

May 3, 2010

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

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

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

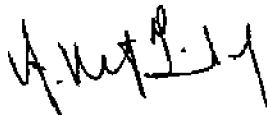
**Re: Interim Final Rules under the Paul Wellstone and Pete Domenici Mental Health Parity
and Addiction Equity Act of 2008**

Dear Secretary Solis, Secretary Sebelius, and Commissioner Shulman:

On behalf of the American Bar Association (ABA) and its more than 400,000 members, I am pleased to submit our enclosed Comments in response to the Departments' Interim Final Rules request for additional comments (Interim Final Rules, 75 Fed. Reg. 5410) published on February 2, 2010, and in response to the Departments' request for additional comments as presented during the Departments' January 29, 2010 constituency briefing on the Interim Final Rules.

Thank you for considering our view on this important subject.

Sincerely,



H. Robert Fiebach
Chair, ABA Standing Committee on Substance Abuse

/Enclosures

cc: Thomas Susman, Director, ABA Governmental Affairs Office
Lillian Gaskin, Senior Legislative Counsel, ABA Governmental Affairs Office
Jared Hess, Legislative Assistant, ABA Governmental Affairs Office

ABA Standing Committee on Substance Abuse Response to Departments' Interim Final Rules Request for Additional Comments re: MHPAEA Implementation

In the Interim Final Rules issued by the Department of the Treasury, Department of Labor and Department of Health and Human Services (the Departments) on January 29, 2010 and published in the Federal Register on February 2, 2010 (the regulations), the Departments invited comments 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. 75 Fed. Reg. 5417. The Departments also invited comments on additional examples that may be helpful to illustrate the application of the nonquantitative treatment limitation rule to other features of medical management or general plan design. 75 Fed. Reg. 5416.

In addition, during the Departments' January 29, 2010 telephonic constituency group briefing on the regulations, the Departments requested additional comments regarding the issue of adequacy of provider networks. The issues of state law preemption and uncertainty over the applicability of the regulations to Medicaid managed care organizations were also presented, and are commented on herein.

Comment 1: Continuum of Care/Scope of Services

A. Level of Care Exclusions under the MH/SUD Benefit are Impermissible under MHPAEA and the Regulations.

1. Statutory and Regulatory Background

ERISA §712(a) [29 USC 1185a] (3)(A)(ii) and (B)(ii) and (iii) were added to require that in the case of a group health plan (or health insurance coverage offered in connection with such a plan) that provides both medical and surgical benefits and mental health or substance use disorder benefits, the treatment limitations applicable to mental health or substance use disorder benefits *are no more restrictive than* the predominant treatment limitations applied to substantially all medical and surgical benefits covered by the plan, and that there are *no separate treatment limitations that are applicable only with respect to mental health or substance use disorder benefits*. A treatment limitation is considered to be predominant if it is the most common or frequent of such type of limit. "The term 'treatment limitation' includes limits on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment." (Emphasis supplied.)

The preamble to the Interim Final Rules (hereinafter referred to as "the regulations") provides: "These regulations specify, in paragraph (c)(2)(ii), six classifications of benefits: inpatient, in-network; inpatient, out-of-network; outpatient in-network; outpatient out-of-network; emergency care; and prescription drugs.... These regulations provide that the parity requirements for financial requirements and treatment limitations are generally applied on a classification-by-classification basis and these are the only classifications used for purposes of satisfying the parity requirements of the Act." 75 Fed. Reg. 5413. The preamble also states that: "The Departments recognize that not all

treatments or treatment settings for mental health conditions or substance use disorders correspond to those for medical/surgical benefits. 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.” 75 Fed. Reg. 5416.

2. (a) Recommendation

The Departments’ implementing regulations should specify that group health plans are required to cover under the MH/SUD benefit, all levels and types of medical/surgical care covered for substantially all medical/surgical benefits (i.e., continuum of care) that are largely analogous under the MH/SUD benefit. Thus, exclusions of levels of care or services along the continuum of care, such as inpatient rehabilitation and/or residential treatment and/or partial hospitalization and/or intensive outpatient services, under the MH/SUD benefit, where there are no such exclusions of analogous levels of care along the continuum of care under the medical/surgical benefit, should constitute a violation of MHPAEA’s “no more restrictive” standard and “separate treatment limitation” prohibition. Group health plans should be required to cover a scope of services and continuum of care under the MH/SUD benefit that is largely comparable to the scope of services and continuum of care provided for substantially all of the medical/surgical benefits under that group plan.

