ABHW

Association for Behavioral Health and Wellness

Advancing benefits and services in mental health, substance use and behavior change.

May 3, 2010

Submitted via the Federal eRulemaking Portal: http://www.regulations.gov

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

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

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 Sir or Madam:

The Association for Behavioral Health and Wellness (ABHW) is writing to offer comments in response to the interim final rules ("IFRs") under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008. The IFRs were issued in the *Federal Register* on February 2, 2010, and are applicable to group health plans and group health insurance issuers for plan years beginning on or after July 1, 2010.

ABHW is an association of the nation's leading behavioral health and wellness companies. These companies provide an array of services related to mental health, substance use, employee assistance, disease management, and other health and wellness programs to over 147 million people in both the public and private sectors. ABHW and its member companies use their behavioral health expertise to improve health care outcomes for individuals and families across the health care spectrum. In particular, ABHW members are all involved in management of behavioral health benefits under group health plans as managed behavioral health organizations (MBHOs).

1101 Pennsylvania Avenue, NW, Sixth Floor, Washington, DC 20004 | Tel 202.756.7726 | Fax 202.756.7308 | www.abhw.org

ABHW has supported mental health and addiction parity for over fifteen years. We were an original member of the Coalition for Fairness in Mental Illness Coverage ("Fairness Coalition"), a coalition developed to win equitable coverage of mental health and addiction treatment through the enactment of federal mental health parity legislation. Members of the Fairness Coalition include the American Hospital Association, American Medical Association, American Psychiatric Association, American Psychological Association, Association for Behavioral Health and Wellness, Federation of American Hospitals, Mental Health America, National Alliance on Mental Illness, and the National Association of Psychiatric Health Systems. At the height of the parity debate, ABHW was the Chair of the Fairness Coalition, was closely involved in the writing of the Senate legislation, and was present during the negotiations of the final bill that became public law. Our extensive involvement in the writing and negotiating of the legislation helps provide an understanding of the meaning and intent of the law.

This involvement is also evidence of ABHW's commitment to the goal of mental health parity. ABHW recognizes the need for regulations to provide the guidance necessary for implementation of Congress' intention in enacting the MHPAEA. Having labored so long to achieve this goal, however, ABHW was dismayed to find that the IFRs reflect a fundamental misunderstanding of the role of and the tools utilized by its member specialty managed behavioral health companies. To be sure, the IFRs provide much needed guidance regarding financial requirements and quantitative treatment limitations. In other important respects, however, the IFRs stray far beyond the scope of both MHPAEA's terms and Congressional intent, calling into question the very structures and procedures that ABHW's members have historically and successfully used in the managed behavioral health area. It is ironic in the extreme that the IFRs so thoroughly undermine these structures and procedures while at the same time the Agencies expend so much time and space in the preamble to the IFRs praising these structures and procedures for their doubly salutary effects of increasing access to mental health care while keeping the costs of such care down. As detailed below, these tools have been developed for particular use in the behavioral health area and have no ready analogs in the medical/surgical area. As a result, and in light of the specific comments discussed more fully below, ABHW believes that the IFRs need to be substantially revised in this and several other respects in order to achieve the goal of meaningful mental health and substance use parity.

I. The Agencies Should Withdraw the IFRs and Republish Them as Proposed Regulations.

The IFRs require far-reaching changes in the way in which mental health and substance use disorder benefits are provided and managed. Most of these changes could not reasonably have been foreseen based on a reading of the statute. In similar situations, an industry being subjected to new and far-reaching rules would expect to be provided with the ability to review specific Agency proposals and to comment directly on the positions the Agency is proposing to take before those positions become final in any way. This notice and comment process, codified in the Administrative Procedure Act, provides the surest way to publication of final rules that equitably set standards for all persons affected by the regulations.

Despite this, the Agencies have short-circuited the process in the present situation. Although the Agencies issued a Request for Information (RFI), this was merely an inquiry process designed to educate the agencies about this complex area. It was in no way a substitute for a real notice-and-comment process. This defective process has produced an IFR which, as detailed below, is confusing, ineffective and may actually inhibit rather than advance true parity.

ABHW believes that the only way to remedy this situation is for the Agencies to withdraw the IFRs and republish them in proposed form. Taking such a step would not work to the disadvantage of any group or individual affected by MHPAEA. The statute is self-executing, and the statutory mental health and substance use disorder standards do not require regulations to become effective. The Agencies themselves have recognized that compliance efforts by companies involved in the administration and management the mental health and substance use disorder benefits are on-going. Although the Agencies state that they issued an IFR due to the need for guidance, the Agencies' rush to publication has produced a regulation that confuses rather than clarifies. ABHW therefore urges the Agencies to take this reasonable step and reissue the regulation in proposed form so that all persons and entities affected by MHPAEA can be heard on an equitable basis.

II. Alternatively, the Agencies Should Postpone the Effective Date of the IFRs Until July 1, 2011.

The IFRs are comprehensive and complex regulations that require many changes in the way MBHOs provide their services. Congress recognized that MHPAEA would require significant changes and therefore delayed its effective date, presuming that the Agencies would use the one year delay to propose and finalize regulations and thereby give the industry both input into the regulatory process and time to adjust to any changes necessitated by the regulations. Despite this long time frame, the agencies did not issue any guidance at all until the issuance of the IFRs and then provided only five months for the industry to read, interpret and begin efforts to comply with the new standards. Indeed, the Agencies recognize at many places in the preamble to the IFRs that they did not have sufficient information to provide detailed guidance or examples, or in some cases, to provide any guidance at all.

