and substance use disorder treatments are routinely determined to be experimental, and are therefore not reimbursed if they do not have higher levels of evidence (e.g., more than one Randomly Assigned Controlled Research studies).
- (ii) Conclusion. In this Example 4 the plan is in compliance with the NQTL proportion test of application of a type of NQTL, scientific criteria, for all medical/surgical and MH/SUD treatments. However, the plan is using a subtype of the NQTL, e.g. requiring higher standards of scientific evidence for mental health and substance use disorder treatments and is applying this NQTL to only 30% of the medical/surgical treatments, but to 100% of mental health and substance use disorder treatments. Therefore, this subtype of the NQTL--requiring MH/SUD treatments to be non-experimental with a higher level of evidence is not in compliance with the proportion test of the general rules governing NQTLs. If the plan were to use the same levels of evidence from its scientific criteria (i.e., only one controlled research study or case studies combined with a specialty consensus panel) that the plan uses for more than 50% of the medical/surgical spending, the plan would be compliant.

Example 5

- (i) Facts. A group health plan limits benefits to all medical/surgical and mental health/substance use disorder inpatient, in-network treatment that is medically necessary. The plan requires concurrent review for more than 50% of medical/surgical inpatient, in-network spending and for most inpatient, in-network mental health and substance use disorder spending. However, the plan requires physician-to-physician reviews on a daily or every other day basis for all concurrent reviews of inpatient mental health and substance use disorder stays before authorizing additional days, while only requiring physician-to-physician reviews for medical/surgical cases if the patient falls outside the norm ("outlier cases"), which is infrequent.
- (ii) Conclusion. In this Example 5, the plan is in compliance with the proportion test in its application of medical necessity to mental health and substance use disorder benefits and the application of a subtype of medical necessity (e.g., concurrent review) as these both meet the test of more than 50% under the medical/surgical benefits. However, the plan requires daily or routine physician-to-physician reviews for all inpatient, in-network mental health and substance use disorders, while the plan only requires physician-to-physician reviews for selected medical/surgical inpatient, in-network cases ("outlier cases"). Thus, the plan does not meet the comparable (as to magnitude) and no more stringent NQTL requirement and is, therefore, out of compliance with this section of the regulations.

Example 6

- (i) Facts. A group health plan limits benefits to all medical/surgical and mental health/substance use disorder inpatient treatment that is medically necessary. The plan requires pre-certification for more than 50% of medical/surgical inpatient, in-network spending and for all MH/SUD inpatient, in-network benefits. However, as part of the pre-certification process, the plan institutes a fail-first policy for addiction inpatient programs (including hospital, non-hospital inpatient and residential), in which a patient is required to have failed outpatient treatment before inpatient treatment can be authorized. The plan does not have similar practices or standards for inpatient medical/surgical benefits.
- (ii) Conclusion. In this Example 6, the plan violates the rules of this paragraph, as the processes for determining the appropriate levels of care are not comparable and are applied more stringently with respect to inpatient MH/SUD benefits as compared to inpatient medical/surgical benefits.

B. Option 2 for Applying a Proportion Test to NQTLs The Proportion Test is Incorporated into the Comparable Test

The Coalition has provided both a legal rationale and a practical guideline with detailed examples above demonstrating how to apply a threshold proportion test prior to the application of the comparable and no more stringent tests. However, we believe that the regulators have another option by which this test can be applied that meets both the legal requirement of MHPAEA and is also consistent with the regulations.

The regulators could simply add a proportion test as a part of the comparable test, requiring that any NQTL type or subtype must be applied to at least 50 percent of the medical/surgical benefits in each respective classification of benefits before a comparable NQTL could be applied to MH/SUD benefits in that classification. As described above, comparability is often defined as having at least two aspects: 1) determining similarity of type or nature; and 2) a magnitude or proportion dimension. As stated, the regulations in fact use comparability in both of these ways in one of the examples set forth therein. We insert *Example 2* from the IFR here to demonstrate this point.

- Example 2. (i) Facts. A plan requires prior approval that a course of treatment is medically necessary for outpatient, in-network medical/surgical, mental health, and substance use disorder benefits. For mental health and substance use disorder treatments that do not have prior approval, no benefits will be paid; for medical/surgical treatments that do not have prior approval, there will only be a 25 percent reduction in the benefits the plan would otherwise pay.
- (ii) Conclusion. In this *Example 2*, the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation medical necessity is applied both to mental health and substance use disorder benefits and to medical/surgical benefits for outpatient, in-network services, the penalty for failure to obtain prior approval for mental health and substance use disorder benefits is not comparable to the penalty for failure to obtain prior approval for medical/surgical benefits. 75 Fed. Reg. 5436, 5443, 5450. (Emphasis supplied).

In this *Example 2*, the Departments have identified two different proportions to which a similar NQTL is applied, e.g., a 100% penalty imposed for MH/SUD benefits and a 25% penalty imposed for medical/surgical benefits. The comparability test is used to determine that the more onerous penalty is not compliant.

We believe that the regulators could add a consistent, proportion test of "at least 50 percent" to the comparability test and therefore incorporate the proportion test as a part of comparability. Such an application of a proportion test would be consistent with the statutory language and intent of MHPAEA and consistent with the regulations. The legal rationale for this is the same as described in Option 1, namely, that the statute contains only one definition for a treatment limitation, and that definition requires the application of a substantially all and predominant test. This test will be met in Option 2 by inserting the proportion requirement in the already established comparability test.

All of the examples outlined under Option 1 can be applied here, with a modification that applies the "at least 50 percent" proportion test as the first factor to considered in comparability testing.

2. Comparability Must Consider Quantitative Factors

The Coalition also proposes that the final regulations provide additional guidance on how quantitative factors are to be considered in determining whether an NQTL is both comparable and no more stringent. We believe there is no statutory rationale for not having a threshold proportionality test and that the absence of such leaves consumers vulnerable to more restrictive management of the MH/SUD benefit. Depending on how the regulators address a fixed quantitative threshold it may be critical to also define that quantitative factors are a key aspect in determining comparability. Comparability is often defined as having at least two aspects: 1) determining similarity of type or nature; and 2) a magnitude or proportion dimension. A simple non health care example will illustrate how impossible it is to determine comparability between various categories without consideration of quantity or proportion. Suppose a company is selling dining room tables to the public and are advertising various prices and types of tables. This company describes two tables that are exactly the same in design, type of wood, and style. However, one table is 10 times larger than the other table even though the tables are similar in all other characteristics. No reasonable person would deem these tables to be comparable. If the company were to advertise that these tables are comparable, then it is likely the company would be accused of misleading the public. This is precisely what is occurring when health plans advise consumers that they are compliant with MHPAEA, even though they are applying many NQTLs to most or all of the MH/ SUD benefits in a classification, while applying the same NQTLs to a small proportion of the medical/surgical benefit.

As stated above, the IFR has already introduced quantity as a factor in determining comparability in Example 2 under the NQTL section of the IFR, in which the comparability test is used to determine that a more onerous penalty is not compliant.

The Departments have already provided some additional guidance as to how quantity needs to be considered in assessing comparability and stringency of NQTLs in the promulgation of FAQS 2 and 5.

FAQ 2

"Q2: For all mental health and substance use disorder benefits, my group health plan requires prior authorization from the plan's utilization reviewer that a treatment is medically necessary, but the plan does not require such prior authorization for any medical/surgical benefits. Is this permissible?

No. The plan is applying a non quantitative treatment limitation to mental health and substance use disorder benefits that is not applied to medical/surgical benefits. This violates MHPAEA's prohibition on separate treatment limitations that are applicable only to mental health or substance use disorder benefits."

FAQ 5

"Q5: I am an employer considering several health insurance policy options. One health insurance policy requires prior authorization for all outpatient mental health benefits but only a few types of outpatient medical/surgical benefits (outpatient surgery; speech, occupational and physical therapy; and skilled home nursing visits.) Is this permissible?

While some differences in plan requirements for prior authorization might be permissible based on recognized clinically appropriate standards of care, it is unlikely that the processes, strategies, evidentiary standards, and other factors considered by the plan in determining that those three (and only those three) outpatient medical/surgical benefits require prior authorization would also result in all outpatient mental health and substance use disorder outpatient benefits needing prior authorization."