Plans should *not* be permitted to either: 1) create a new classification of benefits in order for those benefits to fall outside the ambit of MHPAEA; or 2) exclude clinically recognized licensed levels of care from the MH/SUD benefit based on the plan’s determination that such level of care does not fall within one of the six classifications; or 3) not cover a level of care under the MH/SUD benefit using the justification that there is no directly corresponding medical/surgical benefit. If a plan is offering only one or two types of service or levels of care in each MH/SUD classification, while offering many within each medical/surgical classification, the plan is applying a treatment limitation to the MH/SUD benefit that is more restrictive than the predominant treatment limitation applied to substantially all medical/surgical benefits in the same classification. The plan is also applying separate treatment limitations applicable only to the MH/SUD benefit. In these cases, the plan has violated the requirements of both MHPAEA (also referred to herein as “the Act”) and the regulations.

3. (a) Rationale

As the Departments have recognized, not all treatment services and settings for MH/SUD benefits will correspond to those for medical/surgical benefits. Mental health and substance use disorders are often complex and chronic, featuring medical, psychological, behavioral and social dimensions, rather than strictly medical. The Departments have also recognized that the plain language of MHPAEA prohibits treatment limitations under MH/SUD benefits that are more restrictive than the predominant treatment limitations applied to substantially all medical/surgical benefits. In addition, the regulations require that when a plan “provides [MH/SUD] benefits in any classification of benefits” described in the rule, MH/SUD benefits “must be provided in every classification in

which medical/surgical benefits are provided.” 75 Fed. Reg. 5413. While this statement clearly requires parity *across* classifications in the scope of services that are offered for particular conditions, the Act and the regulations taken as a whole, clearly require parity *within* classifications as well.

There have been historical group health plan exclusions of certain levels of care under the MH/SUD benefit design. Since the effective date of MHPAEA, many group health plans continue to exclude from coverage entire levels of care that are clinically recognized and state licensed, while covering what is viewed by many state licensing boards as analogous clinically recognized levels of care under the medical/surgical benefit. Because both the Act and the regulations make clear that the six classifications of benefits are the *only* classifications to be used, and also make clear that MHPAEA prohibits treatment limitations under the MH/SUD benefit that are more restrictive than under the medical/surgical benefit, it necessarily follows that ***all MH/SUD and medical/surgical services and levels of care must fit into one of these six classifications.*** Moving certain services or levels of care outside the six classes to avoid the requirements of parity would be a clear violation of Congressional intent.

To illustrate the human consequences of how this discriminatory plan design is affecting today’s behavioral health marketplace, a member obtaining SUD treatment may typically be admitted to detoxification level of care, followed by intensive inpatient rehabilitation and monitoring, followed by residential treatment, followed by day treatment/partial hospitalization, followed by intensive outpatient treatment, followed by outpatient counseling or group therapy. Many plans restrict access to MH/SUD care by ***excluding*** one or more of the rehabilitation and/or residential and/or partial hospitalization and/or intensive outpatient levels of care. For example, an insured patient admitted into detoxification may receive authorization for 4 days of treatment at that level of care, followed by authorization for 6 days of intensive inpatient rehabilitation. Thereafter, the patient’s residential treatment, followed by partial hospitalization/day treatment would be denied as “intermediate” care not covered under MH/SUD benefit. The patient is thereby relegated to a strictly outpatient setting for the remainder of his/her treatment, regardless of medical necessity. ***In contrast,*** a member under the same plan may obtain medical/surgical services that span the full continuum from admission to inpatient surgery, followed by intensive care in a monitoring unit, followed by continued hospitalization in a general patient room, followed by rehabilitative therapy in a skilled nursing facility, followed by outpatient rehabilitation and therapy, without facing such treatment limitations.

Absent equitable coverage across the full continuum of care, albeit with appropriate utilization management protocols, parity is not being realized. This is clearly *not* what Congress intended when it sought to remedy the discrimination that has existed under many group health plans with respect to MH/SUD benefits. The Act clearly provides that there be “no separate treatment limitations that are applicable only with respect to mental health or substance use disorder benefits.” The statute also defines the term ‘treatment limitation’ to include “other similar limits on the scope or duration of treatment.” The exclusion of licensed levels of care along the continuum of care on the MH/SUD side, where analogous levels of care are covered on the medical/surgical side, constitutes a

more restrictive limit on the scope and duration of treatment and a separate treatment limitation that violates the parity requirements of the Act.

2. (b) Recommendation

The Department's implementing regulations should clarify that, in cases where there is arguably no analogue between a MH/SUD treatment service or level of care and treatment services or levels for other covered medical/surgical conditions, a group health plan may not refuse to cover a MH/SUD service or level of care because there is no medical/surgical analogue, unless the plan also refuses to cover a medical/surgical service or level of care because there is no MH/SUD analogue. Otherwise, the exclusion of a level of care or treatment service under the MH/SUD benefit would be deemed a violation of MHPAEA's "no more restrictive" standard and "separate treatment limitation" prohibition.