This is without doubt a difficult area, and ABHW and its member organizations want to assure that they implement parity in the most efficient and effective way possible. To that end, ABHW believes that the Agencies should agree to a one year postponement of the applicability date of the IFRs, so that application of the standards in the IFR will begin for plan years beginning on or after July 1, 2011. This would have the dual benefit of providing time for the industry as it develops its compliance mechanisms while at the same time allowing the Agencies to avoid rushing through consideration of the comments received in response to the IFR. Ideally, such a postponement would also facilitate the issuance of a final regulation reflecting the comments from all interested parties before the IFR applicability date.

III The Parity Requirement Should Not Apply to So-Called "Nonquantitative" Treatment Limitations.

The general parity rule set forth in section (c)(2)(i) of the IFRs states that a plan that covers both medical/surgical and mental health/substance use care may not apply any financial requirement or treatment limitation for mental health/substance use care that is more restrictive than the predominant financial requirement or treatment limitation applied to substantially all medical/surgical benefits in the same classification. In adopting this standard, the Agencies followed closely Congress' language in MPHAEA. See ERISA § 712(a)(3)(A), as added by MPHAEA. Similarly, in defining the term "financial requirements," the IFRs directly track the statutory language. In contrast, the definition of "treatment limitations" diverges markedly from the statutory approach by including within its ambit so-called "Nonquantitative Treatment Limitations" ("NQTLs"). This new term is not fully defined, but instead is the subject of an "illustrative list" provided in section (c)(4)(ii) of the IFRs. This list includes: (a) medical management standards based on findings such as medical necessity; (b) formulary design for prescription drugs; (c) network credentialing and reimbursement rates; (d) methods for determining usual and customary charges ("UCRs"); (e) "step therapy" and similar protocols; and (f) exclusion for failure to complete a course of treatment. These practices are to varying degrees central to the activities of MBHOs, and because this is only an "illustrative list," it could if left unchanged provide the basis for subjecting every activity of MBHOs to scrutiny under the parity standard.

ABHW strongly urges the Agencies to eliminate the NQTL category from the treatment limitations subject to the parity rule. There are five compelling reasons for the Agencies to reform the regulation in this way: (a) including the NQTL category exceeds the statutory authority and legislative intent behind MHPAEA; (b) NQTL practices cannot be meaningfully assessed under the "substantially all" and "predominant" tests mandated by Congress, and the alternate test of "comparable to, but not more stringent than" put forth by the Agencies has no basis in the Congressional mandate; (c) including NQTL practices undermines the reasoning and financial analyses announced by the Agencies themselves in the preamble to the IFRs; (d) the Agencies ignore the vast differences between mental health/substance use care and medical/surgical care by essentially forcing

MBHOs to adopt standards from the medical/surgical industry; and (e) the Agencies' approach acts to the detriment of patients by depriving MBHOs of the discretion to deliver optimal, cost effective care. Each of these reasons is explained below, and together, they provide ample basis for the Agencies to conclude that NQTLs should not be included as treatment limitations subject to MHPAEA.

A. Including NQTLs Exceeds the Statutory Authority and Legislative Intent of MHPAEA.

MHPAEA amended section 712(a) of ERISA (and the parallel provisions of the Internal Revenue Code and the Public Health Services Act) by adding new section 712(a)(3), which states that 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 added.] All of the examples used by Congress are limitations that would, under the regulations, fall within the category of "quantitative" limitations. As required by the statute, any other limitations subject to the parity requirement would have to be "similar" to these listed examples. The regulations, however, include nonquantitative limitations and at the same time recognize that the nonquantitative limitations are inherently different from the quantitative limitations and therefore require separate rules. To the extent that these two types of limitations are not "similar," there is no statutory basis for including the nonquantitative limitations in the regulation.

Even beyond the plain words of the statute and a logical reading of this provision, there is ample support for the conclusion that NQTLs should not be included in the IFRs. First, support for this "similarity" analysis can be found by examining the previous mental health parity provisions contained in ERISA § 712 prior to amendment by MHPAEA. Prior to MHPAEA, section 712(b) of ERISA (and the parallel provision of the Internal Revenue Code and Public Health Service Act) provided that the parity requirements were not to be construed "as affecting the terms and conditions (including cost sharing, limits on numbers of visits or days of coverage, and requirements relating to medical necessity) relating to the amount, duration, or scope of mental health benefits under the plan or coverage" except as specifically provided by the statute. With the exception of the medical necessity determination (which is addressed elsewhere in MHPAEA and the IFRs), these terms and conditions are all quantitative in nature, and are thus similar to the limitations included in section 712(a)(3), above. Recognizing that these quantitative limits would be subject to the new parity standards, Congress amended section 712(b)(2) to provide that MHPAEA should not be construed "as affecting the terms and conditions of the plan or coverage relating to such benefits under the plan or coverage, except as provided in subsection (a)." (Emphasis added.) There is no indication in either section 712(a) or (b) as amended by MHPAEA that Congress intended nonquantitative limitations to be included under the new parity rules. Indeed, the language at the end of section 712(b)(2) can only be read as a limitation on the application of the law and on the types of practices that must be subject to parity analysis. This limit on the reach of the parity requirement is essentially eliminated from the law under the IFRs, which would subject virtually all practices and procedures, quantitative or otherwise, to the parity standard.

Second, the legislative history of MHPAEA supports applying the parity standard only to the types of quantitative standards listed in ERISA § 712(a)(3). The Senate Committee Report discussing the Senate version of the bill contains the following statement:

> S. 558 does not prohibit group health plans from negotiating separate reimbursement or provider payment rates, or managing the provision of mental benefits in order to provide medically necessary treatments under the plan.

