

April 29, 2010

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:

I appreciate 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.

The following comments on specific provisions in the regulations will help strengthen consumer protections and 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.¹

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

Higher co-payments, deductibles, and other cost-sharing requirements, as well as restrictions on the number of outpatient visits and inpatient days covered are only the most obvious examples of discriminatory treatment of mental health and substance use care. The provisions in the interim final rules describing non quantitative treatment limits respond to the evidence indicating 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.

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.

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.”² The non quantitative treatment limitations outlined in the interim final rules, including -- medical necessity standards, formulary design, standards for participation in 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 this category. 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.

I strongly support the provisions in the new rules clarifying that prior authorization requirements, fail first policies and step therapy requirements, will be subject to the protections of parity. 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.

I also strongly support applying parity to standards for provider networks including 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 limitations on

²See Employee Retirement Income Security Act of 1974 § 712(a)(3)(B)(iii); Public Health Service Act § 2705(a)(3)(B)(iii); Internal Revenue Code of 1986 § 9812(a)(3)(B)(iii).

treatment and higher financial requirements in the form of higher out-of-pocket costs resulting from the greater likelihood of having to go to an out-of-network provider.

The regulations should 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.

I also strongly support the application of parity to prohibit plans from requiring individuals to exhaust an employee assistance program (EAP) benefit before being eligible for mental health/substance use disorder benefits. Using EAPs to impede access only to other mental health or substance use benefits clearly constitutes an inequitable treatment limitation and should not be permitted.

In addition, the standards used for determining whether a treatment is experimental or investigative should also be comparable and not more stringently applied to mental health and substance use benefits as specified in the interim final rules. Formulary designs and methods for determining usual, customary, and reasonable charges also clearly fall within the definition of treatment limitations and must be subject to the new parity requirements as a result.

Applying the Parity Requirement to Non Quantitative Treatment Limitations

In light of the more complex task of applying parity to the non quantitative treatment limitations, I appreciate the additional test delineated in the parity regulations to specify that any processes, strategies, evidentiary standards or other factors used in applying these non quantitative treatment 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.

I do, however, urge the agencies 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.

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”. I urge the agencies 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 apply that highly restrictive limitation to the majority of mental health and substance use disorder benefits.

Separate Deductibles

I strongly support the provision in the interim final rules prohibiting separately accumulating financial requirements – including deductibles and quantitative treatment limits. Separate deductibles, even if they are set at equal levels, do not impose an equal burden on individuals with mental health or substance use conditions but instead an *additional* burden. Separately accumulating deductibles 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 MHPAEA.

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”³ clearly provide statutory authority for prohibiting *separate* deductibles.

Whether and How MHPAEA Addresses Scope of Services

Comprehensive and thoughtful implementation of the parity requirement has led the agencies to require classification of 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 analysis of treatment limitations and financial requirements for comparable types of care. 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.

As recognized in the interim final rules, standards for determining whether a service is medically necessary or too experimental 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. Application of these standards certainly results in coverage of a certain scope of services or continuum of care. The regulations should specify that application of the parity requirements to treatment limitations, including medical necessity and

³ e.g., sec 712 of ERISA, subsection (a)(3)(A)(i)

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.

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, upon request, the standards used to assess medical necessity for medical and surgical benefits.

With regard to coverage denials, I am 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, set timeframes for these disclosures, and outline the process for appealing coverage determinations. I urge the agencies 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

The regulations 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 regulations should 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

I 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.

Generalist v. Specialist Classifications

In addition, I support the provision in the preamble to the interim final 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 general health care providers. I 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. I urge you to include this important provision in the interim final rules.

Thank you for your consideration of my views.

Sincerely,

Jerry R. Grammer, Ph.D.