FAQ 5 clearly states that the application of an NQTL to a small proportion of the medical benefit while applying this NQTL to all of the MH/SUD benefit is not comparable and/or more stringent. FAQ 2 also brings in another quantitative or proportional factor in analyzing NQTLs by stating that a 100 % application of an NQTL to behavioral benefits while applying that same NQTL to 0 % of the medical benefits is non-compliant.

Despite the IFR example and the Departments FAQs, many health plans take the position that they can apply any NQTL to MH/SUD benefits if that NQTL is applied somewhere in the medical/surgical benefit even if these NQTLs are applied to a small amount of medical or surgical services. The plans hold steadfast that quantity or proportion is not a factor in determining parity of NQTLs. In so doing, plans are ignoring FAQs 2 and 5 as well as Example 2 from the IFR. Further, plans are relying upon the guidance in FAQs 4 and 6 as further evidence that quantity or proportion does not need to be considered. Plans have interpreted these FAQs to justify applying precertification and concurrent review to all psychotherapy visits even if these NQTLs are only applied to physical therapy and occupational therapy visits under the medical benefit. If this interpretation is permitted to continue, then the NQTL section of the IFR is ineffectual.

The Coalition recommends that the final regulations, in the absence of a threshold proportionality test, provide guidance that in determining comparability and stringency, quantity and proportionality are key factors, along with others, in determining whether an NQTL may be applied to the MH/SUD benefit. While this will not provide a specific needed threshold test, it will at least give guidance to plans that a significant imbalance in proportion will be deemed noncompliant.

3. Additional NQTL Examples Unrelated to a Proportion Test

The regulators solicited comments on real-life examples of NQTLs that are creating barriers to the implementation of MHPAEA. The Coalition provides several examples below based on common situations that are separate from the necessity of adding a proportion test and that should be addressed in the final rule.

Below are some examples of the imposition of NQTLs that we hope will help clarify how the current standard in the regulations of "comparable to" and "no more stringent than" is being applied. These examples address common practices of health plans that Coalition members have identified.

Example 1

Facts. A group health plan limits benefits to treatment that is medically necessary. To determine medical necessity for inpatient, in-network mental health and substance use disorder benefits, the plan requires that treatment guidelines be followed. These guidelines have many elements, and every element must be met to have that inpatient stay approved. For inpatient, innetwork medical surgical/benefits, the medical necessity guidelines are general guidelines that do not require every element to be met for the stay to be approved.

Conclusion. In this example, the plan violates the nonquantitative treatment limitation requirements of the regulations. Although the same nonquantitative treatment limitation — medical necessity — applies to both mental health and substance use disorder benefits and to medical/surgical benefits for inpatient, in-network services, the processes, strategies, and evidentiary standards used to determine medical necessity are not comparable and are more stringent for medical necessity determinations for mental health and substance use disorders for inpatient, in-network benefits compared to medical/surgical benefits in that classification.

Example 2

Facts. A group health plan limits benefits to treatment that is medically necessary. The plan requires concurrent review for inpatient, in-network mental health and substance use disorder benefits and medical/surgical benefits. However, the plan requires physician-to-physician reviews on a daily or routine basis for all inpatient mental health and substance use disorder stays before authorizing additional days, while only requiring physician-to-physician reviews for medical/surgical cases if the patient falls outside the norm (outlier cases).

Conclusion. In this example, the plan violates the nonquantitative treatment limitation requirement of the regulations. Although the health plan utilizes concurrent review for inpatient, in-network mental health and substance use disorders and for inpatient, in-network medical/surgical disorders, the health plan applies a more stringent concurrent review process, which is daily or routine physician-to-physician reviews for mental health and substance use disorders compared to physician-to-physician reviews for medical/surgical benefits in only selected cases ("outlier cases").

Example 3

Facts. A group health plan covers several levels and settings of inpatient, in-network medical/surgical benefits (such as inpatient hospital, inpatient rehabilitation facility and skilled nursing facility), but only covers inpatient hospital for mental health and substance use disorders.

Conclusion. In this example, the health plan violates the nonquantitative treatment limitation requirements of the regulations. By not covering similar levels of care and settings for mental health and substance use disorders, such as subacute rehabilitation and residential levels of care, and non-hospital based inpatient rehabilitation and residential facilities, as compared to medical/surgical benefits, the plan is imposing a treatment limitation with respect to the inpatient, in-network classification of mental health and substance use disorder benefits that is not comparable to the same classification of medical/surgical benefits. This treatment limitation is therefore not permitted under the general rule for NQTLs.

Example 4

Facts. A group health plan has a fail-first policy for all inpatient substance use disorder treatment services (in which a patient is required to fail at outpatient treatment before inpatient care can be authorized), but does not require a fail-first policy for all inpatient medical/surgical benefits.

Conclusion. This plan violates the nonquantitative treatment limitation requirements of the regulations. The processes for determining the appropriate levels of care are not comparable and are applied more stringently with respect to inpatient mental health and substance use disorders as compared to inpatient care for medical/surgical benefits.

Suggested Language on NQTLs for Final Rule

In addition, the Coalition suggests that the following commonly experienced treatment limitations be added to the illustrative list of nonquantitative treatment limitations set forth in the IRF (added language is bolded and underlined):

Nonquantitative treatment limitations include--

- (A) Medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;
- (B) Formulary design for prescription drugs <u>including the scope and range of drugs</u> offered;
- (C) Standards for provider admission to participate in a network, including reimbursement rates:
 - (D) Plan methods for determining usual, customary, and reasonable charges;
- (E) Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols); and
 - (F) Exclusions based on failure to complete a course of treatment;
- (G) Exclusions and/or limits in general plan design and/or medical standards or criteria with respect to diagnostic and treatment services that are not medically analogous, for example, no coverage for mental health or substance use disorder diagnostic or treatment services that are not also indicated for medical/surgical conditions; and
- (H) Exclusions in general plan design and/or medical standards or criteria that limit the scope and range of treatments and/or treatment settings within a benefit classification.

4. <u>Guidance Must be Provided on What Constitutes "Recognized Clinically Appropriate Standards"</u>

In the last part of the NQTL general rule, the regulations permit an exception to the "comparable and no more stringently standards" only "to the extent that recognized clinically appropriate standards of care may permit a difference." To ensure the strong parity protections envisioned by Congress, the Departments must adopt a definition of "recognized clinically appropriate standards of care" that is based on external, independent and objective clinical policies and standards.

Coalition members are experiencing plans and issuers justifying the imposition of NQTLs based upon their own internal "expert" opinions of what may be considered clinically appropriate. Plans are in fact deeming their own internal opinions on clinical appropriateness to be protected under the regulations. Clearly defining "recognized" as an external, independent and objective factor,

⁴ 75 Fed. Reg. 5436, 5443, 5450.

is critical to ensuring compliance with the statute and the regulations. As noted, the <u>only</u> exception to the requirements that NQTLs be comparable to and applied no more stringently than is when "recognized clinically appropriate standards of care" permit a difference. Thus, any attempt to bypass the parity requirements will involve finding a "recognized clinically appropriate" standard of care. If adequate requirements are not established to determine when a standard is recognized, the parity requirements will continue to be circumvented. As we have seen, a plan could internally trigger the exceptions simply because its own employees or hired consultants deem a standard "recognized"—with no outside verification.

Such a result opens a loophole that weakens Congress' intended parity protections. Congress' purpose in passing the statute was to ensure meaningful parity between MH/SUD and medical/surgical benefits by expanding previously-approved mental health parity legislation. In the statute, 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 will weaken, (and is already weakening), the equity between MH/SUD and medical/surgical benefits that Congress sought.