Sen. Rep. No. 110-53, 110th Cong., 1st Sess. (2007) at p. 3. The Senate Committee specifically indicated that separately negotiated provider payment and reimbursement rates would not be subject to the parity rule. It is

impossible to square this clear expression of intent with the inclusion of such items within the NQTL illustrative list. Further, with the exception of medical necessity issues (which as noted above are addressed elsewhere in the IFRs), the Committee report clearly indicates an intention that MHPAEA will not interfere with the management of mental health and substance use benefits. Such benefit management would not be possible if the practices listed as NQTLs are open to strict regulation, constant attack and endless second-guessing under the IFRs.

ABHW further notes that the IFRs stray far beyond the Congressional intention of benefit parity and appear to impose a "provider parity" regime. This occurs because the illustrative list of NQTLs includes such matters as provider payment and reimbursement rates and credentialing standards. The IFRs would essentially require an MBHO to match the reimbursement or credentialing approaches taken with respect to medical /surgical benefits. The result of this would be that reimbursement rates and credentialing standards would vary from plan to plan. Further, requiring credentialing to meet the parity requirement will inhibit the ability of MBHOs to contract with a wider variety of providers than is present on the medical/surgical side. An MBHO would also be unable to maintain a single standard for the providers with which it contracts, leading to widespread confusion and diminishing the ability of MBHOs to create efficient, effective provider networks. Section 712(a)(5) of ERISA, amended by MHPAEA, requires only that coverage for mental health and substance use disorders from out of network providers must be provided on par with out of network medical/surgical coverage. The statute in no way addresses the manner in which networks are created, nor the ability of MBHOs (or their counterparts on the medical/surgical side) to negotiate reimbursement rates.

ABHW recognizes that the MHPAEA is an extensive statute that will, by its terms, require adjustments in many of the practices of MBHOs. MHPAEA is not, however, intended to hamstring the use of mental health and substance use care management. By its terms and legislative history, MHPAEA is a statute with clear limits on the extent of the practices and procedures that it covers. By including NQTLs and subjecting them to parity analysis, the IFRs negate the structured language in MHPAEA and apply parity in ways never intended by Congress. For this reason, the NQTL provisions should be eliminated from the regulation.

B. The NQTLs Cannot Be Meaningfully Assessed Under the Standards Mandated by Congress.

A prime example of the fact that NQTLs have no place in the regulation issued pursuant to MHPAEA is that NQTLs cannot, as a practical or legal matter, be assessed under the standard mandated by Congress. The standard employed by Congress for the assessment of parity compliance is that a treatment limitation applied to mental health /substance use disorder benefits must not be more restrictive than the "predominant" limitation of that type applied to "substantially all" medical/surgical benefits ERISA § 712((A)(ii). These standards are adopted in section (c)(2)(i) of the IFRs, apparently with respect to all financial requirements and treatment limitations. This approach is clearly premised on the presence of numerically based requirements or limitations, since determinations of "substantially all" and "predominant" status require a mathematical determination of the portion of benefits actually subject to the limitation. These standards do not, however, work in the case of non-numeric limitations such as NQTLs which by definition defy numerical calculation. Several of the practices listed in the NQTL illustrative list (e.g., provider reimbursement, network credentialing, formulary development) are structural matters that apply to all activities of the MBHO rather than limitations on any treatment a health plan member may obtain. Other practices (e.g., step therapies, requirement to finish a course of treatment) are individual therapeutic tools available for all patients but only used on a case-by-case basis, so they are difficult to assess as a numerical matter.

It is apparent that the Agencies have recognized this difficulty. In a technical assistance meeting with ABHW and other interested industry members on February 19, 2010, representatives of the Agencies stated that the "substantially all" and "predominant" parity standards do not apply to NQTLs. ABHW agrees with this conclusion and indeed believes that this is only conceivably correct reading of the IFRs.

The necessary corollary of this conclusion is that there is no legislative support for the "special rule" (in section (c)(4)(i) of the IFRs) permitting NQTLs in the mental health/substance use area if they are comparable to, and applied "no more stringently" than, those in the medical/surgical area. While this standard may make sense

solely in view of the amorphous nature of NQTLs, it is not the standard established by Congress in MHPAEA. By including NQTLs within the coverage of the IFRs, the Agencies have (as discussed above) not only included business practices Congress did not intend to subject to parity analysis, but also have had to develop a new standard not included in the statute in order to make the regulation work. This unjustified enlargement of regulatory authority can lead to only one conclusion — the NQTL provisions should be removed from the regulation.

C. Including NQTL Practices Undermines the Reasoning and Financial Analyses Announced by the Agencies Themselves in the Preamble to the IFRs.

ABHW is pleased that the Agencies have recognized the extent to which the activities of MBHOs have contributed both to the expansion of services for patients with mental health and substance use disorders and the control of costs incurred for such services by plans and patients alike. As the Agencies noted:

> Since the early 1990s, many health insurers and employers have made use of specialized vendors, known as behavioral health carve-outs to manage their mental health and substance abuse benefits. These vendors have specialized expertise in the treatment of mental and addictive disorders and organized specialty networks of providers. These vendors are known as behavioral health carve-outs. They use information technology, clinical algorithms and selective contracts to control spending on mental health and substance abuse treatment. There is an extensive literature that has examined the cost savings and impacts on quality of these organizations. Researchers have reviewed this literature and estimated reductions in private insurance spending of 20 percent to 48 percent compared to fee-for-service indemnity arrangements. Also, it appears that the rate of utilization of mental health care rises under behavioral health carve out arrangements. The number of people receiving inpatient psychiatric care typically declines as does the average number of outpatient visits per episode.

