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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, NW.
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:

Thank you very much for the opportunity to provide comments on the Interim Final Rules (Interim Final Rules or IFR)¹ under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA). This landmark legislation signed into law on October 3, 2008 seeks to protect the rights of individuals in need of treatment for mental health and/or substance use disorders. The Interim Final Rules and the timely promulgation of Final Rules will help to fully realize this promise.

For the past five years I have had the opportunity to work with sixteen States to assist them in improving their statewide systems for treating youth with substance use/co-occurring disorders. I have been privileged to talk with youth, family members, treatment providers and State officials from the child serving agencies in these States. My comments will reflect this experience.

The Interim Final Rules evidence significant analysis and work. The drafters are to be commended for their efforts to ensure that the implementation will provide strong protections for youth with substance use and/or co-occurring mental health disorders and their families. I appreciate the Departments' consideration of these comments.

Parity Requirements Apply to Services

In MHPAEA mental health benefits are defined as "...benefits with respect to services for mental health conditions."² In like manner, MHPAEA defines substance use disorder benefits as "...benefits with respect to services for substance use disorders."³ The explicit reference to services in the definitions of mental health and substance use disorder benefits in MHPAEA is evidence of the intent of Congress to include services within the definition of mental health/substance use disorder benefits. Under the section "Availability of Plan Information", MHPAEA explains the availability of plan information when "...payment for services with respect to mental health or substance use disorder benefits" is denied.⁴ The use of the term "services" again demonstrates that Congress intended parity in services to be required under MHPAEA.

Scope of Services

The Interim Final Rules do not discuss scope of services. The drafters request 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. Clarifying the scope of services issue is essential to assure that the intent of MHPAEA is realized. It is clear that MHPAEA allows plans to select which mental health or substance use disorders to cover, but once covered plans must provide the continuum of services needed to treat those disorders.

MHPAEA requires that the scope of mental health and substance use disorder (MH/SUD) services are "...no more restrictive than the predominant treatment limitations applied to substantially all medical and surgical benefits covered by the plan."⁵ Thus if a limitation does not apply to substantially all medical/surgical benefits, defined in the law as applying to at least two-thirds of all medical/surgical benefits in that classification, or is not the predominant level, defined

¹ Vol. 75, No. 21; Fed. Reg. 5410 (Feb. 2, 2010).

² Interim Final Rules under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008. §1185a(e)(4).

³ §1185a(e)(4).

⁴ §1185a(e)(4).

⁵ §1185a(a)(3)(A)(ii).

in the law as applying to more than one-half of medical/surgical benefits in that classification, the limitation cannot be applied to MH/SUD benefits.

Quantitative (QTL) and Non-quantitative Treatment Limitations (NQTL)

MHPAEA applies parity requirements to all treatment limitations, both quantitative and non-quantitative. MHPAEA explains the term “treatment limitation” and provides examples when it states “...treatment limitation includes limits on the frequency of treatment, the number of visits, days of coverage, or other similar limits on the scope and duration of treatment.”⁶ The word “includes” indicates that the list not comprehensive but rather gives illustrations of types of treatment limitations.

Non-quantifiable Treatment Limitations (NQTL)

The IFR include both QTLs and NQTLs as part of the umbrella term “treatment limitations.” Thus NQTLs must also satisfy the predominant and substantially all standard. NQTLs are used pervasively to manage both medical/surgical and MH/SUD benefits, with great effect on patient access to care. For example, NQTLs such as medical management, preauthorization, concurrent review, retrospective review, and utilization review procedures often determine whether a youth receives any treatment for a mental health and/or substance use disorder and if so, the treatment is at the appropriate level, in the appropriate setting, and for the needed duration.

NQTLs are a primary means of operationalizing the “managed” in managed care. If used appropriately these NQTLs can be a primary means of assuring effective and efficient care. However unfortunately in some cases NQTLs may be used in a manner that hinders appropriate treatment (i.e., by placing a youth in a lower level of care than is clinically indicated). This may result in the youth failing and consequently being less able to appropriately use the services at the clinically indicated level of care when placed there. Assuring that a “fail first” NQTL is not used for MH/SUD unless also used for medical/surgical care will address this.

