# CLIENT ALERT

## Interim Final Mental Health Parity and Addiction Equity Act Regulations Issued

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On February 2, 2010, the Departments of Labor, Treasury and Health and Human Services jointly released interim final regulations implementing the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 ("MHPAEA"). (We previously discussed MHPAEA in our December 10, 2008 Employee Benefits Alert.) Although MHPAEA required that regulations be issued in October 2009, these interim final regulations are the first regulations to be issued implementing MHPAEA.

The new interim final regulations replace the existing Mental Health Parity Act regulations issued in 1997, largely incorporating those regulations (with modifications to include substance use disorder benefits), and adding several important new rules. As with the 1997 Mental Health Parity Act regulations, enforcement of the new MHPAEA regulations will at least in part be through imposition of an excise tax on noncomplying plans and insurers. The new regulations go into effect on April 5, 2010, although most of the rules governing health plans and insurers will apply only for plan years beginning on or after July 1, 2010 (with a special effective date applicable for certain collectively-bargained plans). For the period between the October 3, 2009 effective date of MHPAEA and the date that the regulations become effective with respect to a plan, the preamble to the regulations states that the Departments "will take into account good-faith efforts to comply with a reasonable interpretation of the statutory MHPAEA requirements with respect to a violation that occurs before the applicability date . . . of these regulations." The preamble, however, notes that the Departments' view of such good-faith efforts does not prevent participants or beneficiaries from bringing a private action alleging a violation of MHPAEA.

Among the most important issues raised and concepts introduced by the new regulations are the following:

**(1) The "Interim Final" Nature of the Regulations.**
Most regulations are issued first in proposed form and then only take effect after the public has submitted comments and the agencies have considered those comments and issued a final rule. In a controversial move, the agencies in the present case decided to publish the MHPAEA regulations as "interim final rules." This means that, although the public will have a chance to submit comments through May 3, 2010, the regulations' effective date (April 5, 2010) occurs before the close of the comment period. The agencies would then be able to consider the comments and make any changes to the regulation going forward. The agencies have justified this process as a response to the need for prompt guidance regarding mental health parity. This approach, however, also means that some new and difficult rules will have almost immediate applicability without a thorough public analysis. We expect that this issue will be an important one as affected entities and industries contemplate compliance efforts and consider filing comments.

**(2) Application of the Parity Rules – Coverage Issues.**
Before discussing the actual parity rules, the regulations and the preamble address the manner in which the rules are to be applied to group health plans and group health insurance policies. This involves the creation of a number of new concepts, as detailed below:

**(a) Treatment Limitations; No Mandated Coverage:** The regulations define *Treatment Limitations* to include both *quantitative treatment limitations* (a limitation that is expressed numerically, such as an annual limit of 30 outpatient visits) and *nonquantitative treatment limitations* (a limitation that is not expressed numerically, but otherwise limits the scope or duration of benefits for treatment; nonquantitative treatment limitations are discussed in more detail below). The regulations specifically provide that a permanent exclusion of all benefits for a specific condition or disorder is not a treatment limitation. As a result, a plan could totally exclude coverage for mental health and/or substance abuse disorders and not violate MHPAEA. Once a plan covers such benefits, however, such coverage must be in parity with the coverage for medical/surgical benefits under the same plan.

**(b) Parity requirements apply to each "Coverage Unit."** The regulations introduce the term *Coverage Unit* to refer to how a plan groups individuals for purposes of determining benefits, premiums or contributions, i.e., coverage for a single participant, for a participant plus a spouse, for a family, etc. Parity requirements are then applied to each coverage unit offered under the plan, but do not require uniformity among different coverage units. For example, if the single participant "coverage unit" limited annual doctor's office visits to 30 per year for both medical/surgical and mental health care, and the limitation for participant plus family coverage unit was 90 visits per year for both types of care, this differential would not result in a violation of the regulations.

**(c) Parity requirements are to be applied and compared using six benefit classifications.** One source of confusion after passage of MHPAEA was the manner in which plans and insurers would be required to compare medical/surgical and mental health/substance abuse coverage across different classes of benefits for parity purposes. The regulations specify that there are only six classes of benefits that may be used for the purpose of parity comparisons: (i) inpatient, in-network; (ii) inpatient, out-of- network; (iii) outpatient, in-network; (iv) outpatient, out-of-network; (v) emergency care; and (vi) prescription drugs. Parity comparisons are required to be made within each classification offered by the plan or policy. While the regulations permit plans leeway in defining the types of benefits that fall within each classification, the regulations emphasize that any such definitions must be applied uniformly to both medical/surgical and mental health/substance abuse care within each such classification. Interestingly, this provision would prohibit the distinction between "specialists" and "non-specialists" currently used in many plans because such a distinction is not one of the six classifications permitted under the regulation for parity purposes.