75 Fed. Reg. 5410, 5422 (February 2, 2010)(footnotes omitted). Noting that OPM has encouraged the use of specialized MBHOs to implement parity for Federal employee health programs, the Agencies continued:

> Thus, parity in a world dominated by behavioral carve-outs has meant increased utilization rates, reduced provider fees, reduced rates of hospitalization and fewer very long episodes of outpatient care. Intensive treatment was more closely aligned with higher levels of severity.

Id. Specifically focusing on the fears that mental health parity could unduly increase costs, the Agencies quoted approvingly from a study in the New England Journal of Medicine:

> [The study] concluded that these fears were unfounded and that "parity of coverage mental health and substance abuse services, when coupled with management of care, is feasible and can accomplish its objectives of greater fairness and improved insurance protection without adverse consequences for health care costs.

Id. at 5424. (Emphasis added.)

These are but three examples of the many ways in which the Agencies depended on the benefit management activities of MBHOs both to justify the approach taken in the IFRs and to provide assurances that costs associated

with mental health parity will not be so large as to encourage plans and insurers to drop coverage altogether. Indeed, all of the cost data relied upon by the Agencies was developed in a marketplace where MBHOs were able to appropriately manage mental health and substance use benefits.

It is therefore ironic that the Agencies, by including NQTLs within the ambit of the IFRs, call into question the continued validity of the very practices they initially justify and condone. Section (c)(4)(i) of the IFRs provide that NQTLs must be assessed for parity compliance both as structured and as applied. This is illustrated in Example (1) in section (c)(4)(iii), where the Agencies conclude that concurrent review of mental health/substance use benefits, although clinically justified in certain individual instances, cannot be applied generally because it is not comparable to retrospective review applied for medical/surgical benefits. In other words, the use of these tools -- tools that have been instrumental in producing the favorable results on which the Agencies rely -- will be open to constant second-guessing, rendering their continued use problematic for MBHOs. If implemented, the inclusion of NQTLs in the regulations will therefore markedly change the mental health and substance use disorder care marketplace, rendering the Agencies' financial projections questionable at best.

Further, it is important to note that the Agencies have provided no cost estimates for the compliance efforts that will be necessitated by the inclusion of NQTLs in the regulations. As noted in Comment IV.D below, ABHW believes that the Agencies have grossly under-estimated the costs of complying with the financial requirement and quantitative treatment limitation provisions of the IFRs. Those costs would, in ABHW's view, pale by comparison to the costs attributable to compliance with the NQTL provisions of the IFRs. Each benefit plan will have to be abstracted, and under the approach taken in the IFRs, each such plan will likely involve all six of the IFRs benefit classifications and potentially at least three coverage units (self, self plus one, and family), so that even the simplest plan will actually involve 18 different benefit arrangements. Further multiplication occurs if the plan offers different benefit packages. See, e.g. 75 Fed. Reg. at 5418 (Examples regarding plan with AD, BD and CD combination packages). Thus, for even a relatively simple employer plan, more than fifty different variations would have to be assessed, and any changes would therefore require multiple state filings. Many of ABHW's members deal with one hundred or more such plans, and there is no total standardization involving plan terms, benefit structures, etc. Inconceivably, the Agencies have imposed the NQTL requirements without in any way assessing these costs or their effects on mental health and substance use disorder benefits and beneficiaries.

The only way to assure the integrity of the cost estimates and projections on which the Agencies have based this regulation is to eliminate NQTLs from the regulation.

D. The Agencies Ignore the Vast Differences Between Mental Health/Substance Use Care and Medical/Surgical Care by Essentially Forcing MBHOs to Adopt Incongruent Standards from the Medical/Surgical Industry.

The Agencies recognize that "not all treatments or treatment settings for mental health conditions or substance use disorders correspond to those for medical/surgical settings." 75 Fed. Reg. at 5416. However, by requiring that the mental health and substance use NQTLs must be "comparable to" limitations in the medical/surgical area, the agencies are inappropriately conflating the two areas, ignoring the fact that (at least with respect to NQTLs) requiring comparability is an attempt at equating apples with oranges. Essentially, this is a mandate that only those care management processes and procedures used for medical/surgical benefits can be employed in the mental health and substance use area, thereby eliminating any creativity for mental health treatment regarding, for example, strategies for recovery. Whereas quantitative limitations and financial requirements are easier to compare across the two types of benefits, NQTLs are not since they directly relate to the nature of the care provided. This lack of comparability means that, in most cases, the use of any NQTL with respect to mental health or substance use care will be suspect. Eliminating this inequity would resolve the issue of systemic lack of comparability between the treatment approaches and settings in the two benefit areas.

A simple example demonstrates this problem. Major depression and diabetes are both chronic illnesses and the treatment for both are similar up to a point. The care provider in both cases can prescribe appropriate medication, advocate for certain behavioral or lifestyle changes, and provide appropriate follow-up and

evaluation. On-going treatment for diabetes, however, is relatively straightforward. Response to treatment is easy to measure and there is little or no care management involved besides follow-up office visits and laboratory work. By contrast, treatment for depression is more complex and requires on-going management. In addition to the treatment tools noted above for both diabetes and depression, treatment for depression involves the use of psychotherapy, which does not equate with any other type of medical intervention. The psychotherapy process varies based on the practitioner's theoretical orientation (for example, cognitive behavioral, psychodynamic, family systems, etc.) and the presence of factors such as life stressors and other conditions that can affect the patient's progress. On-going, concurrent medical management is needed to discuss the treatment process and to ensure that the patient is responding. Without direct consultation with the treating psychiatrist (a process totally absent on the medical side), there is no way to assess the patient's progress. Indeed, it is not unusual to find that a patient diagnosed with major depression will, even after six months of seeing a psychotherapist several times a week, show no response to treatment. In such a case, medical management is necessary in order to advocate for addition interventions and/or second opinions.