Concurrent review may be used to step a youth down to appropriate treatment levels, but it may also result in a denial of continuation of treatment, resulting in at least an interruption of care and at worst premature termination of treatment. Because of the importance and extensive use of NQTLs the Departments should stress that the application of NQTLs for MH/SUD may not be more restrictive than use of the predominant non-quantitative treatment limitations applied to substantially all medical and surgical benefits covered by the plan.

NQTLs must also meet the comparable and the no more stringently standards. The general rule in the IFR that says, “A group health plan (or health insurance coverage) may not impose a non-quantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan (or health insurance coverage) as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the non-quantitative 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.”⁷ This rule sets forth two critical standards (the way the NQTL is applied and how comparable the NQTL is for MH/SUD and medical/surgical conditions) for determining plan compliance with the regulations.

⁶ §1185a(a)(3)(B)(iii).

⁷ 75 Fed. Reg. 5436.

The regulations permit an exception to the comparable and no more stringently standards “...to the extent that recognized clinically appropriate standards of care may permit a difference.”⁸ The Departments should adopt a definition of “recognized clinically appropriate standards of care” that is based on independent and objective clinical policies and standards. The Departments should issue guidance on the application of the all the standards and exceptions to NQTLs, provide more examples of NQTLs, and emphasize the NQTLs in the Final Rules.

Non-analogous Services

The Departments should clarify that a plan that refuses to cover a mental health/substance use disorder service because there is no analogous service on the medical/surgical side violates MHPAEA if it does not also refuse to cover medical/surgical services that have no MH/SUD analogue. MHPAEA requires the NQTLs to be comparable. A plan that refuses to cover a MH/SUD service with no medical/surgical analogue but does not do the opposite would not be applying a comparable NQTL.

Separate Treatment Limitations

The Act also ensures scope of service parity by prohibiting separate treatment limitations applied to MH/SUD services that are not applied to medical/surgical services. The treatment limitations section of the Act states that health plans must ensure that “...there are no separate treatment limitations that are applicable only with respect to mental health or substance use disorder benefits.”⁹ This language should help to assure parity in scope of services.

Parity Both Across and Within Classifications

The Interim Final Rules create six classifications of benefits for purposes of applying the parity rules. They are:

- Inpatient, in-network
- Inpatient, out-of-network
- Outpatient, in-network
- Outpatient, out-of-network
- Emergency care
- Prescription drugs

The Interim Final Rules do not define the inpatient, outpatient or emergency care classification categories and state “...the terms are subject to plan design and that the meanings may differ from plan to plan.”¹⁰ It further states that plans must “...apply the terms uniformly for both medical/surgical and mental health/substance use disorders.”¹¹

The absence of definitions for these terms may unintentionally result in treatment limitations. The term “inpatient,” for example, would be better described as “24-hour care.” “Inpatient” connotes a hospital (acute, sub-acute) level of care. Access to sub-acute levels of care on the medical/surgical side usually requires prior hospitalization (i.e., transfer to residential rehabilitation following orthopedic surgery). The treatment of youth with substance use disorders and some mental health conditions requires little hospital level of care. For example most youth

⁸ 75 Fed. Reg. 5436.

⁹ §1185a(a)(3)(B)(iii).

¹⁰ 75 Fed. Reg. 5413.

¹¹ 75 Fed. Reg. 5413.

with substance use disorders do not require inpatient medically monitored detoxification. However, a subset of youth does require residential substance use disorder treatment. Thus the operational definition of the term “inpatient” must be broad enough to encompass multiple levels of 24-hour care.

For treatment of youth with substance use disorders, the Departments should reference the classifications in the American Society of Addiction Medicine (ASAM) Patient Placement Criteria, Version 2-Revised. The ASAM criteria clarifies that the term “inpatient” is inclusive of several levels of residential treatment including ASAM Level III.1 clinically managed low intensity residential treatment, ASAM Level III.5 clinically managed medium intensity residential treatment, ASAM Level III.7 medically monitored high intensity residential treatment as well as Level IV medically monitored hospital based detoxification. Likewise the ASAM criteria identify three levels of non 24-hour care (i.e., outpatient treatment, intensive outpatient treatment, and partial hospitalization).

