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**Submitted via Federal eRulemaking Portal: <http://www.regulations.gov>**

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

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201  
Attention: CMS--4140 – IFC

Internal Revenue Service  
Department of the Treasury  
1111 Constitution Avenue, NW  
Washington, DC 20224  
Attention: REG-120692-09

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

To Whom It May Concern:

Mental Health America (MHA) appreciates the opportunity to comment on the Interim Final Rules under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), published in the February 2, 2010 Federal Register.

For over a century, we have been dedicated to improving access to quality behavioral health services for all Americans. Along with our network of over 300 state and local affiliates nationwide, we are committed to improving mental health care and addiction treatment and promoting mental wellness. After spending many years advocating in support of federal mental health and addiction treatment parity legislation, we are eager to work with the Departments to ensure that the implementing regulations reflect

Congress' intent to prohibit discriminatory limits on mental health and substance use conditions by employer-sponsored and other group health plans.

### Non Quantitative Treatment Limitations

In enacting the MHPAEA, Congress made clear that the goal of this new law was to remedy the long history of employers and insurers not providing comparable coverage for mental health and substance use conditions relative to the medical and surgical benefits they provide.<sup>1</sup>

The MHPAEA explicitly requires group health plans that provide mental health or substance use benefits to ensure that the financial requirements (for example, co-payments, deductibles, and out-of-pocket expenses) and treatment limitations (for example, limits on the number of visits or days of coverage) are no more restrictive for mental health and substance use disorder benefits than the predominant financial requirements or treatment limitations applied to substantially all medical and surgical benefits covered by the plan.

An overly strict interpretation of the MHPAEA could thwart the fundamental purpose of the new law and result in a situation similar to the outcome following enactment of the Mental Health Parity Act of 1996 (Pub. L. 104-204). The General Accountability Office (GAO) found in a May 2000 review of the 1996 parity act's implementation that 86% of employers surveyed reported that they had complied with the 1996 mental health parity law, but the vast majority of those employers substituted new restrictions on access to mental health benefits, thereby evading the spirit of the law. As GAO documented, employers were routinely limiting mental health benefits more severely than medical and surgical coverage, most often by restricting the number of covered outpatient visits and hospital days, and by imposing far higher copayments, deductibles, and other cost-sharing requirements on mental health care. As a result, many people with "good insurance coverage" were not getting needed treatment for mental health conditions at all.<sup>2</sup>

Clearly these findings by the GAO influenced the legislative language in the MHPAEA leading to the inclusion of deductibles, co-payments, outpatient visit limits, and inpatient day limits as examples of the types of unfair limitations that were to be prohibited. These kinds of treatment limitations were found by the GAO to be most obviously and often used by employers to more strictly limit coverage of mental health

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<sup>1</sup> United States House of Representatives, Committee on Education and Labor, House of Representatives Report No. 110-374, pt. 2 at 12 (2007).

<sup>2</sup> United States Government Accountability Office, Mental Health Parity Act: Despite New Federal Standards, Mental Health Benefits Remain Limited, May 2000.

conditions. However these treatment limits are not the only ways plans inequitably limit mental health and substance use disorder benefits as Congress also recognized in the MHPAEA by stating that other similar treatment limitations would also be subject to the new parity law.

The provisions in the interim final rules describing non quantitative treatment limits respond to the evidence indicating that mental health and substance use benefits have historically been much more strictly managed than medical and surgical benefits in ways that, were they to continue, would circumvent congressional intent and objectives explicitly delineated in the new law.

The following examples indicate the pervasive degree to which mental health and substance use conditions have been more stringently managed. States that have implemented parity laws have not seen large increases in mental health and substance use care utilization, presumably due to strict medical management. Research shows that while health care costs in general have been increasing, the share going to mental health has remained steady with spending on general health care is growing twice as fast as spending on mental health care over a 30-year period through 2002.<sup>3</sup> There have also been reports of low rates of spending on mental health services in health maintenance organizations relative to overall health spending<sup>4</sup> and private insurance spending on substance use treatment has declined over the last decade.<sup>5</sup> Moreover, a recent study reported that about two-thirds of primary care physicians could not get outpatient mental health services for their patients – a rate that was at least twice as high as that for other services – due in part to health plan barriers and inadequate coverage.<sup>6</sup>

As the interim final rules explain, the examples of the types of treatment limitations and financial requirements included in the statutory provisions are illustrative and should not be interpreted as the only treatment limitations and financial requirements to which parity applies under the new law. Use of the term “includes” in the definitions of “financial requirement” and “treatment limitation” makes this point clear.