Definition of "Recognized Clinically Appropriate Standards of Care"

To avoid this result, the Departments should clearly define "recognized clinically appropriate standards of care." This definition should state clearly that any "recognized" standard of care for purposes of the NQTL exceptions test must be: (1) an independent standard that is not developed solely by a single health plan or plans; (2) based on input from multiple stakeholders and experts, such as academic researchers, senior practicing clinicians, and consumer leaders with subject matter expertise in addition to a health plan or its advisory panels; (3) recognized or accepted by multiple nationally recognized provider and consumer organizations and/or nationally recognized accrediting organizations that are responsible for developing quality standards; and (4) based on objective scientific evidence, such as peer-reviewed publications of control group research trials or expert consensus panels.⁵

The Coalition fully appreciates that the purpose of having the exception of a "clinically recognized standard" that permits a more stringent application of an NQTL is to leave unencumbered management techniques that improve the quality of patient care and demonstrate better outcomes. A plan's or insurer's position that MH/SUD is different from medical/surgical in treatment or diagnosis, does not by itself create a standard that allows more restrictive and/or stringent management, unless it can be objectively demonstrated that the specific NQTL will improve the quality of patient care and outcomes if applied in a more

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⁵ These recommendations are consistent with the manner in which numerous government agencies make scientific and clinical judgments. For example, CMS regularly relies on independent expertise when making its coverage determinations. There is clear precedent for CMS to take a rigorous view of the evidentiary basis for Medicare reimbursement of drugs, devices and procedures. In the National Coverage Determination (NCD) process, CMS evaluates all pertinent data, including the scientific data that requesters submit, peer-reviewed medical, technical and scientific literature, and recommendations from expert panels. CMS also can order a health technology assessment to provide an independent analysis of all of the scientific and clinical evidence available on a particular health care technology. The Medicare Coverage Advisory Committee (MCAC) also plays a role in assisting the agency in making sound coverage decisions. MCAC provides independent, expert advice based upon the reasonable application of scientific evidence through members who possess the scientific and technical competence to provide these assessments.

stringent manner. Likewise, showing that a particular NQTL is more effective at cost containment for MH/SUD as compared to medical/surgical does not, by itself, create a clinical standard that allows more restrictive management.

Example 3 under the general rule for NQTLs in the regulations aptly demonstrates this point:

"Example 3. (i) Facts. A plan generally covers medically appropriate treatments. For both medical/surgical benefits and mental health and substance use disorder benefits, evidentiary standards used in determining whether a treatment is medically appropriate (such as the number of visits or days of coverage) are based on recommendations made by panels of experts with appropriate training and experience in the fields of medicine involved. The evidentiary standards are applied in a manner that may differ based on clinically appropriate standards of care for a condition.

(ii) Conclusion. In this Example 3, the plan complies with the rules of this paragraph (c)(4) because the nonquantitative treatment limitation – medical appropriateness – is the same for both medical/surgical benefits and mental health and substance use disorder benefits, and the processes for developing the evidentiary standards and the application of them to mental health and substance use disorder benefits are comparable to and are applied no more stringently than for medical/surgical benefits. This is the result even if, based on clinically appropriate standards of care, the application of the evidentiary standards does not result in similar numbers of visits, days of coverage, or other benefits utilized for mental health conditions or substance use disorders as it does for any particular medical/surgical condition." 75 Fed. Reg. 5436, 5443, 5450. (Emphasis supplied).

This *Example 3* from the regulations in regards to the creation of clinically recognized standards demonstrates that when there is parity in how a clinically recognized standard is formulated between medical/surgical and MH/SUD benefits, even if the application of an NQTL results in different outcomes, the NQTL may <u>not</u> be applied in a more stringent manner.

Conclusion

The Parity Implementation Coalition respectfully requests the following additional regulatory guidance on non-quantitative treatment limitations:

- The general rule for NQTLs must include a proportion test that must be met with respect
 to the application of a type or subtype of NQTL to the medical/surgical benefit before the
 NQTL can be applied to the MH/SUD benefit;
- Additional guidance is needed for proper implementation of the general rule on NQTLS, and;
- 3) Clarifying guidance must be provided with respect to what constitutes "recognized clinically appropriate standards of care."

5. MEDICAID MANAGED CARE PARITY

Background

Congress convened numerous hearings and markups on parity legislation over the 12 years it was debated. There was never a protest that parity applied to Medicaid managed care organizations (MCOs). One issue that was unopposed in the statute was the application of parity to Medicaid managed care plans. Although the application of parity to Medicaid managed care organizations was accomplished by cross reference, Congressional intent was clear in both the House and Senate that these plans were covered by parity as evidenced by the Congressional Budget Office's analyses, which included Medicaid managed care organizations in the financial impact analyses of the parity bills. Coalition members understand the delivery of Medicaid benefits is made complex by the intersection of state and federal responsibilities, but in the absence of a final rule, we have seen very little evidence that parity has been applied in MCO plans.

We urge any final rule to provide guidance clarifying the application of parity in these plans so that individuals do not receive discriminatory limits on access to mental health and addiction benefits just by virtue of being poor or disabled.

Analysis

States that have implemented mandatory managed care (MMC) in the Medicaid programs have generally taken three approaches to the delivery of MH/SUD services. In the first approach, the Medicaid managed care organization (MCO) that provides medical care also provides MH/SUD benefits as part of its program and the benefit is provided and managed internally by the MCO, or the MCO subcontracts with a managed behavioral health organization (MBHO). In the second approach, the state Medicaid agency carves out the MH/SUD benefit from physical health benefit and individuals receive mental health services either on a fee-for-service basis or through a separate MCO specializing in MH/SUD. The third and most common approach is a blend of the first two, in which some MH/SUD benefits are managed and provided by the MCO while others (typically for the seriously ill) are carved out to a specialty behavioral MCO.

CMS issued <u>guidance</u> in 2009 that all SCHIP and Medicaid managed care plans that have any MH/SUD benefit have to be compliant with MHPAEA. CMS indicated in 2010 when the IFR was released that guidance would be forthcoming on application of parity in Medicaid managed care organizations. Unfortunately, CMS has not issued more detailed regulations on MHPAEA for Medicaid managed care plans. In a 2012 information bulletin, CMS reissued the 2009 State Medicaid Director letter without issuing any additional clarifying guidance. If the 2009 Medicaid Director letter was sufficient, MHPAEA would already be implemented in state Medicaid managed care plans. Unfortunately, MHPAEA is not being implemented.

MHPAEA specifically subjects Medicaid managed care plans to its parity requirements if they have any MH/SUD benefit. MHPAEA was a self-implementing law passed in 2008 and the statute went into effect for plan years beginning on or after October 3, 2009. Nothing in statute

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⁶ 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. The Medicaid managed care statute refers to this section and mandates that managed care plans "comply" with its provisions. Specifically, the Social Security Act Section 1932(b)(8) specifies that: "Each Medicaid managed care organization shall comply with the requirements of subpart 2 of Part A of title XXVII of the Public Health Service Act [42 U.S.C.A. 300gg-5 et seq.] insofar as such requirements apply and are effective with respect to a health insurance issuer that offers group health insurance coverage." The statutory reference in the quote refers to the mental health parity provisions as passed in the 1996 Mental Health Parity Act (MHPA) and as modified by the 2008 Act. Thus, the Medicaid managed care statute requires that MMC plans comply with both the 1996 and the 2008 parity requirements.

precludes parity protections for Medicaid beneficiaries. following recommendation:	To clarify this point, we offer the

Recommendation on Medicaid Managed Care

 CMS should issue final regulations clarifying that MHPAEA is in effect for Medicaid managed care plans and provide specific guidance on how Medicaid managed care organizations must implement the law.

CONCLUSION

Members of the Parity Implementation Coalition seek to work with the Departments to fully implement MHPAEA and end the longstanding insurance discrimination against individuals with mental and substance use disorders. We are pleased to meet with the Departments to discuss these proposals in greater detail.

Parity Implementation Coalition

April 30, 2010

BY HAND DELIVERY AND ELECTRONIC SUBMISSION

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

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

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

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

Dear Secretary Solis, Secretary Sebelius, and Commissioner Shulman:

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

The Parity Implementation Coalition is a coalition of addiction and mental health consumer and provider organizations. Its members include the American Academy of Child and Adolescent Psychiatry, American Psychiatric Association, American Society of Addiction Medicine, Betty Ford Center, Bradford Health Services, Faces and Voices of Recovery, Hazelden Foundation, Mental Health America, National Alliance on Mental Illness, National Association of Psychiatric Health Systems, National Council for Community Behavioral Healthcare and The Watershed Addiction

¹ 75 Fed. Reg. 5410 (Feb. 2, 2010).