3. (b) Rationale

Group health plans may justify the exclusion of levels of care from the MH/SUD benefit by stating that there is no corresponding medical/surgical level of care, and therefore such treatment services are not required to be covered under MHPAEA. A plan that refuses to cover a MH/SUD service or level of care because there is no medical/surgical analogue, on its face limits the scope or duration of benefits for treatment under a plan. Thus, such a decision is a nonquantitative treatment limitation (NQTL) subject to the "comparable" and "no more stringent" standards set forth in the regulations. As stated in the regulations:

"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.

The regulations require NQTLs to be "comparable." A treatment limitation 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. If group health plans do not apply this treatment limitation comparably, the plan would be in violation of the regulations. Moreover, the treatment limitations section of MHPAEA 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 parity requirements of the Act because it imposes a separate treatment limitation "applicable only with respect to" MH/SUD benefits.

B. Treatment Setting/Facility Type Exclusions Constitute Impermissible Limitation on Scope of Services and Impermissible NQTL

1. Statutory and Regulatory Background

ERISA §712(a) [29 USC 1185a] (3)(A)(ii) and (B)(ii) and (iii) were added to require that in the case of a group health plan (or health insurance coverage offered in connection with such a plan) that provides both medical and surgical benefits and mental health or substance use disorder benefits, the treatment limitations applicable to mental health or substance use disorder benefits are no more restrictive than the predominant treatment limitations applied to substantially all medical and surgical benefits covered by the plan, and that there are *no separate treatment limitations that are applicable only with respect to mental health or substance use disorder benefits*. A treatment limitation is considered to be predominant if it is the most common or frequent of such type of limit. “The term ‘treatment limitation’ includes limits on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment.” (Emphasis supplied.)

The preamble to the regulations states that: “The Departments recognize that not all treatments or treatment settings for mental health conditions or substance use disorders correspond to those for medical/surgical benefits. 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.” 75 Fed. Reg. 5416. (Emphasis supplied).

2. Recommendation

The Departments’ implementing regulations should require that group health plans recognize and include as covered healthcare providers under the MH/SUD benefit, appropriately state licensed non-hospital facilities, such as freestanding psychiatric and substance abuse treatment facilities and freestanding residential treatment centers, which are uniquely appropriate to provide treatment services under the MH/SUD benefit.

3. Rationale

With the evolution of MH/SUD treatment, standard clinical treatment modalities and treatment settings have changed dramatically from early days. As noted in a 2009 Health Affairs issue, the President of CIGNA Health Solutions stated that a major challenge for health plans in implementing mental health parity and addiction equity is the elimination of “any vestiges of structural differences between coverage of MH/SUD treatment benefits and benefits for general medical care.”¹ Decades ago, those suffering from MH/SUD’s were placed in psychiatric wards of hospitals, often in lock-down, or in detoxification beds in hospitals. Much has changed regarding the medical community’s clinical understanding of such disorders, and along with knowledge, treatment settings

¹ Keith Dixon, “Implementing Mental Health Parity: The Challenge For Health Plans”, Health Affairs, 28(3):663(May-Jun 2009).

and programs have changed as well. As of 2007, in the United States more than 13,000 substance abuse treatment facilities provide medication, counseling, behavioral therapy, case management, and other types of services to persons with substance use disorders.² Of these over 13,000 facilities, merely 1,000 were hospital-based treatment providers.³

Each state has its own substance abuse licensing agency, with a codified regulatory licensure scheme to ensure clinical quality standards of treatment facilities and the levels of care and services they are licensed to provide.⁴ In addition, just as with hospitals on the medical/surgical side, MH/SUD freestanding treatment facilities may also be Joint Commission accredited to demonstrate compliance with national accreditation standards. Such state licensed freestanding treatment facilities, rather than general hospitals, are the far more typical and *available* inpatient treatment setting for the provision of MH/SUD treatment services. These freestanding treatment facilities are specifically licensed to provide the appropriate levels of care along the continuum of care for MH/SUD treatment, including medical detoxification, intensive inpatient rehabilitation, residential treatment, partial hospitalization and intensive outpatient care. Thus, *freestanding substance abuse treatment facilities that are properly licensed for each level of care they provide are the equivalent of properly licensed hospitals on the medical/surgical side.*

The 2010 Government Employees Health Association, Inc. (GEHA) Benefit Plan under the Federal Employees Health Benefits (FEHB) Program is highly instructive on this point. In compliance with MHPAEA, the 2010 GEHA FEHB Plan made changes to its benefit plan design, specifically providing that: "Admissions to out-of-network Residential Treatment Centers are now covered subject to medical necessity review."⁵ This is consistent with the added provision that: "Licensed Professional Counselors... are now covered providers when services are performed within the scope of their license."⁶ With respect to more intensive inpatient levels of care, the 2010 GEHA FEHB plan also defines Hospital to *include* duly licensed freestanding substance abuse facilities that meet clinical staffing and clinical services requisites.⁷