Further, studies have indicated that management procedures that may be ineffective in a medical/surgical setting can improve both costs and outcomes in mental health and substance use disorder cases. For example, pre-certification has been show to have little effect in preventing inappropriate medical admissions.[1] However, the use of the same technique has resulted in decreases of up to fifty percent of inpatient behavioral health admissions, leading to the development and use of less restrictive services unique to the behavioral health setting, such as partial hospitalization, intensive outpatient services and straight outpatient sessions.[2]

The different ways in which mental health and substance use disorder care and benefits are provided must be respected if patients are to be well-served. Inclusion of NQTLs under the regulations provides a means by which use of these tools will be discouraged. The best way to preserve these salutary differences in approach is to eliminate NQTLs from coverage under the regulations.

E. The Agencies' Approach Acts to the Detriment of Patients by Depriving MBHOs of the Discretion to Assure that Behavioral Health Patients Receive Optimal, Cost-Effective Care.

The Agencies have noted that "[a] shift in source of treatment from primary care physicians to mental health professionals could lead to more appropriate care, and thus, better health outcomes." 75 Fed. Reg. at 5423. (Footnote omitted.) ABHW agrees with this assessment, but only if MBHOs are permitted to use their medical necessity criteria and management techniques to determine the best, most cost-effective care. The IFRs, if enforced as is and finalized without change, would preclude the beneficial outcome the Agencies anticipate. As presently structured, the IFRs accord insurers and benefit managers dealing with medical/surgical care unfettered discretion to develop new structures and different approaches, thereby assuring the most appropriate level and quality of care for the patients they insure. By contrast, the IFRs would have MBHOs and group heath plans react to what is done on the medical/surgical area, searching for a comparability of approach rather than concentrating on the needs of the patient.

Even where a MBHO wishes to vary from the medical/surgical model, the IFRs would permit it only "to the extent that recognized clinically appropriate standards of care may permit a difference." IFR at § (c)(4)(i). This is hardly a standard that provides any certainty, and once again reinforces the need for MBHOs to "look over their shoulder" any time they wish to employ proven methods that have no adjunct in the medical/surgical area. In order to be able to accomplish the goals of increased access to better mental health and substance use care, MBHOs must be provided with discretion, just as medical/surgical companies are provided with discretion, to apply appropriate approaches regardless of the approach used in the medical /surgical area. This can only be

---

1 Wickizer, T.M. & Lessler, D. (2002). Utilization Management: Issues, Effects and Future Prospects, *Annual Review of Public Health*, 23, 233-254.

2 Wickizer, T.M. & Lessler, D. (1998). Do Treatment Restrictions Impose Utilization Management Increase the Likelihood of Readmission for Psychiatric Patients? *Med Care* 36(6): 844-850.

accomplished if NQTLs are deleted from coverage under the regulations. Otherwise, it is likely that in an inpatient setting where MBHOs may not be allowed to do utilization review with the frequency that it currently does, a person may stay in a more restrictive setting for a longer period of time instead of being able to go to a less restrictive alternative.

F. Conclusion Regarding NQTLs

ABHW is aware that many mental health and substance use disorder advocacy groups have argued for the broad approach taken by the Agencies in the IFRs that would, as discussed above, adversely affect the ability of MBHOs to continue to provide the services that the Agencies themselves have both relied upon and praised. At the end of the day, however, the Agencies must recognize that MHPAEA, although revolutionary in many respects, is not a provider parity law, or an advocate parity law, or a trade association parity law. By its terms, it is limited; enforcing parity only with respect to financial requirements and quantitative treatment limitations related to health plan member benefits while specifically preserving other plan practices from parity analysis. There is nothing in the statute or the legislative history to indicate that Congress intended the kind of wholesale reconfiguring of the provision of mental health and substance use benefits attempted in the IFRs.

The NQTL provisions in the IFRs impose ambiguous standards on MBHOs, and deprive them of the ability to fashion care and benefits in light of the unique nature of mental health and substance use disorders. The only way to abide by Congress' intent, preserve the validity of the cost projections published by the Agencies and assure continued access to optimal, cost effective care in the wake of MHPAEA is to eliminate NQTLs from the regulation.

IV. Additional Comments.

A. The Agencies Should Not Address the Scope of Services Issue.

The preamble to the IFRs notes that "these regulations do not address the scope of services issue." 75 Fed. Reg. at 5416. The Agencies do, however, invite 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." Id. at 541617. ABHW believes that the Agencies were correct in not including scope of services within the coverage of the IFRs and they should maintain this approach in the final regulations.

The issue of scope of services (also referred to by the Agencies as "continuum of care") was raised by many of the respondents to the Agencies' Request for Information in April 2009. The Agencies chose to address the issue in connection with its explanation of NQTLs. As explained above, ABHW believes that the NQTL category should be eliminated from the statute. In such a case, there would be no basis in the regulation for including any discussion of scope of services.

Beyond that, however, ABHW believes that there is nothing in MHPAEA that would support regulating the scope of mental health and substance use services covered by a plan. As noted above, ERISA § 712(b)(2) preserves most plan provisions from the parity requirement unless specifically provided in section 712(a). This section by itself appears to discourage the expansion of regulation beyond the limits set in the statute and to leave issues such as scope of service determinations to each plan.

The legislative history also evidences Congress' intent that such issues should not be regulated under MHPAEA. The Senate Committee Report includes the following statement with respect to the application of the parity requirements:

> The bill would not require plans to offer mental health benefits, nor would it require that those plans cover all types of mental health services or ailments if the plan covered any mental health services or ailments.

