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 Madame:

ValueOptions, Inc. (VO) 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.

VO is the nation's leading privately-held managed behavioral health organization (MBHO). VO provides mental health, substance use, employee assistance, disease management, and health and wellness services to over 23 million people in both the public and private sectors. VO has over 25 years experience in the field, and has been an early and consistent supporter of

240 Corporate Boulevard | Norfolk, VA 23502 | www.valueoptions.com

mental health and addiction parity.

VO recognizes the need for regulations to provide the guidance necessary for implementation of Congress' intention in enacting the MHPAEA. However, the IFRs reflect a fundamental misunderstanding of the role of and tools utilized by MBHOs. The IFRs go beyond the scope of both MHPAEA's terms and Congressional intent, undermining the structures and procedures that VO and other MBHOs have developed and successfully applied.

VO is a member of the Association for Behavioral Health and Wellness (ABHW). VO is aware of the comments to the IFRs being submitted by ABHW and joins in them. VO's individual comments will focus on the Nonquantitative Treatment Limitations (NQTLs) provisions of the IFRs.

I. The Parity Requirement Should Not Apply to So-Called "Nonquantitative" 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 abuse care may not apply any financial requirement or treatment limitation for mental health/substance abuse 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 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 all central to the activities of behavioral health and wellness companies, and because this is only an "illustrative list," it could if left unchanged provide the basis for subjecting every activity of a behavioral health and wellness organization to scrutiny under the parity standard. The Agencies should eliminate the NQTL category from the treatment limitations for five reasons: (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; (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 abuse care and medical/surgical care by essentially forcing behavioral health and wellness companies to adopt medical/surgical standards; and (e) the Agencies' approach will harm patients by depriving

behavioral health and wellness companies of the discretion to coordinate optimal, cost effective care.

A. The NQTLs Exceed 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 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 prior mental health parity provisions contained in ERISA § 712 prior to amendment by MHPAEA. Prior to MHPAEA, section 712(b) of ERISA (and the parallel provisions 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 limits 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 limitation 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 type of quantitative standards listed in ERISA § 712(a)(3). The Senate Committee Report discussing the Senate version of the bill that ultimately became MHPAEA 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 abuse benefits. Such management would not be possible if the practices listed as NQTLs are open to constant attack and second-guessing under the IFRs.

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

The standard employed by Congress for the assessment of parity compliance is that a treatment limitation applied to mental health /substance abuse 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. They work well in the case 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 behavioral health and wellness company rather than limitations on treatment.

It is apparent that the Agencies have recognized this difficulty, for the IFRs contain a "special rule" (in section (c)(4)(i)) permitting NQTLs in the mental health/substance abuse 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 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 is an unjustified enlargement of regulatory authority.

C. Including NQTL practices undermines the reasoning and financial analyses announced by the Agencies themselves in the preamble to the IFRs.

The Agencies have recognized the extent to which the activities of behavioral health and wellness have contributed both to the expansion of services for patients with mental health and substances abuse 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 behavioral health and wellness companies 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: study concluded that these fears were unfounded and "that parity of coverage of 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.))

All of the cost data relied upon by the Agencies was developed in a marketplace where behavioral health and wellness companies were able to manage mental health and substance abuse benefits. Including NQTLs in the IFRs calls into question the continued validity of the

very practices on which they rely. 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 abuse 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 behavioral health and wellness companies. If implemented, the inclusion of NQTLs in the regulations will therefore markedly change the mental health and substance abuse care marketplace, rendering the Agencies' financial projections questionable at best. The only way to assure the integrity of the estimates and projections on which the Agencies have based this regulation is to eliminate NQTLs from the regulation.

D. <u>The Agencies ignore the vast differences between mental health/substance abuse care and medical/surgical care by essentially forcing behavioral health and wellness companies to adopt standards from the medical/surgical industry.</u>

The Agencies recognize that "not all treatments or treatment settings for mental health conditions or substance abuse disorders correspond to those for medical/surgical settings." 75 Fed. Reg. at 5416. However, by requiring that the mental health and substance abuse NQTLs must be "comparable to" limitations in the medical/surgical area, the agencies mandate that only those care management processes and procedures used for medical/surgical benefits can be employed in the mental health and substance abuse area. Whereas quantitative limitations and financial requirements are easier to compare across the two types of benefits, NQTLs are not since they 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 abuse 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.

E. <u>The Agencies' approach acts to the detriment of patients by depriving behavioral health and wellness companies of the discretion to deliver optimal, cost effective care.</u>

The IFRs accord care providers, insurers and benefit managers dealing with medical/surgical care discretion to develop new structures and different approaches, thereby assuring the most appropriate level and quality of care for their patients. By contrast, the IFRs would have behavioral health and wellness companies and professionals 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.

Unlike medical-surgical care, there are no governmentally endorsed targets for acceptable

hospital courses of treatment in behavioral health. Unlike medical-surgical care, there is a broad range of beneficial alternative settings to hospital care in behavioral health. There is greater availability and practitioner discretion in behavioral health than in medical-surgical care. These facts require specific comprehensive medical management to assure that each patient receives effective, efficient care in settings most appropriate to his or her individual needs.

Where a behavioral health and wellness company or professional wishes to vary from the medical/surgical model, the IFRs permit it only "to the extent that recognized clinically appropriate standards of care may permit a difference." IFR at § (c)(4)(i). This standard is vague and forces medical management by exception rather than by a system designed for behavioral health. In order to be able to accomplish the goals of increased access to better mental health and substance abuse care, behavioral health and wellness companies and professionals must be treated on par with their counterparts in the medical/surgical area. This can only be accomplished if NQTLs are deleted from coverage under the regulations. It is likely that in many cases this approach, it will force unnecessarily restrictive care because MBHOs will be unable to intervene concurrently to suggest alternatives to inpatient hospitalization. Ironically, it may also force heavy emphasis on retroactive review for medical necessity needlessly causing a significant increase in retrospective medical necessity denials and the attendant financial disruption to patients and providers. A tailored system of behavioral health medical management prevents that result in addition to assuring effective and efficient treatments.

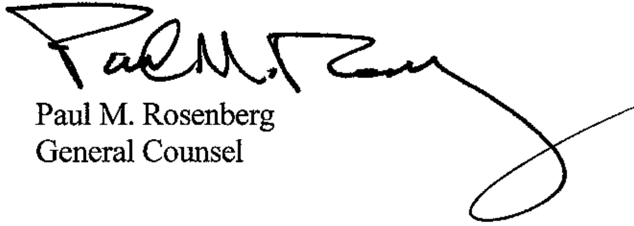
Conclusion

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 abuse benefits attempted in the IFRs.

The NQTL provisions in the IFRs impose ambiguous standards on behavioral healthy and wellness companies, and deprive them of the ability to fashion care and benefits in light of the unique nature of mental health and substance abuse 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.

VO is pleased to have had the opportunity to provide the above comments on the IFRs. Thank you for this opportunity and your consideration of our concerns. Please feel free to contact me at paul.rosenberg@valueoptions.com or (757) 459-5498.

Respectfully submitted,



Paul M. Rosenberg
General Counsel