The operational definitions of the IFR classifications should be broad enough to clarify that all empirically supported levels of care and types of services must be available in the scope of services for mental health/substance use disorders if all empirically supported levels of care and types of services are allowed in the predominant treatment limitations that are applied to substantially all medical and surgical benefits covered by the plan. The IFR have identified classifications but without definitions of terms the intent of the classifications may not be realized.

In addition to operational definitions of classifications there is a need for clear guidance about a scope requirement within each benefit class. The Act and the regulations define and require parity in scope of services across and within the required six classifications. The Final Rules should clarify that benefits for MH/SUD must be comparable in scope to the benefits provided in medical/surgical both across and within each classification. The regulations require that when a plan “...provides (MH/SUD) benefits in any classification of benefits” described in the rules, MH/SUD benefits “...must be provided in every classification in which medical/surgical benefits are provided.”¹²

The MHPAEA regulations state, “...if a plan provides benefits for a mental health condition or substance use disorder in one or more classifications but excludes benefits for that condition or disorder in a classification (such as outpatient, in-network) in which it provides medical/surgical benefits, the exclusion of benefits in that classification for a (MH/SUD) otherwise covered under the plan is a treatment limitation.”¹³ This statement requires parity across classifications in the scope of services that are offered for a particular condition.

Although the regulations do not require a plan to cover identical MH/SUD and medical/surgical services within any classification, they do require that the limitations in each MH/SUD classification be no more restrictive than the limits in the corresponding medical/surgical classification. The Departments should clarify that this language requires parity in scope of services within each classification.

Definitions of Substantially All and Predominant

The Departments’ definition of “substantially all” in the IFR is clear, logical and will help to ensure the strong parity protections envisioned by Congress. Under the regulations, a financial requirement or treatment limitation applies to substantially all benefits in a classification if it applies to at least two-thirds of the benefits in that classification. If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of the medical/surgical

¹² 75 Fed. Reg. 5433.

¹³ 75 Fed. Reg. 5413.

benefits in a classification, that type of requirement or limitation cannot be applied to MH/SUD benefits in that classification. This is similar to the requirement in the Mental Health Parity Act of 1996.

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

Denials

Denials may take the form of refusing to provide any treatment, denying a more intensive level of treatment, or denying the continuation of treatment. Currently some youth and families are experiencing significant problems in accessing appropriate MH/SUD care because of denial decisions. While it is within the purview of the health plan to deny services, it is also the right of the youth/parent to appeal the denial. The statute clearly requires that a plan disclose the reason for any denial of reimbursement or payment for services with respect to MH/SUD benefits. The final rule should assure that the criteria for the denial of treatment for MH/SUD is no more restrictive than the criteria for denying treatment for medical/surgical conditions.

Understanding the importance of the denial decision and its significant effect on youth treatment, the Final Rules should also require plans to disclose the reason for the denial as soon as possible but no later than within three days. Specifically, when the denial is based on a medical necessity determination, plans should be required to provide the plan’s medical necessity criteria and reason for the denial immediately. Without this information the youth/parent may be delayed in filing an appeal. The timeliness of the appeal is particularly critical when the denial is for continued treatment. The Final Rules should also clarify that actions taken by the plan pending the outcome of an appeal should be no more restrictive for MH/SUD than for medical/surgical conditions.

The Interim Final Rules state that “...if a plan is subject to ERISA, it must provide ‘the reason for the claim denial in a form and manner consistent with the requirements of 29 CFR 2560.503–1 for group health plans.’”¹⁴ Even for non- ERISA plans, a plan that follows the requirements of 29 CFR 2560.503–1 for group health plans complies with the requirement to provide a reason for denial.

According to 29 CFR 2560.503–1, if an internal guideline, rule, protocol, or other similar factor was relied upon in making the adverse determination, the notification must either include the specific guideline, rule, protocol, or other similar factor, or the notification must include a statement that such a guideline, rule, protocol, or other similar factor was relied upon in making the adverse determination and that a copy of such rule, guideline, protocol, or other criterion will be provided free of charge to the claimant, upon request. If a plan relies upon internal medical necessity criteria in denying MH/SUD benefits, this requirement should require disclosure of these criteria. The specific reasons for the Plan’s decisions should be shared with the consumer. As all denials of MH/SUD treatments can only be judged as compliant or noncompliant with MHPAEA when compared with the same policies and or criteria used for medical/surgical treatments, the plan should also share the corresponding medical coverage criteria that are used for substantially all medical/surgical benefits.