Historical inequities in benefit design include, most markedly, the exclusion of freestanding adult and adolescent substance abuse treatment facilities, freestanding residential treatment facilities and freestanding adolescent psychiatric treatment facilities

² SAMHSA 2007 National Survey of Substance Abuse Treatment Services (N-SSATS), available at: <http://www.oas.samhsa.gov/nssats2k7/NSSATS2k7Ii.htm>. See also, National Institute on Drug Abuse, Principles of Drug Addiction Treatment: A Research Based Guide, Second Edition (2009) available at: <http://www.drugabuse.gov/PODAT/Treatment/IIS.html>.

³ Table 2.3 of SAMHSA 2007 National Survey of Substance Abuse Treatment Services (N-SSATS), available at: <http://www.oas.samhsa.gov/nssats2k7/NSSATS2k7Tb12.3.htm>.

⁴ See SAMHSA's Directory of State Substance Abuse Agencies, available at: <http://findtreatment.samhsa.gov/ufds/abusedirectors>.

⁵ 2010 Government Employees Health Association, Inc. FEHB Plan, Section 2, p. 9.

⁶ *Id.*

⁷ *Id.* at Section 3, p. 12, definition of "Hospital" includes: "(3) An institution which is operated pursuant to law, under the supervision of a staff of doctors and with 24 hours a day nursing service and which provides services on the premises for the diagnosis, treatment, and care of persons with mental/substance abuse disorders and has for each patient a written treatment plan which must include diagnostic assessment of the patient and a description of the treatment to be rendered and provides for follow-up assessments by or under the direction of the supervising doctor."

from coverage under a plan's MH/SUD benefit.⁸ Many plans continue to restrict MH/SUD benefits to services rendered only by hospitals or facilities affiliated with hospitals. As a result, many group health plans do not include appropriately licensed and accredited freestanding treatment facilities in their definition of "hospital" or "qualified treatment facility." Other plans expressly exclude freestanding psychiatric and substance abuse treatment facilities and/or freestanding residential facilities from the scope of coverage, notwithstanding appropriate state licensure and/or national accreditation. For example, one of the largest national employer group plans containing both inpatient and outpatient medical/surgical and MH/SUD benefits, effective January 1, 2010 provides: "Treatment received at a freestanding residential substance abuse treatment center or at a freestanding psychiatric residential treatment facility is not a covered benefit." This inequity in health plan benefit design deprives participants and beneficiaries of the ability to access covered treatment from the very healthcare providers that specialize in and are specifically licensed to render those services that member requires.

Not only does the exclusion of properly licensed facilities from the scope of coverage under the MH/SUD benefit constitute a treatment limitation applicable to MH/SUD benefits that is more restrictive than the predominant treatment limitations applied to substantially all medical/surgical benefits covered by the plan, as well as a separate treatment limitation applicable only with respect to MH/SUD benefits, it also constitutes a preauthorization determination based on the *setting* in which the care is provided, rather than whether or not the service is medically necessary. Parity cannot be achieved if the implementing regulations do not prohibit this type of treatment limitation on the scope of services. Without closing this significant loophole in plan benefit design, plan participants are left with a tremendous obstacle in accessing their MH/SUD benefits.

Comment 2: Nonquantitative Treatment Limitations (NQL's)

A. The Need for Consistent Processes, Strategies and Evidentiary Standards in Medical Management

1. Statutory and Regulatory Background

ERISA §712(a) [29 USC 1185a] (3)(A)(ii) and (B)(ii) and (iii) were added to require that in the case of a group health plan (or health insurance coverage offered in connection with such a plan) that provides both medical and surgical benefits and mental health or substance use disorder benefits, the treatment limitations applicable to mental health or substance use disorder benefits are no more restrictive than the predominant treatment limitations applied to substantially all medical and surgical benefits covered by the plan, and that there are *no separate treatment limitations that are applicable only with respect to mental health or substance use disorder benefits*. A treatment limitation is considered to be predominant if it is the most common or frequent of such type of limit. "The term 'treatment limitation' includes limits on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment." (Emphasis supplied.)

⁸ SAMHSA's National Expenditures for Mental Health Services and Substance Abuse Treatment published in 2007 shed light on the lack of access to these treatment settings.

The regulations state that: “A group health plan may not impose a nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are 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, except to the extent that recognized clinically appropriate standards of care may permit a difference.” 75 Fed. Reg. 5436. The regulations illustrate that: “*Nonquantitative treatment limitations include – (A) Medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness...*” 75 Fed. Reg. 5436. (Emphasis supplied). The regulations further state 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.” 75 Fed. Reg. 5416.