Sen. Rep. No. 110-53, 110th Cong., 1st Session (2007) at p. 7. The House Energy and Commerce Committee Report includes similar language:

> In addition, this requirement does not change the current ability of an insurer or provider to determine medically necessary and appropriate care and treatment for their patients. It merely ensures that patients are not denied mental health coverage based on the specific disorder they have. For example, a person cannot be denied coverage by their health plan merely because they have autism. A plan may determine, however, whether a treatment is medically necessary or appropriate for a given person at a given time based on their individual situation.

(H. Rep. 110-374, Part 3, 110th Cong., 2nd Session (2008)).

Given this expression of Congressional intent, and in view of the Agencies' statement that it has not by these IFRs taken any position with respect to scope of services, the only way to read the IFRs is as permitting plans to cover some, but not all mental health and substance use disorder services or treatments. For example, section (c)(2)(ii) of the regulations states that, if mental health and substance use disorder benefits are provided in any classification under a plan, they must be provided under all classifications. Consistent with the statements of Congress and the Agencies, ABHW does not read this provision as stating that if any treatment is covered, then all treatments must be covered. Rather, this provision must mean that employers, group health plans, insurers and MBHOs continue to have the flexibility to design and administer mental health and substance use disorder benefits in a way that avoids mandating coverage for any particular treatment or approach.

Similarly, ABHW calls the Agencies' attention to the fact that many disorders straddle the line between medical/surgical and mental health/substance use characterization. As discussed in connection with Comments IV.B and C below, medical treatment is frequently provided in connection with a disorder that may have mental health or substance use disorder characteristics. If such medical treatment is deemed also to involve the provision of mental health or substance use disorder benefits, the Agencies would then be mandating coverage despite the clear command from Congress to the contrary.

Accordingly, ABHW believes the MHPAEA is not intended to require group health plans or group health insurance to cover any specific services or treatments, or settings of care, or to cover all services, treatments or care settings if the plan or insurance provide only limited coverage. To conclude otherwise would, in our view, result in a coverage mandate at odds with MHPAEA.

B. <u>The Definitions of Mental Health Benefits and Substance Use Disorder Benefits Should be Revised to Refer Only to the Terms of the Plan and Applicable State Law.</u>

ERISA § 712(e)(4) and (5) as amended by MHPAEA provide that the terms "mental health benefits" and "substance use disorder benefits" are to be defined by reference to "the terms of the plan and in accordance with applicable federal and state law." Section (a) of the IFRs, however, expands this reference to include the Diagnostic and Statistical Manual (DSM), the International Classification of Diseases (ICD) or other similar generally accepted medical standard. The Agencies' stated reason for this divergence from a clear statutory standard is its fear that plans may purposefully misclassify a mental health or substance use disorder "in order to avoid compliance with the parity requirements." 75 Fed. Reg. at 5412.

The Agencies' approach to this issue suffers from two problems. First, the statutory provision cited above specifically notes the basis on which these definitions must be determined – the provision of the plan and applicable state and federal law. Prior versions of the bills that became MHPAEA contained references to DSM and other standards, but those standards were rejected by the Senate and did not find their way into the final statutory provision. See Sen. Rep. No. 110-53, 110th Cong. 1st Sess (2007) at p. 3.

The second problem with the IFR approach is the inaccuracy of the Agencies' underlying assumption that reference to state law and the generally accepted medical standards will in all cases produce a consistent result.

Many state laws require that certain disorders (including, for example, autism and eating disorders) must be covered by health plans as medical disorders. Multiplying the number of standards that a plan must comply with does not assure accurate coverage; rather it only adds to the confusion in an already confusing area. The standard adopted by Congress does not permit the interpolation of any standards other than the relevant plan language and applicable federal and state law. Those are the only standards that would apply in the case of determination of whether a disorder was medical in nature. If the Agencies are interested in actual parity, they would allow the same standard to apply to the definitions of mental health and substance use disorders and benefits.

C. The Agencies Should Clarify that Inclusion of Drugs for the Treatment of Mental Health or Substance Use Disorders Under a Prescription Drug Plan, or the Provision of Medical Treatment in Connection with a Mental Health or Substance Use Disorder, Does Not Constitute the Provision of Mental Health or Substance Use Disorder Benefits for the Purposes of Applying the Parity Requirement.

Section (c)(2)(ii) of the IFRs contains the six-classification approach adopted by the Agencies for the application of the general parity standard. This section further notes that if a plan provides mental health and substance use disorder benefits in any one of those categories, it must provide such benefits in all categories in which medical/surgical benefits are provided. This provision presupposes that it is easy to distinguish between the two types of benefits. However, there are many situations in which a type of benefit or care straddles this distinction, leading to the possibility that a plan may be viewed as providing mental health or substance use disorder benefits when it in reality does not.

The prime situation exemplifying this concern occurs with respect to prescription drug coverage. Many prescription drug plans include coverage for drugs that are used for the treatment of mental health or substance use disorders. In many cases, the coverage of these drugs is unrelated to any other coverage for any other kind of mental health or substance use treatment. Indeed, these drugs are often prescribed by medical doctors (including primary care physicians) in an exclusively medical care setting. ABHW is concerned that, because the Agencies have determined that prescription drugs are one of the six benefit classifications to which the parity rule is applied, the mere inclusion of drugs commonly prescribed in connection with mental health or substance use disorders in a formulary would cause a plan that does not otherwise cover such disorders to be subject to the parity rules. Such formularies are, as noted above, currently included under the IFR as NQTLs. ABHW fears that the ambiguities surrounding parity compliance for NQTLs would lead such plans to drop coverage for such prescriptions in order to avoid subjecting their entire plan to the parity requirements.

