GROOM LAW GROUP

March 3, 2010

MEMORANDUM TO CLIENTS

Re: New Interim Final Regulations on Mental Health Parity and Addiction Equity Act of 2008

The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (the "Act") was signed into law on October 3, 2008. Generally, the Act prohibits group health plans from applying financial requirements (*e.g.*, copays) or treatment limitations (*e.g.*, number of annual visits) that are more restrictive than those applied to the group health plan's medical and surgical benefits. On February 2, 2010, the Internal Revenue Service ("IRS"), Department of Labor ("DOL") and Centers for Medicare and Medicaid Services ("CMS") (collectively, "the agencies") published interim final regulations (the "Regulations") implementing the Act.

The Regulations replace the prior mental health parity regulations effective April 5, 2010, and generally apply to group health plans and health insurance issuers for plan years beginning on or after July 1, 2010 (there is a special rule for collectively bargained plans – see section G below). This means the provisions would be applicable on January 1, 2011 for most calendar year plans. The rules generally apply to employers who employed an average of more than 50 employees on business days during the preceding calendar year.

Overall, the Regulations were more expansive than many had anticipated and contained some surprises. Plan sponsors (many of whom adopted changes to their plan designs to comply with the Act without the benefit of interpretive guidance) will now need to review their plan designs to determine whether their plans are in parity under the rules as set forth in the Regulations – particularly with regard to non-quantitative treatment limitations (such as medical management tools). Additionally, the parity tests for financial requirements and quantitative treatment limitations are complex and will require in-depth analysis. The Regulations provide a good faith compliance period until the applicability date, but there may be certain aggressive plan designs that plan sponsors may wish to change prior to the applicability date. These issues are discussed in more detail below.

Comments regarding the Regulations are due on or before May 3, 2010.

The Act's Statutory Requirements

The Act amends the Employee Retirement Income Security Act ("ERISA") (and makes parallel changes to the Public Health Services Act (“PHSA”) and the Internal Revenue Code ("Code")) to prohibit group health plans that provide medical and surgical benefits and mental health or substance use disorder benefits from applying "financial requirements" or "treatment limits" that are more restrictive than the "predominant" financial requirement or treatment limit that applies to "substantially all" medical and surgical benefits. ERISA § 712(a)(3)(A). The Act defines "financial requirements" to include deductibles, copayments, coinsurance, and out-of-pocket expenses. The Act defines "treatment limitations" to include limits on the frequency of

visits, number of visits, days of coverage, or other similar limits on the scope or duration of treatment. The Act does not include a definition of when a financial requirement or treatment limit applies to "substantially all" medical and surgical benefits. The Act defines the term "predominant" to mean the most common or frequent of such type of limit or requirement. ERISA § 712(a)(3)(B).

The Regulations

Below, we highlight the key requirements and issues under the Regulations.

A. Definition of "Treatment Limitations" and "Financial Requirements"

1. Treatment Limitations

The Regulations provide that the parity requirements apply to both quantitative and non-quantitative treatment limitations. 29 C.F.R. §2590.712(a) (definition of Treatment limitations). A quantitative treatment limit is one that is expressed numerically, such as an annual limit of 50 outpatient visits. Other examples of quantitative treatment limits include annual, episode, or lifetime day and visit limits. The Regulations make clear that quantitative treatment limits may not accumulate separately. 29 C.F.R. §§2590.712(c)(3)(v). In other words, it appears that a plan cannot have an annual limit of 50 outpatient visits for medical/surgical benefits and a separate annual limit of 50 outpatient visits for mental health/substance use disorder benefits.

A non-quantitative treatment limitation is a limitation that affects the scope or duration of benefits under the plan that is not expressed numerically. This requirement extends to:

- medical management standards limiting benefits based on medical necessity or an exclusion for experimental/investigational treatments;
- prescription drug formulary design;
- standards for determining provider admission in a network, including reimbursement rates;
- determinations of usual and customary charges;
- refusal to pay for higher cost therapies until lower cost therapies are used (fail-first policies or step therapy protocols); and
- conditioning benefits on completion of a course of treatment.

29 C.F.R. §2590.712(c)(4).

The Regulations provide that, with respect to non-quantitative treatment limitations, any processes, strategies, evidentiary standards or other factors used in applying the non-quantitative treatment limitation to mental health or substance use disorder 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 in the same "classification" (as described below). These requirements allow variation only to the extent that recognized clinically appropriate standards of care may permit a difference, and apply to the terms of the plan as written and in operation. 29 C.F.R. §2590.712(c)(4)(i).