**(d) Mental Health and Substance Abuse Disorder Benefits Must Be Defined Consistent with Independent Standards**: Under the regulations, *Medical/Surgical Benefits*, *Mental Health Benefits* and *Substance Abuse Disorder Benefits* are generally defined by reference to the terms of the health plan providing benefits. Mental health benefits and substance abuse disorder benefits, however, also (1) are defined by reference to applicable Federal and State law, and (2) must be defined "consistent with generally recognized independent standards of current medical practice." Examples of the applicable standards are the most current version of the Diagnostic and Statistical Manual of Mental Disorders ("DSM"), the most current version of the International Classification of Diseases ("ICD"), or a state guideline. This definition raises a question as to how plans and insurers are to reconcile conditions and labels that are creations of state legislation, such as Biologically-Based Mental Illnesses and Severe Mental Illnesses, when such conditions and terms are not also present in the DSM, ICD or other source.

**(3) Specific Parity Requirements.**
Having established the focus of the parity inquiry, the regulations establish specific rules that must be applied in order to comply with MHPAEA. The following are the most important of these rules:

**(a) Parity Requirements Apply to the "Predominant" Financial Requirements and Treatment Limitations Applicable to "Substantially All" Benefits**. The interim final regulations provide that plans and health insurance issuers are prohibited from applying any financial requirements (including deductibles, copayments, coinsurance and out-of-pocket maximums) or treatment limitations (including annual, episode, and lifetime day and visit limits) to mental health or substance use disorder benefits that are more restrictive than the "predominant" financial requirement or treatment limitation applied to "substantially all" medical/surgical benefits under the plan.

"Predominant" is defined under the regulations to mean the most common or frequent of a type of financial requirement or treatment limitation. The regulations specify that if a financial requirement or treatment limitation applies to more than one-half of the medical/surgical benefits in that classification, it will be considered to be predominant. Even if no single financial requirement or treatment limitation exceeds the one-half threshold, however, the regulations provide rules for combining multiple levels of the same type of requirement or limitation until they exceed the one-half level. Alternatively, the regulations permit plans to treat the least restrictive level of financial requirement or treatment limitation as being the predominant level if the one-half threshold is not otherwise exceeded. Finally, the regulations specify that a separate determination must be made to determine the predominant level for each coverage unit.

"Substantially all" is generally defined to mean at least two-thirds of the benefits in a classification. If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of the medical/surgical benefits in a classification, it cannot be applied to mental health or substance use disorder benefits in that classification.

**(b) Special Rule for Nonquantitative Treatment Limitations**: As noted above, the regulations provide that treatment limitations can be either quantitative or nonquantitative in nature. Because nonquantitative limitations cannot be assessed numerically, the agencies felt it was necessary to include a special rule regarding parity in the application of such limitations. The regulations generally prohibit the imposition of any nonquantitative treatment limitation to mental health or substance abuse disorder benefits unless certain requirements (discussed below) are met. The regulations list several examples of nonquantitative treatment limitations, including medical management standards, prescription drug formulary design, step therapy protocols and determination of usual, customary and reasonable amounts, among other examples.

The regulations provide that any processes, strategies, evidentiary standards or other factors used in applying a nonquantitative limitation to mental health or substance abuse benefits must be comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in applying the limitation with respect to medical/surgical benefits. The regulations provide one exception to this general rule, namely that variations may be permitted to the extent that recognized clinically appropriate standards of care may allow such a difference. Finally, the regulations note that these requirements apply not only to the terms of the plan as written, but also to the actual operation of the plan.

The regulations' provisions regarding nonquantitative limitations may make it more difficult to apply managed care practices to mental health and substance abuse care. The agencies specifically state in the preamble that they expect managed care practices to continue to help reduce costs of care. Yet the preamble also states that the agencies are not making any findings regarding the differences in the type and nature of treatment needed for medical/surgical care on the one hand and mental health/substance abuse care on the other. In reality, the decision not to address this distinction essentially requires that the two different types of treatment must be treated the same. For example, the regulations address situations involving plans that require participants to exhaust employee assistance program ("EAP") benefits before they may become eligible for the major medical program's mental health or substance use disorder benefits. EAP benefits frequently assist employees and help them avoid the need for more extensive mental health treatment. The agencies, however, chose to treat such a requirement as a "gatekeeper" requirement akin to the pre-certification requirement imposed for in-patient medical treatment. Under the regulations, using the EAP as a gatekeeper is a nonquantitative treatment limitation subject to the parity requirements. If similar gatekeeping processes with a similar exhaustion requirement are not applied to medical/surgical benefits, the EAP-as-gatekeeper requirement would violate the parity rules.