2. Recommendation

The Departments’ implementing regulations should require group health plans to use consistent processes, strategies and evidentiary standards by which medical necessity criteria are to be utilized and applied for both medical/surgical treatment services and MH/SUD services alike.

Agencies within the Department of Health and Human Services, private health plans, the American Society of Addiction Medicine, and the Substance Abuse and Mental Health Services Administration (SAMSHA) funded and participated in the development of an evidence-based managed care approach to providing the appropriate level of services across the continuum of care. In the SUD area, this continuum of care is represented by the Patient Placement Criteria of the American Society of Addiction Medicine (“ASAM”).⁹ These criteria, initially published in 1991, provide a nationally recognized standard, using common language, for appropriate placement of individuals within the continuum of care for treatment of SUDs. Such a nationally recognized standard utilized in the implementation of parity, would result in far greater consistency in the processes, strategies and evidentiary standards used in applying medical management standards that limit or exclude benefits based on medical necessity or medical appropriateness.

3. Rationale

Medical necessity determinations are a critical aspect of establishing equity and parity between medical/surgical and MH/SUD benefits. Under the MH/SUD benefit, determinations are made in the context of specific levels of care along the continuum of care. One of the most difficult and frustrating aspects of MH/SUD medical necessity

⁹ American Society of Addiction Medicine Patient Placement Criteria for the Treatment of Substance-Related Disorders (2nd edition) ASAM PPC-2 (1996), ASAM PPC-2R (2001).

determinations is the fact that the definitions of terms and the various dimensions that are considered as part of a determination vary widely across health plans and employer groups. A critical issue for the implementing regulations to provide guidance on is the need for plans to have an equitable and consistent process as to the medical criteria used under the medical/surgical and MH/SUD benefit alike.

As MH/SUD providers continue to be faced with a multitude of widely varied medical necessity criteria both within and among plans, the opportunity for the Departments to provide guidance as to consistency in the context of MHPAEA implementation is both highly appropriate and timely. Of note are the observations made in the SAMHSA sponsored Special Report on Medical Necessity in Private Health Plans: Implications for Behavioral Health Care (“SAMHSA Special Report”).¹⁰ The Special Report provides an exhaustive review of research findings and case law as well as state and federal laws pertaining to medical necessity reviews and determinations. In the Executive Summary, the authors note that: “Rather than turning simply on whether a proposed treatment meets professional medical standards, the prevailing definition of medical necessity is broadly framed, multidimensional, and controlled by the insurer, not the treating professional.”¹¹

The SAMHSA Special Report suggests that a major challenge in making medical necessity determinations for MH/SUD services, compared to medical/surgical services, is an underlying debate among health plans and review organizations as to whether “medical necessity” is the appropriate term, or, whether “clinical appropriateness” is a more accurate term for evaluating services under the MH/SUD benefit. This is because medical necessity reviews for MH/SUD benefits focus less on the clinical services to be rendered and more on an assessment of “what level of services in which settings are most clinically appropriate for a given patient in light of his or her clinical social needs.”¹² Thus, medical necessity determinations of MH/SUD services often focus on the “form and manner” of treatment, rather than on whether treatment services will be provided.

The SAMSHA Special Report also notes that in “behavioral health, unlike general medicine, most inpatient admissions are unplanned and occur because a person (or family member or provider on behalf of that person) seeks emergency crisis admission.”¹³ Although these types of services may be approved initially, disputes about the medical necessity of subsequent services are common and are related to the review criteria which are considered the “guideposts” used by utilization review staff. Nationally recognized criteria, such as the ASAM Patient Placement Criteria, would provide operational consistency in medical management processes, strategies and evidentiary standards that limit or exclude benefits based on medical appropriateness.

¹⁰ Rosenbaum, S., Kamore, B., Manery, D.R., Walitt, B. Medical Necessity in Private Health Plans: Implications for Behavioral Health Care, Substance Abuse and Mental Health Services Administration (SAMHSA) DHHS Pub. No. (SMA) 03-3790 (Nov. 2003).

¹¹ *Id.*

¹² *Id.* at 14.

¹³ *Id.* at 15.

B. The Need For Clear Definition of “Recognized” Clinically Appropriate Standard of Care

1. Regulatory Background

The regulations state that: “A group health plan may not impose a nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are 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, *except to the extent that recognized clinically appropriate standards of care may permit a difference.*” 75 Fed. Reg. 5436. (Emphasis supplied).

2. Recommendation

The Departments’ implementing regulations should provide a clear definition of “recognized” in the analysis of whether a NQTL is permitted because “recognized clinically appropriate standards of care may permit a difference.” In so doing, CMS should adopt recognized best practices in defining “recognized clinically appropriate standards of care.”