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<sup>3</sup>Richard G. Frank, Howard Goldman, and Thomas G. McGuire, “Trends in Mental Health Cost Growth: An Expanded Role for Management,” *Health Affairs*, May/June 2009.

<sup>4</sup>M. Audrey Burnam and Jose J. Escarce, “Equity in Managed Care for Mental Disorders: Benefit Parity is Not Sufficient to Ensure Equity,” *Health Affairs*, September/October 1999.

<sup>5</sup>Jon Gabel, *et al.*, “Substance Abuse Benefits: Still Limited After All These Years,” *Health Affairs*, July 2007.

<sup>6</sup>Peter Cunningham, “Beyond Parity: Primary Care Physicians’ Perspectives on Access to Mental Health Care,” *Health Affairs*, April 2009.

Treatment limitations are defined in the statute as *including* “limits on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment.”<sup>7</sup> The non quantitative treatment limitations outlined in the interim final rules, including -- medical necessity standards, formulary design, standards for participation in a provider networks, methods for determining usual, customary and reasonable charges, fail first and step therapy requirements, and exclusions based on failure to complete a course of treatment -- clearly fit within the category of treatment limitations. This list of examples includes some of the most common methods used by health plans to inequitably limit mental health and substance use disorder services.

Opponents of this interpretation have argued that treatment limitations must be quantitative to qualify as “similar”. Whereas the reference to “similar limits on the . . . duration of treatment” may support that interpretation, inclusion of the phrase “similar limits on the scope” of treatment clearly refers to a broader set of limitations than strictly quantitative. The Merriam-Webster’s dictionary defines scope as “1) intention, object; 2) space or opportunity for unhampered motion, activity, or thought; 3) extent of treatment, activity, or influence; 4) range of operation” (emphasis added). Thus, reference in the MHPAEA to *similar limits on the scope of treatment* clearly includes other types of limits on treatment beyond simply durational or other quantitative limits.

As we pointed out in our comments on the *Request for Information Regarding the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008* (MHPAEA), published in the April 28, 2009 Federal Register, utilization management techniques clearly qualify as treatment limitations to which parity should apply because they are often used by health plans to limit coverage for mental health or substance use disorder in a more restrictive manner than is applied to medical or surgical benefits. We strongly support the provisions in the new rules clarifying that fail first policies and step therapy requirements will be subject to the protections of parity.

These examples of non quantitative treatment limitations should also include prior authorization and concurrent review requirements because of their widespread use and potential for abuse.

Equally important for ensuring equitable coverage of mental health and substance use disorder benefits is requiring comparable standards for determining medical necessity or appropriateness as included in the interim final rules. Furthermore, the final regulations should specify through examples or otherwise that the different

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<sup>7</sup>See Employee Retirement Income Security Act of 1974 (ERISA) § 712(a)(3)(B)(iii); Public Health Service Act § 2705(a)(3)(B)(iii); Internal Revenue Code of 1986 § 9812(a)(3)(B)(iii).

components of the standards used by plans to determine medical necessity must be applied to mental health and substance use disorder services in a comparable and no more stringent manner than those that are applied to medical/surgical services. Medical necessity determinations often focus on the following criteria: customary standard of practice, i.e., whether the treatment accords with professional standards of practice; evidence-base, i.e., whether there is sufficient evidence to demonstrate effectiveness; medical service, i.e., whether the treatment is considered medical rather than social or custodial; and cost, i.e., whether the treatment is considered cost-effective by the insurer. Medical necessity standards are undoubtedly one of the primary means of imposing treatment limitations and as a result a comprehensive explanation of how the parity law dictates equitable application of these standards to mental health and substance use benefits is warranted.

In response to objections to the application of parity to these non quantitative treatment limits, we would like to point out that the regulations nonetheless still allow management techniques to be used and merely require that they not be used in a discriminatory fashion to more stringently limit mental health and substance use disorder care than medical/surgical care. Moreover, the rules allow for variation in the application of these standards and management techniques as endorsed by “recognized clinically appropriate standards of care.”