Treatment Programs, Inc. In an effort to end discrimination against individuals and families who seek services for mental health and substance use disorders, these organizations have advocated for more than twelve years in support of parity legislation and are committed to the prompt and effective implementation of the Mental Health Parity and Addiction Equity Act of 2008 ("MHPAEA" or "Act").

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

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

- The Department should make clear that MHPAEA requires parity with respect to scope of services and makes clear that the parity requirements apply to both quantitative and non-quantitative treatment limitations;
- The Departments should clarify that all medical/surgical and MH/SUD benefits must be included within the six classifications created in the Interim Final Rules, and plans must ensure parity both across and within classifications;
- To ensure clarity and consistency with the Act and previous regulations, the Departments should adopt the Interim Final Rules' definitions of substantially all and predominant in the Final Rules, and maintain the requirement for a single deductible;
- The Departments should clarify that NQTLs are subject to the predominant and substantially all standard and the comparable and no more stringently standards, and ensure that exceptions to these standards are based on independent and objective clinical policies and standards;
- To ensure patients are able to effectively understand and respond to benefit claims denials, the Departments should require plans to disclose the reason for the denial within a specific timeframe;
- The Departments should remain consistent with the statute and prior regulations by using actual costs as the basis for the increased cost exemption;
- The Interim Final Rules' preemption provisions will normally allow stronger state parity laws to remain in force, and should therefore be included in the Final Rules;
- To ensure effective implementation of the MHPAEA in Medicaid, the Departments should release any additional regulations related to the application of MHPAEA to

Medicaid managed care organizations in a timely manner and should clarify that the IFR applies to Medicaid managed care organizations currently;

- The Departments should establish best practices that plans must use when defining a MH/SUD, including basing such definitions on an independent, national or international standard or state government guideline; and
- To remedy existing inequities and ensure effective implementation of the Act pending issuance of the Final Rules, the Departments should issue timely guidance on issues currently addressed in the regulations.

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

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

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

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

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

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

² 75 Fed. Reg. 5416-17.

³ Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act, 29 U.S.C.A. § 1185a(e)(4) (2009).

⁴ *Id.*

⁵ *Id*.

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

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

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

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

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

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

^{6 § 1185}a(a)(3)(A)(i).

⁷ § 1185a(a)(3)(A)(ii).

Proponents of limiting services may point to the statutory definition of MH/SUD benefits to argue that there is no scope of service parity because a plan has the ability to define the services under the terms of the plan. The statute defines MH/SUD benefits as "benefits with respect to services for mental health conditions, as defined under the terms of the plan and in accordance with applicable Federal and State law.⁸ Proponents of limiting services might argue that plans maintain the flexibility to determine which services to provide because the Act specifically allows them to be "defined under the terms of the plan." The Coalition reads this language to mean that it is the mental health conditions and substance use disorders that are "defined under the terms of the plan," not the MH/SUD services. Under this reading, the plan appears to have flexibility as to what mental health conditions and substance use disorders it covers. However, once it decides to cover the condition or disorder, it is subject to the parity requirements governing services that are described below (predominant and substantially all, comparable and no more stringently, all services must be within one of the six classifications, etc).

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

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

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

^{8 § 1185}a(e)(4), (5).

⁹ § 1185a(a)(3)(B)(iii).

¹⁰ *Id*.

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

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

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

- II. The Departments Should Clarify that All Medical/Surgical and MH/SUD Benefits Must Be Included Within the Six Classifications Created in the Interim Final Rules, and Plans Must Ensure Parity Both Across and Within Classifications.
 - A. The Interim Final Rules Create Six Classifications Within which All MH/SUD Benefits Must Be Included, and Plans are Prohibited from Creating New Classifications.

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

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

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

¹¹ *Id*.

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

^{13 75} Fed. Reg. 5413.

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

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

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

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

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

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

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

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

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

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

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

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

Although the regulations do not require a plan to cover identical MH/SUD and medical surgical services within a classification, they do require that the limitations in each MH/SUD classification be no more restrictive than the limits in the corresponding medical/surgical classification. If limitations were being applied in a no more restrictive manner in the situation above, it is unlikely that only one MH/SUD service would be covered while many medical/surgical

services are covered. Presumably, the plan has developed some reasoning for excluding coverage of other MH/SUD services. If the reason the plan is offering such limited MH/SUD services in a classification is that the plan is applying a treatment limitation to MH/SUD benefits that is more restrictive than the predominant treatment limitation applied to substantially all medical/surgical benefits in the same classification, the plan has violated the requirements of the parity regulations.

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

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

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

In most cases, a plan that refuses to cover a MH/SUD service because it claims there is no medical/surgical analogue will make this decisions based on a NQTL, as opposed to a numbers-based QTL. Accordingly, this action will be subject to the "comparable" and "no more stringently" standard. ¹⁶

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

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

¹⁵ 75 Fed. Reg. 5412.

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

¹⁷ Id.

^{18 § 1185}a(a)(3)(A)(ii).

parity requirements of the statute because it imposes a treatment limitation "applicable only with respect to" MH/SUD benefits.

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

- III. To Ensure Clarity and Consistency with the Act and Previous Regulations, the Departments Should Adopt the Interim Final Rules' Definitions of Substantially All and Predominant in the Final Rules, and Maintain the Requirement for a Single Deductible.
 - A. The Substantially All and Predominant Definitions in the Regulations are Clear, Logical, and Consistent with the Implementation of Previous Mental Health Parity Laws.

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

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

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

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

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

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

²⁰ § 1185a(a)(3)(B)(ii) (2009).

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

- IV. The Departments Should Clarify that NQTLs are Subject to the Predominant and Substantially All Standard and the Comparable and No More Stringently Standards, and Ensure that Exceptions to these Standards are Based on Independent and Objective Clinical Policies and Standards.
 - A. The Regulations Define and Apply NQTLs in a Manner Consistent with the Parity Statute.

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

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

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

²¹ § 1185a(a)(3)(B)(iii).

²² Id.

²³ 75 Fed. Reg. 5416.

rule is in cases where "recognized clinically appropriate standards of care...permit a difference." This rule sets forth two critical standards for determining plan compliance with the regulations.

The first standard for determining plan compliance is the manner in which the processes, strategies, evidentiary standards, and other factors are used in *applying* the NQTL. The regulation states that a plan may not impose a NQTL unless the processes, strategies, evidentiary standard, or other factors "used in applying" the NQTL are comparable to and "applied" no more stringently in medical/surgical than in MH/SUD.²⁵ Under this construct, plans can have the same NQTL in both MH/SUD and medical/surgical and still violate the parity requirements by applying these NQTLs differently. The regulation states explicitly that the no more stringently standard was "included to ensure that any processes, strategies, evidentiary standards, or other factors that are comparable on their face are applied in the same manner to medical/surgical and to MH/SUD benefits."²⁶

The examples provided in the regulations illustrate this principle clearly. Example 1 of Section (c)(4)(iii) states that a health plan limits benefits to treatment that is medically necessary. The plan requires concurrent review for MH/SUD benefits, and retrospective review for medical/surgical benefits. In such a case, the same NQTL-medical necessity-applies to both MH/SUD and medical surgical benefits. However, the plan violates the parity rules because the process of applying the NQTL is not comparable. Concurrent review is not comparable to retrospective review.²⁷ Similarly, example 4 presents a situation in which a plan violates the parity requirements by applying the same NQTL in a non-comparable manner. In the example, a plan covers medically appropriate treatments. The plan automatically excludes coverage for antidepressant drugs that are given a black box warning by the Food and Drug Administration, but provides coverage for other black box drugs if the physician obtains authorization from the plan that the drug is medically appropriate for the individual. In this example, the NQTL-medical appropriateness—is applied to both MH/SUD and medical/surgical. However, the unconditional exclusion of antidepressants is not comparable to the conditional exclusion of other drugs with a black box warning. 28 Thus, plans must ensure that the manner a NQTL is applied is comparable and no more stringent in MH/SUD than in medical/surgical, even if the NQTL itself is the same.²⁹

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

 $^{^{24}}$ Id.

²⁵ Id.

²⁶ Id.

²⁷ 75 Fed. Reg. 5436.