3. Rationale

The regulations provide useful guidance in defining the term “recognized” clinically appropriate standards of care, and do indicate that the standards must meet a basic threshold. Example 3 of Section (c)(4) of the regulations discusses a plan that uses evidentiary standards in determining whether a treatment is medically appropriate. 75 Fed. Reg. 5436. The standards are developed based on “recommendations made by panels of experts with appropriate training and experience in the fields of medicine involved.” *Id.* The plan in this instance complies with parity, in part because “[t]he processes for developing the evidentiary standards” are comparable and applied no more stringently between medical/surgical and MH/SUD benefits. *Id.* In addition, other parts of the regulation provide a useful guide for how to determine which standards are “recognized.” The regulations state that plan terms defining benefits for MH/SUD conditions must be consistent with “generally recognized independent standards of current medical practice.” 75 Fed. Reg. 5412. In defining these terms, the regulations state that a plan “may follow the most current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), the most current version of the International Classification of Diseases (ICD), or a State guideline.” *Id.* Thus, the regulations demonstrate that there are a number of recognized sources for defining which standards are “recognized.”

CMS also provides useful guidance. CMS regularly relies on independent expertise when making its coverage determinations. For example, there is clear precedent for CMS to take a rigorous view of the evidentiary basis for Medicare reimbursement of drugs,

devices and procedures. In the National Coverage Determination (NCD) process, CMS evaluates all pertinent data, including the scientific data that requesters submit, peer-reviewed medical, technical and scientific literature, and recommendations from expert panels. The Medicare Coverage Advisory Committee (MCAC) 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.¹⁴

It is foreseeable that, absent the establishment of adequate requirements for when a standard is recognized, the parity requirements may be readily evaded. Attempts to circumvent the parity requirements will simply involve finding a “recognized clinically appropriate” standard of care. For example, a plan could claim the exception simply because its own employees or hired consultants deem a standard “recognized” with no independent verification. This potential loophole would weaken parity protections, and is not what Congress intended. Congress intended to ensure meaningful parity between MH/SUD and medical/surgical benefits and was clear that treatment limitations should be “no more restrictive” in MH/SUD benefits than in medical/surgical benefits. Permitting an exception to parity based on a plan’s internal review alone would surely weaken this intended protection.

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

C. NQTL’s Must Meet Both Predominant and Substantially All and the “Comparable” and “No More Stringently” Tests.

1. Statutory and Regulatory Background

ERISA §712(a) [29 USC 1185a] (3)(A)(ii) and (B)(ii) and (iii) were added to require that in the case of a group health plan (or health insurance coverage offered in connection with such a plan) that provides both medical and surgical benefits and mental health or substance use disorder benefits, the treatment limitations applicable to mental health or substance use disorder benefits are no more restrictive than the predominant treatment limitations applied to substantially all medical and surgical benefits covered by the plan, and that there are no separate treatment limitations that are applicable only with respect to

¹⁴ 68 Fed. Reg. 55440.

mental health or substance use disorder benefits. A treatment limitation is considered to be predominant if it is the most common or frequent of such type of limit. "The term 'treatment limitation' includes limits on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment."

The regulations state that: "A group health plan may not impose a nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are 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, except to the extent that recognized clinically appropriate standards of care may permit a difference." 75 Fed. Reg. 5436.

2. Recommendation

The Departments' implementing regulations should clarify that, consistent with the plain language and intent of MHPAEA, the regulations should be interpreted to apply both the "predominant" and "substantially all" standard under MHPAEA, and the "comparable" and "no more stringently" standards of the regulations to NQTLs.

3. Rationale

MHPAEA set forth that 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. This phrase contains three separate 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. 75 Fed. Reg. 5412-13, 5419, 5440, 5446. MHPAEA applies the three-part test to *all* treatment limitations, which "... includes limits on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment." The use of the word "includes" means that the listed treatment limitations are examples, not an exhaustive list of all possible treatment limitations subject to parity. Thus, the regulations' inclusion of both quantitative treatment limitations (QTLs) and NQTLs under the definition of treatment limitations is consistent with MHPAEA. 75 Fed. Reg. 5413.

The regulations also establish a methodology for implementing the predominant and substantially all standards. 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." 75 Fed. Reg. 5414. If the treatment limitation does not meet this test, it cannot be applied in the MH/SUD benefit. The next 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. *Id.* 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.

Under the regulations, the “more restrictive” test for QTLs is expressed and applied numerically (e.g., a plan covering 25 outpatient days per year under the MH/SUD benefit, and 40 outpatient days per year under the medical/surgical benefit, is applying a more restrictive QTL). Because NQTLs are not expressed numerically, the regulations apply the comparable and no more stringently standards to determine whether a NQTL is more restrictive. For example, pre-certification processes can be a limited or multifaceted process applied differentially and with very different results. The comparable and applied no more stringently test operationalizes MHPAEA’s no more restrictive standard for NQTLs by ensuring that pre-certification requirements are demonstrably comparable in operation and application. Under this interpretation of the regulations, the comparable and no more stringently standards are in addition to the predominant and substantially all standard. If the predominant and substantially all test is not applied to NQTLs, a plan could apply a NQTL to a nominal percentage of medical/surgical benefits and then apply the same NQTL to a much greater percentage of benefits on the MH/SUD side. This is inconsistent with the clear language of MHPAEA which applies the predominant and substantially all standards to *all* treatment limitations.