We also note that it is absurd to argue that having to apply these medical management techniques in comparable ways will impede the ability of health plans and providers to ensure that individuals with mental health or substance use conditions receive adequate and appropriate treatment. Medical or utilization management should not be confused with or characterized as equivalent to case management services, which are critical benefits that help ensure individuals with mental health or substance use conditions receive adequate and appropriate services. Medical or utilization management is focused primarily on restricting unnecessary care but not on helping individuals to access care.

We also strongly support applying parity to standards for provider networks including provider reimbursement rates. Offering a disproportionately limited network of providers for mental health and substance use disorder services compared to medical or surgical care undoubtedly results in inequitable treatment limitations. A more limited network may also result in higher out-of-pocket costs (i.e., financial requirements) resulting from the necessity to seek care out of network. In our comments on the *Request for Information*, we listed lower provider fees, limitations on coverage of specific types of providers, more restrictive provider licensure requirements, more limited preferred provider networks or phantom networks with invalid phone numbers and names of providers no longer practicing or accepting new patients -- as examples of

treatment limitations that health plans disproportionately use to limit treatment for mental health and substance use conditions.

The regulations should also require that plans provide information to consumers regarding the relative availability of in-network and out-of-network providers for each of the medical specialties in order to evaluate the adequacy of the networks and their equivalence.

We also strongly support the prohibition on plans requiring individuals to exhaust an employee assistance program (EAP) benefit before being eligible for their health plan's mental health or substance use disorder benefits. Using EAPs to impede access to other mental health or substance use benefits clearly constitutes an unequal treatment limitation and should not be permitted.

In addition, as is specified in the interim final rules, the standards used for determining whether a treatment is experimental or investigative should be comparable and not require a more stringent standard for mental health or substance use disorder benefits than medical/surgical services. More explicit examples illustrating this treatment limitation may be useful including examples of plans setting higher standards for evidence of effectiveness for mental health or substance use disorder treatments than are applied to medical and surgical treatments.

The MHPAEA also prohibits "separate treatment limitations applicable only with respect to mental health or substance use disorder benefits" and this provision could be clarified in the regulations to outlaw the requirement used by some plans to limit coverage for inpatient mental health or substance use care only to situations when a person is considered a threat to self or others. This treatment limitation undoubtedly is a separate limitation only applied to mental health or substance use benefits.

### Applying the Parity Requirement to Non Quantitative Treatment Limitations

In light of the more complex task of applying parity requirements to the non quantitative treatment limitations, we appreciate the additional test delineated in the interim final rules to specify that any processes, strategies, evidentiary standards or other factors used in applying these limits must be comparable to and applied no more stringently for mental health and substance use conditions than for medical and surgical benefits except to the extent that recognized clinically appropriate standards may permit a difference. This standard for non quantitative treatment limitations is grounded in the statutory requirement that treatment limitations must be "no more restrictive" for mental health and substance use disorder benefits than for medical and surgical benefits.

We do, however, urge the Departments to provide further guidance on what is meant by “recognized standards of care” so as to prevent this exception from becoming an unmanageable loophole in this critical requirement. We recommend that the final rules specify that these standards for allowing an exception must –

- not be developed solely by a health plan or plans;
- be 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 the health plan or its advisory panels;
- be 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
- be based on objective scientific evidence, such as peer-reviewed publications of control group research trials or expert consensus panels.

Furthermore, the statute clearly requires that *all* treatment limitations applicable to mental health or substance use benefits must be “no more restrictive than the predominant treatment limitations applied to substantially all medical and surgical benefits covered by the plan”. We urge the Departments to clarify in the regulations how to apply the “substantially all” and “predominant” standards to non quantitative treatment limitations. Without this additional clarification, health plans may take a highly restrictive non quantitative treatment limitation that only applies to a small minority of medical/surgical benefits and inequitably apply that highly restrictive limitation to the majority of mental health and/or substance use disorder benefits.

### Separate Deductibles

We strongly support the provision in the regulations prohibiting separately accumulating financial requirements – including deductibles and quantitative treatment limits. Aside from the disparate impact these separately accumulating requirements have on access to care, this new requirement is in keeping with the overall movement to better integrate care that is strongly supported throughout the general health, mental health, and addiction treatment communities as well as being a key goal of health care reform. We view this requirement as resulting in better coordination of care as a result of different claims systems having to “talk to each other.”