¹⁴ 75 Fed. Reg. 5437.

Preempting State Parity Laws

State parity laws with stronger protections than those contained in the MHPAEA and which do not act to prevent the application of MHPAEA should not be preempted. The regulations state that MHPAEA requirements are not to be construed to supersede any provision of State law "...except to the extent that such standard or requirement prevents the application of a requirement of MHPAEA",¹⁵ and that "States have significant latitude to impose requirements on health insurance issuers that are more restrictive than the federal law."¹⁶ These provisions should be included in the Final Rules.

Application of the Interim Final Rules to Managed Care for youth in Medicaid, CHIP Medicaid expansions and freestanding CHIP plans

Medicaid, CHIP Medicaid expansions and CHIP freestanding plans cover some of the most vulnerable youth in need of treatment for mental health and/or substance use disorders. Increasingly Medicaid has used managed care models to deliver services to these youth and their families. The Departments should clarify that MHPAEA applies to Medicaid and CHIP Medicaid expansion managed care plans. As the Social Security Act Section 1932(b)(8) specifies, "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."¹⁷ The statutory reference in the quote refers to the mental health parity provisions as passed in the 1996 Mental Health Parity Act (MHPA) and as modified by the 2008 Act. Thus, the Medicaid managed care statute requires that Medicaid managed care plans comply with both the 1996 and the 2008 parity requirements. The Departments should address how MHPAEA relates to freestanding CHIP managed care plans.

The regulations should clarify that the Early and Periodic Screening, Diagnosis and Treatment (EPSDT) provisions of Medicaid law are still in effect and that the application of MHPAEA may not dilute the requirements of EPSDT. Given the number of vulnerable youth with mental health and/or substance use disorders enrolled in Medicaid/CHIP managed care the Departments should issue timely regulations related to the application of MHPAEA to Medicaid/CHIP managed care organizations and provide guidance to the field as soon as possible.

Single Deductible

The IFR call for a single deductible for medical/surgical and mental health/substance use disorder treatment. For the treatment of substance use disorders, there are a number of examples that support having one deductible across all types of treatment, including laboratory services and medical and specialty treatment. For example, detoxification performed in a medical facility is currently billed within the medical benefit while substance abuse treatment following detox is most often covered through the substance use disorders benefit. Likewise medication-assisted treatment for addiction is often administered in primary care through the medical benefit, while specialty counseling and psychotherapy is covered through the substance use disorders benefit. In both cases, the consumer will do better having one understandable deductible which would include both general and specialty components of addiction treatment. Thus, the single deductible is the better choice.

¹⁵ 75 Fed. Reg. 5418.

¹⁶ 75 Fed. Reg. 5430.

¹⁷ 42 U.S.C. 1396u-2(b)(8)(2000).

That said, the operationalization of a single deductible especially in the case of MBHOs will require significant knowledge and effort. “The imposition of a single deductible requires entities providing medical/surgical and mental health/substance use disorder benefits to develop and program a communication network referred to as an ‘interface’ or ‘accumulator’ that will allow them to exchange data necessary to make timely and accurate determinations of when participants have incurred sufficient combined medical/surgical and mental health and substance use disorder expenses to satisfy the single deductible.”¹⁸ The construction of interfaces developed to implement MHPAEA should be undertaken within the context of the larger changes in health information technology resulting from the recently passed health reform law. The Departments should provide technical assistance, including information on the most current electronic health record information and the outcomes of current discussions on consumer privacy laws especially in respect to 42 CFR, to all entities implementing the single deductible. The Departments are aware that mental health and substance use disorders specialty care providers did not share in funds for information technology improvement. While a bill is currently in the House to remedy this, in the short term the specialty care sector may need additional assistance in order to implement the single deductible requirement in a timely manner.

Timely Guidance on Issues Currently Addressed in the Regulations

The comments of the Interim Final Rules will raise important issues that need clarification in the short term. The MHPAEA is already in effect and health plans are interpreting the statute and making critical decisions on implementation. Given the often lengthy process of issuing Final Rules, the Departments should provide guidance related to issues currently in question as soon as possible.

Thank you for the opportunity to comment on the MHPAEA Interim Final Rules.

Respectfully,
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¹⁸ 75 Fed. Reg. 5425.