Another example occurs in the treatment of autism. Autism is frequently treated and defined as a medical condition, and there are certain specific medical treatments that are frequently used in connection with autism regardless of how the disorder is characterized. However, because autism is also often viewed as a mental health disorder, provision of these treatments could, via the operation of section (c)(2)(ii), subject an entire plan to parity analysis when the plan otherwise does not provide coverage for mental health or substance use disorders.

A third example occurs because emergency treatment is one of the six listed classifications. A person who has attempted suicide will in all likelihood be brought into an emergency room. The treatment provided in the emergency room will probably involve both medical/surgical and mental health or substance use disorder treatment, at least in the short term. This is especially true in the cases where the use of drugs or alcohol is involved. As currently written, section (c)(2)(ii) could be applied so that this provision of needed emergency care would result in the requirement that all classifications under that plan must provide mental health and substance use disorder coverage.

ABHW fears that the over-expansiveness of this provision in the IFRs would, if left unchanged, cause plans to drop certain types of coverage, or lead to the exclusion of specified treatments in order to avoid the need to comply with the regulations. Such a result would be disastrous to patients. Accordingly, ABHW believes that the six classifications contained in the regulation should be modified so that (1) prescription drug plans and emergency care are included under the parity requirement only when mental health and substance use disorders are covered under at least one other classification within the same group health plan; and (2) the provision of medical treatment in connection with a mental health or substance use disorder will not have the effect of causing the plan to be covered by the parity requirement.

D. The Agencies Should Permit Separate but No More Restrictive Deductibles for Mental Health/Substance Use Disorder Benefits and Medical/Surgical Benefits.

The Agencies (in section (c)(3)(v) of the IFRs require that plans providing both mental health/substance use benefits and medical/surgical benefits must have a unified deductible rather than separate but no more restrictive deductibles as has been the common practice in the industry. The Agencies take this position despite their conclusion that "the statute can be interpreted to support either position." 75 Fed. Reg. at 5415. Purportedly, the Agencies were most concerned that individuals needing both kinds of care would be disadvantaged by having to fulfill two deductibles. Further, the Agencies rejected voluminous cost data submitted by the behavioral health and wellness industry about the costs that would accompany the imposition of the unified deductible approach.

It is difficult to identify the relevance of the Agencies' anecdotal concern about the effect of the separate but no more restrictive deductible on individual cases. Entities currently imposing separate deductibles are unlikely to switch to a cumulative unified deductible without an increase in the overall deductible level. Anecdotal evidence provided by ABHW members already indicates that this is occurring, particularly in situations in which the previous separate mental health and substance use disorder deductible was lower than the medical/surgical deductible. This would clearly work to the disadvantage of individuals who need only one type of service. Before the IFRs, an individual could satisfy the separate and lower deductible without having to worry about the deductible for the other type of care. If the IFR goes into effect without change, such individuals would have to incur greater out of pocket expenses to access the same care and as a result may seek less treatment. In other words, when viewed from the point of view of the individual patient, the advantages and disadvantages of the single or separate but no more restrictive deductibles will depend solely on the health care situation of that individual.

Of more concern to ABHW is that the Agencies have chosen a course of action that imposes a cost when there is no discernable resulting benefit. ABHW, along with many others in the behavioral health field, submitted estimates of the costs that would be necessitated by a shift to a cumulative deductible system, and we hereby incorporate by reference the estimates provided in our RFI response. Even under the lower cost estimates adopted by the Agencies, the shift to a single deductible will impose millions of dollars in additional costs industry wide, along with an overwhelming administrative burden.

This cost and administrative burden has been drastically under-estimated by the Agencies. Even today, the reconfiguration of benefit plans to adopt this unified model is a manual process since most benefit plan information is still received in paper form. As such, any change (let alone changes of the magnitude required by the IFRs) will be a labor-intensive process. Separate exchanges of accumulator data will need to be established for each vendor, and because each vendor's relationship with each plan is unique, file identification must occur at the plan level. Complex, multi-vendor feeds are required where (as is common) a plan has multiple medical, mental health and prescription drug vendors. Further complexity is added if (as is also common) there are multiple coverage units and claims platforms involved. Unlike with HIPAA (where the Agencies moderated a process that took several years leading to a standardized information exchange process) there is no standardized accumulator file layout for use between health plans. As a result, the format of each exchange must be negotiated between and among plans and vendors. This lack of a standard file layout also means that there will be none of the cost savings touted by the Agencies as a result of the use of batch

processing. ABHW understands that in the case of a plan with three vendors, establishing the necessary interfaces will require on average between 300 and 545 hours per plan customer.

Additional costs will be involved in on-going audit, reconciliation and compliance efforts. Even here, the Agencies' cost estimates are extremely low. For example, the Agencies estimated that it would take a lawyer one-half hour at an hourly charge of $120/hour to complete a compliance review and make any necessary document changes required by these regulations. This assumes not only an unrealistically low hourly rate, but also a level of document standardization that simply does not exist in the real world. Indeed, because of the confusing nature of the IFRs it would take substantially longer to determine what the compliance standards are and how to apply them than the one-half hour the Agencies have posited as the only time needed to complete a compliance review.

It is difficult to identify any benefit that will result from these additional costs. The Agencies have already noted that both approaches are fully supportable by the statute. As noted above, the advantages or disadvantages of a unified deductible will vary from person to person. The net effect of the IFRs will most likely be to subject the vast majority of plan participants who never require mental health or substance use disorder benefits to higher deductibles and those who only access the behavioral health benefit will also face higher costs. Although the Agencies have indicated their belief that the policy behind MHPAEA is to assure that mental health and substance use disorders are viewed as an integral part of the health care system, it is difficult to see how the unified deductible, with its increased costs and uncertain practical advantages, in any way relates to that goal. Indeed, the primary goal of MHPAEA is parity, and the easiest way to achieve that in this area is to permit plans the leeway to impose either a unified or separate but no more restrictive deductible. This is the easiest and least invasive way to place both types of benefits on par with each other.