Separate deductibles for behavioral health and other health services constitute unequal financial requirements. Separate deductibles, even if they are equivalent, impose an *additional* burden on persons with mental health or substance use disorder conditions. In order to access services for mental health or substance use conditions, these

individuals have to meet an additional deductible on top of the deductible that generally applies to all other health services.

Moreover, the provisions in the statute prohibiting “separate cost-sharing requirements that are applicable only with respect to mental health or substance use disorder benefits”<sup>8</sup> clearly provide statutory authority for prohibiting *separate* deductibles.

Separately accumulating deductibles have the effect of imposing significant additional barriers to accessing needed care that are not generally applied to other types of benefits. They thus represent the type of discriminatory practice disadvantaging individuals in need of mental health or substance use treatment that Congress meant to remedy with enactment of the MHPAEA.

### Whether and How the MHPAEA Addresses Scope of Services

The Departments requested comments on whether and how the MHPAEA addresses scope of services. Comprehensive and thoughtful implementation of the parity requirement has led the Departments to categorize health plan benefits into six classes (i.e., inpatient in-network, inpatient out-of-network, outpatient in-network, outpatient out-of-network, emergency care, and prescription drugs) to facilitate comparison of treatment limitations and financial requirements for comparable types of care. This classification of benefits is also supported by the statutory provisions requiring coverage of out-of-network mental health and substance use disorder benefits if out-of-network medical or surgical benefits are covered.

Furthermore, as pointed out in the interim final rules, failure to provide mental health and substance use disorder services in any of these classes would constitute a treatment limitation. As the regulations explain, if medical/surgical benefits are provided in any of the six classes, mental health and substance use disorder benefits must also be provided in those corresponding classes of benefits otherwise the lack of mental health or addiction treatment services in a class for which medical/surgical benefits are provided would constitute an unequal treatment limitation. The resulting requirement that mental health and substance use condition services must be provided across a set of benefit classes comparable to the benefits provided for medical/surgical care does represent a scope of services or continuum of care that plans must provide on an equitable basis under the new parity law.

Other statutory provisions that indicate that parity applies to the scope of services include the definition of treatment limitations, which includes well-known examples of

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<sup>8</sup> See e.g., ERISA § 712(a)(3)(A)(i).

treatment limitations and then the following language - “or other similar limits on the scope or duration of treatment” - specifically referencing scope of treatment.

Furthermore, although the MHPAEA grants health plans discretion to determine which mental health and substance use *conditions* to cover, limitations on *which treatments* are covered is clearly subject to the parity requirement. This interpretation of the statute is supported by the definitions of mental health benefits and substance use disorder benefits in the MHPAEA 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.” These provisions clearly grant discretion to choose which *conditions* to cover but not necessarily which *services* to cover.

Within each classification of benefits, the parity requirement with regard to treatment limitations, including non quantitative treatment limitations, should ensure a comparable scope of service. However, additional clarification on this point is needed. As recognized in the interim final rules, standards for determining whether a service is medically necessary or experimental, as well as other non quantitative treatment limitations, are primary means of limiting the scope or duration of treatment and as such must be administered in an equitable manner in order to comply with the new parity law. The regulations should specify that application of the parity requirements to treatment limitations, including medical necessity and evidentiary standards, should result in a scope of service for mental health and substance use disorders that is comparable to a medical/surgical continuum of care.

We recommend further clarification in the final rules that plans may not establish additional classifications of benefits that would be exempt from the parity requirements. Allowing additional classifications that are exempt would undermine the whole purpose of establishing benefit classifications to facilitate comparison of mental health and substance use disorder benefits versus medical/surgical benefits in order to determine how the parity requirements apply.

We do, however, recommend that the Departments expand the classes of benefits to which the new parity requirements do apply to include preventive services and rehabilitative services. These two categories warrant special attention because mental health and substance use disorder benefits are often very limited with regard to these types of services, particularly as compared to medical/surgical benefits. As a result, research has indicated that 50 percent of mental health disorders start by age 14, but because the early signs of a disorder are often missed, the average diagnosis regularly

occurs 10 years or more after the onset of symptoms.<sup>9</sup> Ensuring equal coverage of preventive services for mental health and substance use disorders under the new parity law would undoubtedly increase early identification of mental illness and greatly reduce the cost of these conditions to society. The lack of private insurance coverage of rehabilitative services specific to mental health or substance use conditions causes many people with these conditions to rely on Medicaid in order to receive the care they need. Improving access to rehabilitative services through private insurance plans, would lessen the cost to Medicaid and other government programs.