²⁸ *Id*.

²⁹ Id.

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

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

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

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

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

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

^{31 75} Fed. Reg. 5436.

^{32 29} U.S.C. 1185a(a)(3)(A)(ii).

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

Importantly, the statute applies the three-part test to <u>all</u> 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." 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. Thus, the regulations' inclusion of both QTLs and NQTLs under the definition of treatment limitations is consistent with the statute.

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." If the treatment limitation does not meet this test, it cannot be applied in the MH/SUD benefit. The second step involves identifying the predominant treatment limitation. The predominant treatment limitation is the level that applies to more than one-half of medical/surgical benefits subject to treatment limitations in that class.³⁹

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

³³ Id.

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

^{35 § 1185}a(a)(3)(B)(iii).

³⁶ *Id*.

³⁷ 75 Fed. Reg. 5413.

^{38 75} Fed. Reg. 5414.

³⁹ *Id*.

⁴⁰ 75 Fed. Reg. 5412.

allows 50 outpatient days per year in the medical/surgical benefit but only 30 outpatient days per year in the MH/SUD benefit, the QTL is clearly more restrictive in the MH/SUD benefit. However, the "more restrictive" test is more difficult to apply to NQTLs. Because NQTLs are not expressed numerically (i.e., are qualitative in nature), the "more restrictive" is not self-proving as it is with quantitative QTLs. Thus, a second standard or test must be established to operationalize the "no more restrictive" statutory test for NQTLs.

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

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

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

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

⁴¹ 75 Fed. Reg. 5436.

⁴² 75 Fed. Reg. 5412-13.

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

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

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

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

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

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

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

Such a result opens a potential loophole that would weaken Congress' intended parity protections. Congress' purpose in passing the Act was to ensure meaningful parity between MH/SUD and medical/surgical benefits by expanding previously-approved mental health parity legislation.⁴⁴ In the Act, Congress was very clear that treatment limitations should be "no more

⁴³ 75 Fed. Reg. 5416.

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

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

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

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

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

⁴⁴ In 1996, Congress passed and the President signed the Mental Health Parity Act (MHPA). The MHPA equates aggregate lifetime limits and annual limits for MH/SUD benefits with aggregate lifetime limits and annual limits for medical/surgical benefits. Thus, the statute gave a measure of protection from the costs of MH/SUD services. Legislation to expand mental health parity was introduced in the House from 1997 until the passage of the Mental Health Parity and Addiction Equity Act. It was in this context that the Act was passed.

⁴⁵ These recommendations are consistent with the manner in which numerous government agencies make scientific and clinical judgments. For example, CMS regularly relies on independent expertise when making its coverage determinations. There is clear precedent for CMS to take a rigorous view of the evidentiary basis for Medicare reimbursement of drugs, devices and procedures. In the National Coverage Determination (NCD) process, CMS evaluates all pertinent data, including the scientific data that requesters submit, peer-reviewed medical, technical and scientific literature, and recommendations from expert panels. CMS also can order a health technology assessment to provide an independent analysis of all of the scientific and clinical evidence available on a particular health care technology. The Medicare Coverage Advisory Committee (MCAC) also plays a role in assisting the agency in making sound coverage decisions. MCAC provides independent, expert advice based upon the reasonable application of scientific evidence through members who possess the scientific and technical competence to provide these assessments.

⁴⁶ 75 Fed. Reg. 5416.

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

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

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

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

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

⁴⁷ 75 Fed. Reg. 5443.

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

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

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

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

⁴⁸ 75 Fed. Reg 5412.

⁴⁹ Specifically, the statute states that "the reason for any denial under the plan (or coverage) of reimbursement or payment for services" with respect to MH/SUD benefits "shall, on request or as otherwise required, be made available by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary." 29 U.S.C.A. § 1185a(a)(4).

A requirement to disclose medical necessity criteria is in harmony with the ERISA regulations discussed in the Interim Final Rules. The statute itself states that the notification shall be provided "in accordance with regulations." For purposes of implementing this requirement, the Interim Final Rules state that if a plan is subject to ERISA, it must provide "the reason for the claim denial in a form and manner consistent with the requirements of 29 CFR 2560.503–1 for group health plans." Even for non-ERISA plans, "a plan that follows the requirements of 29 CFR 2560.503–1 for group health plans complies with" the requirement to provide a reason for denial. 51

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

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

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

The Act permits an exception to the mental health parity requirements for plans that experience a cost increase of over one percent as a result of the Act.⁵⁴ The Act is clear that actual

⁵⁰ *Id*.

⁵¹ *Id*.

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

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

^{54 29} U.S.C. 1185a(c)(2)(A).

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

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

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

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

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⁵⁵ Id.

 $^{^{56}}$ § 1185a(c)(2)(E)(ii)(II), (III).

⁵⁷ § 1185a(c)(2)(C).

^{58 62} Fed. Reg. 66955.

⁵⁹ *Id*.

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

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

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

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

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

^{60 75} Fed. Reg. 5418.

⁶¹ *Id*.

^{62 75} Fed. Reg. 5430.

⁶³ *Id*.

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

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

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

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

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

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

^{66 42.} U.S.C. 300gg-5(a)(3) (2000).

^{67 42} U.S.C. 1396u-2(b)(8) (2000).

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

⁶⁹ H.R. REP. NO. 110-374, pt. 1 (2007) (Educ. & Labor Comm.); H.R. REP. NO. 110-374, pt. 2 (2007) (Ways & Means Comm.); H.R. REP. NO. 110-374, pt. 3 (2007) (Energy & Commerce Comm.).

^{70 42} U.S.C. 1396u-2(b)(8) (2000).

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

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

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

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

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

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

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

⁷³ 75 Fed. Reg. 5412.

⁷⁴ Id.

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

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

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

XI. Conclusion

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

Sincerely,

Carol McDaid

Co-Chair

Parity Implementation Coalition

of Mylad

Irvin L. Muszynski, JD

Co-Chair

Parity Implementation Coalition

Attachments:

Appendix 1: A Framework for Providing Scope of Service Parity in an Affordable and Equitable Manner

Appendix 2: Non-Quantitative Treatment Limitations Are Applied More Stringently on MH/SUD Benefits

Milliman MHPAEA Scope of Services Research

APPENDIX 1

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

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

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

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

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

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

⁷⁵ The Parity Implementation Coalition includes: the American Academy of Child and Adolescent Psychiatry, American Psychiatric Association, American Society of Addiction Medicine, Betty Ford Center, Bradford Health Services, Faces and Voices of Recovery, Hazelden Foundation, Mental Health America, National Alliance on Mental Illness, National Association of Psychiatric Health Systems, National Council for Community Behavioral Healthcare and The Watershed Addiction Treatment Programs, Inc.

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

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

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

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

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

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

proposed by a consumer or provider have to be funded? Who would define what is "evidence-based" and under what set of rules?

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

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

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

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

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

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

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

- 1. Complies with MHPAEA's requirements;
- 2. Does not establish a mandate of coverage for a specific MH or SUD conditions or groups of disorders

- 3. Provides for a "floor" for benefit limits; and
- 4. Is consistent with the typical provisions used for medical/surgical coverage as broadly requested by the health plan/insurance community in response to the Departments' Request for Information (RFI).

This analysis will address the following categorical issues:

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

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

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

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

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

After a plan has exercised its statutory authority to "choose" whether or not to offer coverage for a condition then their flexibility is limited in that these covered "benefits" or "treatments" must be

offered in a no more restrictive manner in regards to "financial requirements" and "treatment limitations." Requiring that a similar range and scope of treatments be reimbursed for a specific MH/SUD as compared to medical/surgical refers only to treatment services for that specific MH/SUD. It in no way commits a plan to extend coverage for additional MH/SUDS.

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

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

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

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

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

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

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

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

settings (group homes and supervised apartments) similar to the medical/surgical supervised living settings for MH/SUD patients.

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

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

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

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

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

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

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

care for addictive disorders. The American Psychiatric Association has treatment guidelines for virtually all prevalent mental illness conditions.

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

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

- 1. Do contractual limitations apply? Is care consistent with professional standards of practice?
- 2. What is the patient's condition/acuity and severity e.g., is treatment delivered in a safe and effective manner?
- 3. What is the cost? Is there an equally effective and safe but less costly alternative? Is the level of care/service intensity appropriate to the patient's condition?