**(c) Special Parity Requirements Applicable to Prescription Drug Benefits**: The interim final regulations provide a special three-part rule for applying the general parity requirements to prescription drug benefits. First, a prescription drug program will have to satisfy the nonquantitative treatment limitation requirements discussed above. Application of those standards would be especially important with respect to decisions regarding which drugs to include when designing a program's formulary. Second, if a program imposes different financial requirements on different tiers of included prescription drugs (for example, different copayments or reimbursement rates), such limitations must be based on "reasonable factors" (i.e., cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up). Finally, where different levels of financial requirements are imposed, they must be applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or mental health or substance use disorder benefits. This last factor may prove particularly challenging in the case of drugs prescribed solely for the treatment of mental health or substance abuse disorders. Generally, however, if the financial requirements and treatment limitations imposed with respect to drugs prescribed for medical/surgical conditions are the same as the financial requirements and treatment limitations imposed with respect to drugs prescribed for mental health conditions and substance abuse disorders, the parity requirements will be met.

**(d) Combined Deductible**: The preamble addresses whether a plan may have deductibles that accumulate separately for medical/surgical benefits, mental health benefits and substance use disorder benefits, or whether under MHPAEA a plan may only require participants to satisfy a single combined deductible that includes both medical/surgical benefits and mental health and substance abuse disorder benefits. The preamble notes that the language of the statute can be interpreted to support either position, because the statute does not specifically *preclude* either interpretation. The regulations, however, prohibit separately accumulating deductibles as being contrary to the policy goals behind MHPAEA. Therefore, under the regulations, a plan may not apply separate cumulative financial requirements or cumulative quantitative treatment limitations to mental health or substance use disorder benefits. For example, any deductibles for such benefits may only be combined with the deductibles for medical/surgical benefits.

**(e) Employer Plans Must Be Combined for Parity Purposes**. The preamble notes that, because the regulations apply only to plans that provide both mental health or substance abuse disorder benefits *and* medical/surgical benefits, employers could potentially seek to circumvent the regulations by adopting separate medical/surgical plans and mental health/substance abuse disorder plans. To prevent this abuse, the regulations include a rule that combines the medical care benefits provided by an employer or employee organization for parity purposes. Specifically, if an employee can simultaneously receive coverage for medical/surgical benefits and coverage for mental health and/or substance abuse disorder benefits, then any available combination of these coverages will be considered for purposes of the regulations to be a single group health plan. For example, if an employer offers three different medical/surgical benefit packages (A, B, and C) and separately offers a mental health and substance abuse disorder benefits package (D), then the parity requirements must be satisfied as to A and D as a group, B and D as a group and C and D as a group.

.**(4) Additional Issues.**

**(a) New Disclosure Requirements**: The interim final regulations implement two new disclosure requirements contained in MHPAEA. First, the regulations require that a plan must, upon request, provide a participant, beneficiary or contracting provider with a copy of the plan's criteria for medical necessity determinations relating to mental health or substance abuse disorder benefits. (The agencies specifically requested separate comments regarding this general disclosure requirement.) Second, the regulations provide that the plan must provide a participant or beneficiary with the reason for any denial of reimbursement or payment for services with respect to mental health or substance abuse disorder benefits. The regulations state that, for any ERISA-covered plans, this disclosure must be in a form and manner consistent with the ERISA claims procedure regulations. For plans that are not covered by ERISA, the regulations provide that compliance with the ERISA claims procedure regulations will satisfy this disclosure requirement.

**(b) Exemptions.** The regulations provide two exemptions to the imposition of the parity requirements. First, plans of small employers (i.e., employers with fewer than 50 employees on business days during the preceding calendar year) are exempt. Second, plans may receive an exemption if they can demonstrate that compliance with MHPAEA and the regulations will result in an increase in costs above a threshold amount. The increased cost exemption, however, can only be claimed after a full year of compliance with the parity requirements, and can only be claimed for one year, at which point a new full year of compliance is mandated. Therefore, at best the increased cost exemption can only be claimed in alternating plan years. The agencies have indicated that they intend to issue additional guidance regarding such exemptions in the near future.

**(c) Sale of Non-Parity Health Insurance Prohibited**: The regulations prohibit a health insurance issuer from selling any policy, certificate or contract of insurance that fails to comply with the parity regulations, unless it is sold to a plan for a year in which the plan is otherwise exempt from the parity requirements.

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As noted above, comments on the interim final regulations are due to the agencies by May 3, 2010. The preamble to the regulations states that special comments on the requirements regarding disclosure of medical necessity criteria may be submitted to the Office of Management and Budget through April 5, 2010. The preamble further notes that, in order to ensure

consideration of these special comments, the Office of Management and Budget requests that comments be received within 30 days of publication of the interim final regulations, i.e., by March 2, 2010.

If you have any questions about these interim final regulations, or about any other employee benefits matter, please contact the attorneys listed below or your usual Crowell & Moring contact.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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