E. The Agencies Should Amend the "Substantially All" Test to Permit Combinations of All Types of Cost-Sharing as a Single Financial Requirement.

As currently drafted, section (c)(3)(i)(A) of the IFRs states that if no single financial requirement applies to "substantially all" (i.e., two-thirds of) medical/surgical benefits, then no financial requirement of the same type may be applied to mental health and substance use disorder benefits. Because the regulation further provides for comparison only to the same "type" of financial requirement, co-payments may only be compared to co-payments, deductibles to deductibles, etc. This approach creates the anomalous result that, on the medical/surgical side, all benefits could be subjected to some sort of financial requirement, while no financial requirements at all could be placed on mental health or substance use benefits. This would occur, for example, if 55 percent of the medical surgical benefits are the subject of co-payments, and another, different 45 percent to co-insurance. In such a case, all of the medical/surgical benefits are the subject of some kind of cost-sharing. However, because no single type of cost sharing applies to two-thirds of the medical surgical benefits, no cost sharing at all would be permitted with respect to mental health and substance use disorder benefits. If the IFRs are not changed in this respect, they will be imposing "hyper-parity" on the provision of mental health and substance use disorder benefits.

ABHW emphasizes that this is not a hypothetical problem. This problem is especially acute with respect to out-patient behavioral benefits. ABHW understands that one of its members faces a situation in which approximately 1 million fully insured members, in addition to self-insured members, will require plan design changes if this problem is not solved.

The Agencies can rectify this by allowing for the combination of all financial requirements in order to determine whether the substantially all standard has been met. Once the standard is met, the plan in question would then be able to satisfy the parity standard by adopting the same limitations for mental health and substance use disorder benefits as are applied in the medical/surgical arena. As stated previously in other comments included in this letter, parity entails equality of treatment. Adopting ABHW's proposal in this respect will assure such equality going forward.

F. Inclusion of NQTLs Under the IFRs Will Have a Catastrophic Effect on Medicaid in Terms of Both Cost and Quality of Care.

The Centers for Medicare and Medicaid Services (CMS) has stated that, although MHPAEA does not apply directly to Medicare or Medicaid, the standards under MHPAEA will apply in the Medicaid context "insofar as a State's Medicaid agency contracts with one or more managed care organizations (MCOs) or Prepaid Inpatient Health Plans (PIHPs) to provide medical/surgical benefits as well as mental health or substance abuse disorder benefits . . . ."[3] For the past twenty years, MBHOs have been engaged under state Medicaid programs to assure the provision of appropriate, cost-effective mental health and substance use disorder benefits. These management activities have not only improved the quality of care for this population, but also have enabled states to exercise crucial controls on the costs involved in providing this care.[4] These advances have occurred while at the same time there has been little or no management of ambulatory medical/surgical benefits under Medicaid.

ABHW notes that the IFRs do not by their terms apply to Medicaid managed care organizations. However, we believe that there is a significant likelihood that CMS, in adopting regulations for such organizations, will rely on the work already done by HHS and the other agencies in issuing the IFRs. As a result, ABHW feels it is necessary to note that inclusion of NQTLs in the IFR will provide a means for undoing all of this progress. The absence of medical/surgical ambulatory care management under Medicaid means that employment of managed care techniques for mental health or substance use disorder Medicaid benefits will be difficult at best under the approach taken in the IFRs. This highlights the differences between medical/surgical care and mental health and substance use disorder treatment in the starkest way possible. The lower income population covered by Medicaid is frequently the population most in need of the types of services provided by behavioral health organizations, especially in terms of treatment design and follow-up. Such services are all implicated by the vague and expansive nature of the NQTLs covered by the IFRs, leading to the likelihood that use of such techniques will be greatly diminished.

The disincentive to use managed care techniques also poses significant cost issues to state Medicaid programs. It is common knowledge that states are currently searching for any and all ways to control Medicaid costs in the current economy. As noted above, mental health managed care under Medicaid has resulted in significant cost savings for the states. NQTLs, however, include virtually all mental health care management techniques currently in use. The IFRs, if finalized without change and applied to Medicaid MCOs by CMS, will essentially rob the States of the ability to control the costs of mental health and substance use benefits in any meaningful way. In light of this, and especially because the Agencies have provided no cost estimates as to the effect of including NQTLs in the regulations, ABHW urges that the Agencies remove this category from the regulations.

* * * *

ABHW is pleased to have had the opportunity to provide the above detailed comments on the IFRs. Thank you for this opportunity and your consideration of our concerns. Please feel free to contact me at greenberg@abhw.org or (202) 756-7726 if you have any questions.

Respectfully submitted,

Pamela Greenberg, MPP
President and CEO

---

[3] CMS Letter to State Health Officials (November 4, 2009) at http://www.cms.hhs.gov/SMDL/downloads/SHO110409.pdf .

[4] E.g., "Mental Health Costs and Access Under Alternative Capitation Systems in Colorado," Health Services Research (April 2002), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1430372/ (surveying literature and analyzing cost savings in Colorado program); "Medicaid and Mental Health: Be Careful What You Ask For," 22 Health Affairs 101, 109 (January/February 2003) (use of managed behavioral health care in Medicaid programs results in significantly lower costs, and in many cases, greater access to higher quality treatment).