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

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

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

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

Applying this CDC comparability requirement in defining a scope of benefits does not establish a specific benefit mandate per se. It does require a plan that chooses to provide coverage to establish benefits for MH/SUD using the same criteria it uses for medical/surgical and apply similar factors in making coverage determinations.

Moreover, providing for comparable coverage establishment and determination processes does not enfranchise all available treatments and providers in the mental health/substance use disorder delivery system(s). Health plan policy conditions and exclusions can contractually limit coverage so long as comparable factors are applied to medical/surgical, a point which is more fully addressed below.

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

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

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

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

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

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

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

Experimental: Refers to paying for treatments that are not "proven" based on scientific evidence such as controlled research studies or expert consensus panels. If

the treatment is a drug or device that requires FDA review then the FDA's approval can provide the necessary review that the treatment is both safe and effective.

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

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

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

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

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

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

Part of the confusion in this area is the lack of a standard definition of what is considered "long term care" or care in a long-term care setting and the difficulty in separating that

definition from what is typically reimbursed by most health plans. For example, one common definition of long term care is:

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

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

Conclusion

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

APPENDIX 2

PARITY IMPLEMENTATION COALITION⁷⁶ Non-Quantitative Treatment Limitations Are Applied More Stringently on MH/SUD Benefits

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

Non-Quantitative Treatment Limitations Rooted in Substantial MHPAEA Legislative History

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

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

Coalition Survey of Health Plan Policies and Practices

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

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

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

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

⁷⁶ The Parity Implementation Coalition includes: the American Academy of Child and Adolescent Psychiatry, American Psychiatric Association, American Society of Addiction Medicine, Betty Ford Center, Bradford Health Services, Faces and Voices of Recovery, Hazelden Foundation, Mental Health America, National Alliance on Mental Illness, National Association of Psychiatric Health Systems, National Council for Community Behavioral Healthcare and The Watershed Addiction Treatment Programs, Inc.

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

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

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

- Various Large Health Insurers
 - Out-of-network MH/SUD services not located in the state where the policy is written are not covered.
- Large Managed Behavioral Health Organizations (MBHO)
 - O Persons accessing out-of-network providers for MH/SUD can be stabilized only, and must be transferred to an in-network provider in order for coverage to be in effect. No similar provision for out-of-network medical/surgical.
 - O Precertification and concurrent review protocols for all out-of-network mental health/substance use disorder care; no corresponding precertification or concurrent review protocols for out-of-network medical/surgical care.
- Various Blue Cross/Blue Shield Plans
 - O Will not make medical necessity criteria available upon request to patients who are seeking MH/SUD out-of-network services, as required under MHPAEA. Will only make medical necessity criteria available after an out-of-network coverage determination is made.

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

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

- Access to care;
- Choice of provider;
- Treating clinician's qualifications;

- Duration of treatment; and
- Type of treatment.

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

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

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

Major Multi-state Employer Benefit Plan:

EXCLUSIONS

Mental Health/Substance Abuse

- Services that extend beyond the period necessary for short-term evaluation, diagnosis, treatment, or crisis intervention.
- Treatment of conduct and impulse control disorders, personality disorders, paraphilias and
 other mental illnesses that will not substantially improve beyond the current level of
 functioning, or that are not subject to favorable modification or management according to
 prevailing national standards of clinical practice, as reasonably determined by the Mental
 Health/Substance Abuse Designee.
- Treatment provided in connection with or to comply with involuntary commitments, police detentions and other similar arrangements, unless authorized by the Mental Health/Substance Abuse Designee (the employer/health plan).
- Services or supplies that in the reasonable judgment of the mental health/substance abuse designee are not, for example, consistent with certain national standards or professional research.

Several Blue Cross/Blue Shield Plans and Self-Insured Employers: EXCLUSIONS

- All substance abuse services (even though the plan offers a full array of mental health benefits).
- Treatment for illicit drugs.

Coverage Exclusions for Types and Levels of MH/SUD Treatment

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

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

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

- Multiple Blue Cross/Blue Shield plans exclude:
 - o MH/SUD residential treatment services
 - o SUD partial hospitalization
 - O SUD intensive outpatient programs
- Multi-state Employer Plans/Several Blues Plans/MBHOs
 - O Admission criteria for inpatient MH/SUD services that require patients to be homicidal or suicidal before being eligible for coverage while there is no similar restriction on medical benefits.
- Major Managed Care Organizations/Blue Plans/MBHOs
 - O Plans are covering mental health benefits and dropping substance use disorder benefits altogether claiming that MHPAEA (even after a plan decides to offer MH/SUD coverage) requires them to cover either MH or SUD at parity with medical/surgical, but not both.
- Major managed care organizations
 - o MH/SUD services that extend beyond the period necessary for short-term evaluation, diagnosis, treatment, or crisis intervention.
 - Residential treatment services.
 - Treatment provided in connection with or to comply with involuntary commitments, police detentions and other similar arrangements, unless authorized by the Mental Health/Substance Abuse Designee.

Conclusion

NQTLs pose significant barriers to accessing care for those with MH/SUD conditions. There is a strong statutory basis for NQTLs under MHPAEA and there is a strong need for clarifying regulations since plans are interpreting the regulations in a way that continues to limit access to equitable MH/SUD care. The survey conducted by the Coalition documents the need for additional

examples of NQTLs in the final regulations, and special attention should focus on out-of-network parity NQTLs where access is particularly constrained. Elimination of entire levels of care essential to the range and scope of services for effective MH/SUD care must not be permitted under the final rules when there is a comparable range and scope of medical/surgical services.

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



1099 Eighteenth Street Suite 3100 Denver, CO 80202-1931

Tel +1 303 299 9400 Fax +1 303 299 9018

milliman.com

April 30, 2010

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

Re: MHPAEA Scope of Services Research

Dear Carol:

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

Results

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

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

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



Carol McDaid April 30, 2010 Page 2 of 3

to a complete continuum of evidence-based care alternatives is vital for achieving best practices in care delivery.

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

Our Approach

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

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

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

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

- Assist clinicians in making informed decisions in many healthcare settings including
 hospital, acute and subacute medical and rehabilitation, skilled nursing, home healthcare,
 and ambulatory facilities. When the continuum of care is used, more intensive levels of
 care are reserved for patients who cannot be managed safely and effectively at lower
 levels.
- Communicate a range of demonstrated best practices, not average or minimally acceptable practices.
- Display quality measures from US national organization quality initiatives such as the Centers for Medicare and Medicaid Services Hospital Quality Alliance initiative, the National Committee for Quality Assurance HEDIS® measures, and the Joint Commission's National Patient Safety Goals.



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- Provide information to reduce unnecessary variation in healthcare practice because substantial unnecessary variation still pervades medicine.
- Display the current best evidence used in developing the Care Guidelines to encourage clinician participation in the practice of evidence-based medicine. Key points are enhanced with footnotes, explanations, annotations, or references to describe the evidence base for each guideline conclusion.
- Encourage patient education and patient choice. Informed patients can cooperate with caregivers to achieve better outcomes and can make better choices about their healthcare.
- Use a concise, accessible format to support rapid assimilation of information.

Caveats

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

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

Stephen P. Melek, FSA, MAAA

Consulting Actuary

PATRICK J. KENNEDY 1ST DISTRICT, RHODE ISLAND

WASHINGTON OFFICE 407 CANNON HOUSE OFFICE BUILDING (202) 225-4911 FAX: (202) 225-3290 Email: patrick.kennedy@mail.house.gov

DISTRICT OFFICE 249 ROOSEVELT AVENUE, SUITE 200 PAWTUCKET, BL02860 (401) 729-5600 (800) 392-5772 FAX (401) 729-5608

www.house.gov/patrickkennedy



Congress of the United States **Couse of Representatives** Washington, DC 20515

December 14, 2010

The Honorable Hilda Solis Secretary U.S. Department of Labor 200 Constitution Ave, NW Washington, DC 20210

The Honorable Kathleen Sebelius Secretary U.S. Department of Health and Human Services 200 Independence Ave, SW Washington, DC 20201

The Honorable Timothy Geithner Secretary U.S. Department of the Treasury 1500 Pennsylvania Ave, NW Washington, DC 20220

Dear Secretaries Solis, Sebelius and Geithner:

We are writing to urge you to issue final regulations or sub-regulatory guidance prior to January 1, 2011 on the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA). Allowing the law to be implemented without specific guidance on scope of service, disclosure of medical criteria, and non-quantitative treatment limitations increases the likelihood that patients will continue to be subjected to discriminatory practices by health insurers, and suffer because they do not have access to needed services, treatments, and benefits; this was clearly not Congressional intent.