Comment 3: Adequacy of Provider Networks

1. Statutory Background

ERISA §712(a) [29 USC 1185a] (3)(A)(i) and (B)(i) and (ii) were added to require that in the case of a group health plan (or health insurance coverage afforded in connection with such a plan) that provides both medical and surgical benefits and mental health or substance use disorder benefits, the financial requirements applicable to mental health or substance use disorder benefits are no more restrictive than the predominant financial requirements applied to substantially all medical and surgical benefits covered by the plan, and if there are no separate cost sharing requirements that are applicable only with respect to mental health or substance use disorder benefits. A financial requirement is considered to be predominant if it is the most common or frequent of such type of requirement. The term “financial requirement” includes deductibles, co-payments, co-insurance and out of pocket expenses.

2. Recommendation

The Departments’ implementing regulations should clarify that in order to achieve parity, group health plans should be required to provide an in-network selection of quality inpatient and outpatient providers that is comparable to the availability of in-network providers for inpatient and outpatient medical/surgical benefits.

3. Rationale

The greatest out-of-pocket expense now incurred by plan participants requiring access to their MH/SUD benefits, is the gap between what is covered and what is not covered, in terms of the expenses incurred when accessing out-of-network providers. Thus, the

optimum way for members requiring these services to reduce that out-of-pocket exposure is to utilize an in-network provider. However, under present group health plans, a great disparity exists between the abundance of options available for in-network providers of medical/surgical services as opposed to the scarcity of options for in-network providers of MH/SUD services.

Limitation of network providers is a means of imposing both financial requirements and treatment limitations on MH/SUD benefits that are more restrictive than the predominant treatment limitations and financial requirements placed on substantially all of the medical/surgical benefits. The existence of a sufficient quantity and quality of network providers is vital to the efficacy of MHPAEA. Many plans simply lack adequate network providers for the treatment of MH/SUDs. The term “phantom networks” is often used to describe networks offered by plans that lack an acceptable quantity, quality and geographic placement of providers to offer real options for treatment services for those suffering from MH/SUD disorders.

There are a number of steps that plans could take to ensure that the size and quality of their provider networks are adequate. For example: 1) expanding provider networks to ensure adequate geographic coverage, taking into account the location of a plan’s insured population; 2) allowing a period of time during which all nonparticipating providers are invited to apply for membership in the provider network; 3) evaluating not only the size of a plan’s provider network, but also the quality of clinical providers in that network to ensure that the network includes a sufficient number of licensed facilities for all levels of care, sufficient relative numbers of psychiatrists, psychologists, mental health counselors and clinical social workers. Plans should be encouraged to have flexibility in the plans parameters in order to locate the quantity and quality of providers that are willing to work within a plan’s parameters. Providing plan participants with a network under the MH/SUD benefit that is relatively comparable to the network provided under the medical/surgical benefit is vital to real parity in benefits as Congress so intended.

Comment 4: Consider Further Guidance on MHPAEA Preemption of State Parity and Mandate Laws Only to the Extent that They Prevent the Application of MHPAEA – e.g. Geographic Location of Facility Restrictions

1. Statutory and Regulatory Background

ERISA §731 [29 USC 1191(a)] provides that ERISA supersedes provisions of state law which establish, implement or continue in effect any standard or requirement relating to health insurance issuers in connection with group health plans when such state law standards or requirements prevent the application of §712.

ERISA §712(a) [29 USC 1185a] (3)(A)(ii) and (B)(ii) and (iii) were added to require that in the case of a group health plan (or health insurance coverage offered in connection with such a plan) that provides both medical and surgical benefits and mental health or substance use disorder benefits, the treatment limitations applicable to mental health or substance use disorder benefits are no more restrictive than the predominant treatment limitations applied to substantially all medical and surgical benefits covered by the plan, and that there are no separate treatment limitations that are applicable only with respect to

mental health or substance use disorder benefits. A treatment limitation is considered to be predominant if it is the most common or frequent of such type of limit. "The term 'treatment limitation' includes limits on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment."

The regulations state that MHPAEA requirements are not to be "construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement... *except to the extent that such standard or requirement prevents the application of a requirement of MHPAEA.*" 75 Fed. Reg. 5418. (Emphasis supplied).