### Need for Further Clarification on Disclosure Requirements Regarding Medical Necessity and Coverage Denials

With regard to medical necessity, the regulations should –

- Set timeframes for disclosure of medical necessity criteria;
- Include a detailed description of appeal and enforcement mechanisms with the disclosure of the medical necessity criteria;
- Clarify that disclosure of the criteria used to make medical necessity determinations must include the standards used to determine medical necessity judgments (*e.g.*, standard of practice, strength of the evidence base, definition of medical conditions); and
- Make available to beneficiaries the standards used to assess medical necessity for medical and surgical benefits.

With regard to coverage denials, we are pleased to see the new parity regulations incorporate the requirements from the regulations under Employee Retirement Income Security Act (ERISA) directing, for example, that disclosure of reasons for denial must be automatic and free of charge, setting timeframes for these disclosures, and outlining the processes for appealing coverage determinations. We urge the Departments to extend this requirement to all plans (not just ERISA plans) instead of merely recommending that all plans comply with these requirements.

### Need for Further Clarification on Cost Exemption

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<sup>9</sup> Kessler R.C., Berglund P., Demler O., et al., Lifetime Prevalence and Age-of-Onset Distributions of DSM-IV Disorders in the National Comorbidity Survey Replication, Arch Gen Psychiatry, 2005; 62:593-602.

The final rules should clarify that assessment of whether a plan qualifies for a cost exemption must be determined on a retrospective basis and based on real experience with increased cost instead of hypothetical costs. The statutory provision authorizing this cost exemption clearly refers to an increase in “actual” costs.<sup>10</sup>

These regulations should also provide guidance on the evidence that would be required to attribute any cost increase to the provision of equitable services as opposed to other market conditions.

### Defining Mental Health and Substance Use Disorder Benefits

We also support steps taken in the interim final rules to prevent plans from misclassifying mental health or substance use disorder benefits in order to avoid having to comply with the parity law. Requiring that mental health and substance use disorder benefits must be defined in accordance with generally recognized independent standards of current medical practice (including the Diagnostic and Statistical Manual of Mental Disorders, the International Classification of Diseases, and state guidelines) should help to prevent any attempts to undermine application of the critical consumer protections called for by the parity law.

One example of such an attempt would be a plan only covering medication therapy and arguing that parity does not apply because no mental health or substance use disorder *services* are covered. Independent standards of current medical practice would undoubtedly recognize prescription drug therapy for these conditions as a mental health or substance use disorder benefit. Furthermore, the inclusion of prescription medication among the six classes of benefits designated to facilitate application of the new parity requirements should also make this point clear. However, further clarification in the final rules on this issue would be helpful.

### Generalist v. Specialist Classifications

In addition, we support the provision in the rules directing that separate classifications of generalists and specialists will not be permitted in determining the predominant financial requirement (e.g., co-pays or co-insurance) for medical and surgical benefits compared to mental health and substance use disorder benefits. This important component to the parity analysis will again help improve access to mental health care and addiction treatment by keeping co-pay and co-insurance levels comparable to those of general health care providers. In addition, this aspect of the parity regulations reinforces the importance of integrating mental health into general health care. As

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<sup>10</sup> See e.g., ERISA § 712(c)(2).

pointed out in the preamble to the interim final rules, about half of mental health care is delivered by primary care physicians and this trend may be attributable to the higher cost-sharing required for mental health professionals. Moreover, research has shown that a relatively small percentage of individuals treated in the general health system receive minimally adequate care compared to a much high percentage who are treated by mental health specialists.<sup>11</sup> We note that this direction to plans not to classify mental health and substance use provider in a group of specialty providers was only discussed in the preamble but not included in the actual regulations. We urge you to include this important provision in the final rules.

We appreciate the thoughtful leadership demonstrated by the three Departments in developing this comprehensive set of regulations. We look forward to working with you to ensure that the final rules appropriately reflect Congressional intent with enactment of MHPAEA to end discriminatory treatment of mental health and substance use conditions by group health plans and to establish strong consumer/patient protections. Thank you for your consideration of our views.

Sincerely,



David L. Shern, Ph D  
President and CEO

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<sup>11</sup> 75 Fed Reg 5410 at 5423 (Feb. 2, 2010, effective April 5, 2010).