In September 2009 and May 2010, 73 House Members, Chairmen and Subcommittee Chairmen of the three committees of jurisdiction encouraged you to issue regulations clarifying Congressional intent on scope of service, among other issues. This letter again urges timely final regulations or guidance addressing these issues, and further clarifies Congressional intent on these topics.



Attachment 2 COMMITTEE ON APPROPRIATIONS

SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES AND **FDUCATION**

SUBCOMMITTEE ON COMMERCE. JUSTICE, STATE AND JUDICIARY

FOUNDER AND VICE-CHAIRMAN NATIVE AMERICAN CAUCUS

FOUNDER AND CO-CHAIRMAN PORTUGUESE-AMERICAN CAUCUS

FOUNDER AND CO-CHAIRMAN 21st CENTURY HEALTH CARE CAUCUS

Congress of the United States Washington, DC 20515

May 18, 2011

The Honorable Hilda Solis Secretary U.S. Department of Labor 200 Constitution Avenue, NW Washington, DC 20210 The Honorable Timothy Geithner Secretary U.S. Department of the Treasury 1500 Pennsylvania Avenue, NW Washington, DC 20220

The Honorable Kathleen Sebelius Secretary U.S. Department of Health and Human Services 200 Independence Avenue, SW Washington, DC 20201

Dear Secretaries Solis, Sebelius and Geithner:

We are writing to urge you to issue final or sub-regulatory guidance on the *Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008* (MHPAEA). Allowing the law to be implemented without specific guidance on scope of service, disclosure of medical criteria, and non-quantitative treatment limitations increases the likelihood that plans will continue to offer only very limited behavioral health benefits while offering an array of medical benefits and claim compliance with MHPAEA; this was clearly not Congressional intent.

In September 2009 and May 2010, 73 House Members and Chairmen and Subcommittee Chairmen of the three committees of jurisdiction encouraged you to issue regulations clarifying Congressional intent on scope of service and medical management parity, among other issues. We remain committed to ensuring the implementation of the MHPAEA reflects the Congressional intent behind the law. We have a particular interest in the following areas:

Scope of Services: Although there are differing interpretations of whether the Interim Final Regulations confer a scope of services, the preamble states that no scope of services is conferred and solicits additional comments on this issue. We continue to believe that without clear guidance on this issue, we will continue to see plans deleting all intermediate levels of behavioral health care, as well as other essential treatment and diagnostic services, while offering a full continuum of treatment levels for medical and surgical conditions.

There are many examples in the marketplace that document the current practices in place by insurers. For instance, plans are excluding residential treatment for substance use and eating disorders and applying pre-authorization requirements to mental health/addiction benefits that are not applied to medical benefits covered by the plan. We believe these examples illustrate violations of the quantitative and non-quantitative treatment limitation rules as applied to general plan design, and violate scope of services and continuum of care parity as inherently addressed in the statute and defined in the regulations.

Let us be unequivocal – while the MHPAEA was never intended to be a mandate for coverage of specific mental health conditions or addictive disorders – once a plan has chosen to provide coverage for a specific mental health or substance use disorder, the basic framework of the law is to equalize behavioral and medical benefits and end the discrimination that has for so long limited access to behavioral benefits, as compared to the medical benefits covered by plans. Plan participant and beneficiary access to a similar scope of services and continuum of care on the behavioral health side as is provided on the medical side was clearly an integral part of the MHPAEA.

Some contend that clarifying a scope of services requirement in the regulations may somehow establish a mandate for coverage of mental health conditions or substance use disorders. While the MHPAEA does not mandate that a plan provide a mental health or substance use disorder benefit, once the plan does so, the primary purpose of the MHPAEA is to ensure that such behavioral health benefits are on par with the medical/surgical benefits provided under the plan. Despite claims that equalizing the continuum of medical and behavioral health benefits will drive up costs.

Need for Disclosure of Medical Criteria: It is necessary to assess whether medical management or other forms of cost containment techniques are applied to behavioral health conditions in a manner that is comparable to and no more stringent than the medical management applied to other medical conditions. To that end, plans should be required to disclose the medical management criteria and policies used to manage medical and surgical conditions, as well as the medical criteria used to manage behavioral health conditions. Without having access to both sets of criteria, there is no ability to make the necessary comparison of the behavioral health and the medical management criteria used. We fail to see how the statute or regulations can be enforced without this information.

While we thank the Department of Labor for releasing a Frequently asked Questions (FAQ) on its website advising that plans must provide medical necessity criteria for both medical/surgical and mental health/addiction benefits, this guidance is non-binding and, to date, plans are still not complying.

Need for Specific Guidance on Enforcement of Non-Quantitative Treatment Limits: Final regulatory or sub-regulatory guidance is also needed to address how non-quantitative treatment limitations, such as discriminatory pre-authorization requirements, geographic limitations and other forms of discriminatory utilization review will be enforced. The statute and the Interim Final Regulations are very specific that treatment limitations include both quantitative and non-quantitative treatment limits. Final guidance on non-quantitative treatment limits should also clarify that inappropriate scope of services limitations are a form of limitation on treatment services. Without additional guidance on how agencies will enforce non-quantitative treatment limits, consumers and providers have no ability to know whether they will receive services or reimbursement for essential behavioral health care. To provide more certainty, the Departments of Labor and Health and Human Services should provide sub-regulatory guidance on non-quantitative treatment limitations with specific examples and an enforcement timetable so that providers and consumers will have some ability to plan for the delivery of their care in the immediate future.

We hope this helps to clarify the Congressional intent on these three important issues. We look forward to working with you to ensure that clarifying guidance is issued so all Americans can fully access the benefits promised to them under the law.

Sincerely,

Paul D. Tonko

Member of Congress

John Sullivan

Member of Congress

Tammy Baldwin
Member of Congress

Bruce Braley

Member of Congress

Mary Bono Mack

Mary Bond Mack Member of Congress Lois Capps

Member of Congress

Andre Carson

Member of Congress

David Cicilline

Member of Congress

U. livili

John Convers

Member of Congress

Joe Courtney

Member of Congress

Danny Davis Member of Congress	Susan Davis Member of Congress
Diana DeGette Member of Congress	Rosa DeLauro Member of Congress
Keith Ellison Member of Congress	Bob Filner Member of Congress
Barney Frank Member of Congress	Raul Grijalva Member of Congress
Mazie Hirono Member of Congress	Rush Holt Member of Congress
Dennis Kucinich Member of Congress	James Langevin Member of Congress

Carolyn Maloney Member of Congress	Betty McCollum Member of Congress
James McGovern Member of Congress	George Miller Member of Congress
Gwen Moore Member of Congress	James Moran Member of Congress
Jerrold Nadler Member of Congress	Grace Napolitano Member of Congress
Bill Pascrell Bill Pascrell Member of Congress	Jared Polis Member of Congress
Milalaida	

Mike Quigley

Member of Congress

Linda Sanchez

Member of Congress

anice Schakowsky Member of Congress

Louise McIntosh Slaughter Member of Congress

Chris Van Hollen Member of Congress

Timothy Walz
Member of Congress

David Wu

Member of Congress

John Yarmuth

Member of Congress

Scope of Services

The Congressional intent of this legislation was that patients have access to the full scope of mental health and substance use disorder benefits medically-appropriate for their condition. The basic framework of the law is to equalize mental health and substance use disorder benefits and medical benefits, and end the discrimination that has for so long limited access to mental health and substance use disorder benefits as compared to the medical benefits covered by plans. Plan participant and beneficiary access to a similar scope of services and continuum of care on the mental health and substance use disorder side, including both in-network and out-of-network services, as is provided on the medical side, was part of the very impetus of MHPAEA.