The regulations state that: "A group health plan may not impose a nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are 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, except to the extent that recognized clinically appropriate standards of care may permit a difference." 75 Fed. Reg. 5436.

2. Recommendation

The Departments should consider developing and implementing regulations that would provide for the enhancement of state insurance laws (including parity laws and group plan benefit designs that follow said state laws) that currently contain requirements which prevent the application of MHPAEA because they provide for treatment limitations that are more restrictive than the predominant treatment limitations applied to substantially all the medical/surgical benefits, and/or they include separate treatment limitations applicable only to MH/SUD benefits (e.g. geographic location of facility restrictions).

3. Rationale

Group health plans often include restrictions as prompted by state mandates and parity laws. Such mandates and parity laws are not preempted *only* to the extent that they do not prevent the application of MHPAEA. For example, a State law that mandates the inclusion of MH/SUD benefits in fully insured group health plans clearly "does not prevent the application of MHPAEA." However, that State mandate may include requirements for state-specific facility and clinician licensure for coverage under the MH/SUD benefit, while state-specific hospital and clinician licensure is not required under the medical/surgical benefit. Thus, under the plan, members are covered under the MH/SUD benefit only if they receive treatment from facilities and/or clinicians licensed by the state in which the plan is issued. The medical/surgical benefit in such plans requires that facilities and/or clinicians are appropriately licensed by the state in which the health care provider is located and, accordingly, the state in which the services are rendered. Such licensure restrictions under the MH/SUD benefit result in geographic

restrictions on participants, thereby resulting in treatment limitations that do not exist (and are therefore in no way comparable) under the medical/surgical benefit.

To illustrate, a participant in a group health plan issued in the state of Kansas, that contains an out-of-network benefit, may obtain covered medical/surgical treatment from an out-of-state center of healthcare excellence licensed and located in New York. However, that participant under the same plan cannot leave the state of Kansas in order to obtain covered MH/SUD treatment from a reputable, licensed provider of his/her choosing, because the state mandate and hence the plan benefit design requires that the MH/SUD treatment facility be licensed under Kansas statutes. In this case, the portion of the state law mandate that prevents the application of MHPAEA could be required to be enhanced to provide parity between the medical/surgical out-of-network benefit and the MH/SUD out-of-network benefit, and the plan benefit design could be required to eliminate such geographic restrictions accordingly.

Comment 5: Medicaid Managed Care Organizations (MCOs) are Required to Comply with the Regulations

1. Statutory and Regulatory Background

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.” 42 U.S.C. 1396u-2(b)(8)(2000). The statute quoted, 42 U.S.C.A. 300gg-5 *et seq.*, is the 1996 Mental Health Parity Act (MHPA), as modified in 2008 by MHPAEA.

2. Recommendation

The Department’s implementing regulations should clarify that Medicaid managed care plans (MCOs) are required to comply with the parity provisions of MHPAEA and the regulations as issued by the Departments.

3. Rationale

The Act, its legislative history, and the regulatory history of the 1996 Mental Health Parity Act (MHPA) make clear that Medicaid MCOs must comply with the parity requirements as set forth in the regulations. In 1997, the Balanced Budget Act (BBA) made a number of changes to the Medicaid statute including adding Section 1932(b)(8), quoted to above, which requires that MCO plans comply with the parity requirements of the 1996 MHPA.¹⁵ The Health Care Financing Administration (HCFA) (predecessor to CMS), subsequently released a number of letters to State Medicaid Directors explaining the effect of the BBA on Medicaid managed care organizations. In a letter dated January 20, 1998, Sally Richardson, the Director of the Center for Medicaid and State Operations, stated that the parity requirements of the 1996 MHPA “apply to Medicaid managed care

¹⁵ 42 U.S.C. 1396u-2(b)(8) (2000).

organizations without exemptions.”¹⁶ 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.”

While Director Richardson’s letter was written during implementation of the 1996 Act, its reasoning continues to apply with respect to the 2008 Act. The legislative history of MHPAEA is consistent with this conclusion. In the Senate Committee on Health, Education, Labor, and Pensions (HELP)’s Report accompanying the bill issued on April 11, 2007, 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.”¹⁷ Because the 2008 MHPAEA simply added a section to the original 1996 MHPA, this new section falls within the scope of Section 1932(b)(8)’s requirement that managed care organizations must comply with the parity requirements. Moreover, the regulations state that they are “implementing” the Act and do not contain an exemption for MCOs from compliance with the requirements therein. Since the Act’s requirements apply to Medicaid MCOs, and since the regulations that implement the Act give no indication that separate rules apply to MCO plans, MCOs must comply with these regulations.

¹⁶ 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/smd/downloads/SMD012098d.pdf>.

¹⁷ S. REP. NO. 110-53, at 5 (2007) (Sen. Comm. on Health, Educ. & Labor, 2007).