Need for Disclosure of Medical Criteria

To assess whether any medical management is properly applied to mental health and substance use disorder conditions in a manner that is comparable to and no more stringent than the medical management applied to other medical conditions, plans must be required to disclose the medical management criteria and policies used to manage medical and surgical conditions, as well as the medical criteria used to manage mental health and substance use disorder conditions. Without having access to both sets of criteria, there is no ability to make the necessary comparison of the medical management criteria used. Proper enforcement depends on this information.

Need for Specific Guidance on Enforcement of Non-Quantitative Treatment Limits

Final regulations or sub-regulatory guidance is also needed to address how non-quantitative treatment limitations such as discriminatory pre-authorization requirements, geographic limitations, and other forms of discriminatory medical management will be enforced. The statute and the Interim Final Regulations are very specific that treatment limitations include both quantitative and non-quantitative treatment limits. Final guidance on non-quantitative treatment limits should also clarify that inappropriate scope of services limitations are a form of limitation on treatment services. Without additional guidance on how agencies will enforce non-quantitative treatment limits, consumers and providers have no ability to know whether they will receive services or reimbursement for essential behavioral health care.

We look forward to continuing to work with you on the implementation and enforcement of these important protections for the tens of millions of Americans affected by mental health and substance abuse conditions.

Sincerely,

George Miller

Chairman

Committee on Education and Labor

Robert E. Andrews

Subcommittee on Health, Employment,

Labor and Pensions, Education and

Labor Committee

Member of Congress

United States Senate WASHINGTON, DC 20510

May 12, 2011

The Honorable Hilda Solis Secretary U.S. Department of Labor 200 Constitution Ave, NW Washington, DC 20210 The Honorable Kathleen Sebelius Secretary U.S. Department of Health and Human Services 200 Independence Ave, SW Washington, DC 20201

The Honorable Timothy Geithner Secretary U.S. Department of the Treasury 1500 Pennsylvania Ave, NW Washington, DC 20220

Dear Secretaries Solis, Sebelius, and Geithner:

We are writing to follow up on our previous correspondence requesting additional guidance regarding the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA). As the Interim Final Regulations went into effect for plan years beginning on or after July 1, 2010, we ask that this guidance be released before plans make decisions on 2012 benefit packages in May or June of this year. We are concerned that allowing the law to be implemented without specific guidance on scope of service, disclosure of medical criteria, and non-quantitative treatment limitations is resulting in insurance plans offering only limited behavioral health benefits in 2011. While MHPAEA was not intended to be a mandate for coverage of mental health or substance abuse services, once a plan has chosen to provide coverage for a specific mental health or substance use disorder, the law requires that behavioral and medical benefits be equivalent.

With regard to scope of services, there are differing interpretations of the Interim Final Regulations. Its preamble states that no scope of services is conferred and solicits additional comments on this issue. The regulations themselves confer a scope of service by requiring that plans cover a minimum of six types of services. However, without clear guidance and clarification, health insurance plans are limiting the degree to which intermediate levels of behavioral health services are accessed.

We also believe that plans should be required to disclose the criteria and policies they use to manage medical and surgical conditions and behavioral health conditions. This information is necessary to assess whether medical management or other forms of cost containment techniques are applied to behavioral health conditions in a manner that is comparable to and not more stringent than the medical management applied to other medical conditions. Without access to both sets of criteria, regulators are unable to make the necessary comparison for effective enforcement of the law. While we thank the Department of Labor for releasing a 'Frequently Asked Questions' document on its website advising that plans must provide medical necessity criteria for both medical/surgical and mental health/addiction benefits. However, this guidance is non-binding and, to date, plans are still not complying.

Final regulatory or sub-regulatory guidance is also needed to enable proper enforcement of the law regarding non-quantitative treatment limitations, such as discriminatory preauthorization requirements and geographic limitations. The statute and the Interim Final Regulations specify that treatment limitations include both quantitative and non-quantitative treatment limits. Without additional guidance on how agencies will enforce non-quantitative treatment limits, consumers and providers cannot know whether they will receive services or reimbursement for essential behavioral health care. We request that Departments of Labor and Health and Human Services provide guidance on non-quantitative treatment limitations with specific examples and the timetable for enforcement so that providers and consumers may plan for appropriate care.

We hope this clarifies congressional intent on these three important issues. We look forward to working with you to ensure that clarifying guidance is issued as soon as possible.

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Al Franken	Tom Harkin
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Patrick Leahy	John Kerry
Ron Wyden Ron Wyden	Mark Begich
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Sherrod Brown	Carl Levin
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Buh Box	MIL
Barbara Boxer	Jeff Bingaman
An Auli	Nelle Leterow
Richard Durbin	Debbie Stabenow

Vamil K. Fraka	Oach Read
Daniel Akaka	Jack Reed
Mouk R. Lankyber	Rafut Meneny.
Frank Lautenberg	Robert Menendez
BufSander	Jon Odare
Bernard Sanders	Tom Udall
Patty Murray	Jeff Merkley

Congress of the United States Washington, DC 20515

October 18, 2012

The Honorable Hilda Solis Secretary U.S. Department of Labor 200 Constitution Ave, NW Washington, DC 20210

The Honorable Kathleen Sebelius Secretary U.S. Department of Health and Human Services 200 Independence Ave, SW Washington, DC 20201

The Honorable Timothy Geithner Secretary U.S. Department of the Treasury 1500 Pennsylvania Ave, NW Washington, DC 20220

Dear Secretaries Solis, Sebelius and Geithner:

We are writing to inquire regarding the status of implementation and enforcement of the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA).

We thank the Departments for releasing an Interim Final Rule in February of 2010 and subsequent sub-regulatory guidance. Unfortunately, because patients are still having trouble accessing mental health and addiction benefits, we urge the Departments to issue a final rule clarifying grey areas in the regulation and update Congress on the status of MHPAEA enforcement actions taken to date.

As healthcare costs rise, it is imperative we spend wisely. For example, illicit drug use costs America \$193 billion annually - over \$11 billion in health costs, \$61 billion in crime-related costs, and \$120 billion in lost workplace productivity. This far exceeds the annual direct and indirect costs of diabetes. In contrast, multiple studies have found \$1 invested in addiction treatment saves \$7, with the largest savings attributed to reduced crime and increased employer earnings. Only with full implementation and enforcement of MHPAEA will these savings be realized.

The Interim Final Rules released in February 2010 requested comments on areas such as "scope of service," thereby leaving these issues unresolved. Specifically, patients and providers consistently report that plans continue to: exclude non-hospital based mental health and addiction facilities from coverage; eliminate vital types and levels of mental health and addiction treatments while covering the full continuum of treatments for medical conditions; manage mental health and addiction benefits more stringently than the medical benefits covered by the plan, and refuse to disclose the criteria used to make denials on comparable medical benefits. At its core, MHPAEA is about achieving equity between behavioral and other medical benefits. Without requiring plans to disclose criteria used to make medical determinations, there is no

basis for compliance testing. We applaud the Administration for sub-regulatory guidance in this area and hope you will actively enforce it.

The Government Accountability Office (GAO) released a report on May 31, 2012, which found that plans have increased the number of exclusions for mental health and addiction treatments since MHPAEA was enacted. For example, in plan years 2010 and 2011, 15% of plans surveyed excluded residential mental health and addiction treatment. In comparison, in 2008, 11% of plans surveyed excluded residential treatment. The purpose of this law was to increase access to addiction and mental health treatments, not to reduce access.

We ask the Departments to provide written responses to the following issues:

- When do the Departments anticipate releasing final rules clarifying these outstanding regulatory issues?
- We also ask that the Departments provide an update on enforcement actions undertaken to date. While we understand voluntary compliance programs are often confidential, we ask that the Departments provide a report to us on enforcement actions the Departments have taken without disclosing specific plan names.
- Additionally, we understand guidance is forthcoming on the application of MHPAEA to Medicaid managed care plans. Can the Departments please advise regarding when such guidance may be released?

Again, we thank the Departments for steps taken to date to implement and enforce MHPAEA and we look forward to working with you to ensure that all Americans can fully access the benefits promised to them under the law.

Sincerely,

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