The Regulations also make clear that if an employee assistance program ("EAP") is used as a gatekeeper for mental health or substance use disorder benefits, but no similar gatekeeper is required for medical benefits, the non-quantitative treatment limitations rule would be violated. 29 C.F.R. §2590.712(c)(4)(iii)(Example 5).

2. Financial Requirements

The parity requirements also apply to financial requirements (*e.g.*, deductibles, copayments, coinsurance and out-of-pocket expenses) under a plan. The Regulations recognize that financial requirements, such as copayments and coinsurance typically apply separately with respect to each expense, but deductibles or out-of-pocket maximums reflect accumulated expenses, or "cumulative financial requirements."

The Regulations address two key issues with respect to financial requirements. First, they make clear that separately accumulating deductibles or out-of-pocket maximums (or any other cumulative financial requirement) is now prohibited. 29 C.F.R. §2590.712(c)(3)(v). Second, the preamble to the Regulations also make clear that a plan may not establish a lower copayment for primary care providers for medical and surgical benefits but apply a higher specialist copayment for mental health and substance use disorder providers.

B. Determining Parity Under The Regulations

The Act requires that treatment limits (*e.g.*, day and visit limits) and financial requirements (*e.g.*, copays, deductibles, out of pocket expenses) that apply to mental health or substance use benefits be "no more restrictive than the predominant [treatment limits or financial requirements] applied to substantially all medical and surgical benefits covered by the plan". Under the Regulations, in order for a type of limit to be applied to mental health or substance use it must first apply to substantially all medical and surgical benefits and then it must be the predominant level of the limit that applies. In any event, the use of "predominant" (which was defined in the Act) and "substantially all" (which was not defined in the Act) raises a number of interpretive questions that the agencies have sought to answer in the Regulations.

1. Parity Must Be Determined Classification-By-Classification

Under the Regulations, a plan's financial requirements and treatment limitations for mental health/substance use disorder benefits are compared against the plan's requirements and limitations for medical/surgical benefits on a classification-by-classification basis. The specific classifications required by the Regulations are:

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

29 C.F.R. §2590.712(c)(2)(ii).

There is also a special rule for multi-tiered prescription drug benefits. If a plan applies different levels of financial requirements to different tiers of prescription drug benefits based on reasonable factors (such as cost or efficacy, generic vs. brand name, mail order vs. pharmacy pick-up) without regard to whether the drug is generally prescribed with respect to medical and surgical benefits or mental health or substance use disorder benefits, the plan satisfies the parity requirements with respect to the prescription drug classification. 29 C.F.R. §2590.712(c)(3)(iii).

Additionally, financial requirements and treatment limitations must be evaluated separately by coverage unit. 29 C.F.R. §2590.712(c)(3)(ii). For example, in a plan that has individual and family levels of coverage, parity is measured between (a) individual medical/surgical coverage and individual mental health coverage, and (b) family medical/surgical coverage and family mental health coverage.

2. Determining if a Limitation Applies to "Substantially All" Medical and Surgical Benefits Within a Classification

Under the Regulations, a "type" of financial requirement or quantitative treatment limitation applies to substantially all medical and surgical benefits in a classification if it applies to at least two-thirds of the benefits in that classification. The portion of plan payments subject to a financial requirement or quantitative treatment limitation is based on the dollar amount of all plan payments for medical and surgical benefits within the classification expected to be paid by the plan for the plan year. Any reasonable method may be used to determine the dollar amount expected to be paid under the plan. Benefits at a zero level of a type of financial requirement (*e.g.*, $0 copay for well-baby visits or no copayments imposed on office visits for allergy shots) are treated as not being subject to a copayment. 29 C.F.R. §2590.712(c)(3)(i)(A).

If a "type" of financial requirement (*e.g.*, deductible, copay) or quantitative treatment limitation does not apply to at least two-thirds of the medical and surgical benefits in a classification, that type of requirement or limitation (*e.g.*, the deductible or copay) cannot be applied to mental health or substance use disorder benefits in that classification.

3. Determining the Predominant Limitation

If the two-thirds test is met for a particular type of financial requirement or quantitative treatment limitation at the same level (*e.g.*, a $10 co-pay applies to two-thirds of the benefits in a classification), then it is also considered the "predominant level", and the analysis is complete – mental health or substance use disorder benefits must be in parity with that particular financial requirement quantitative treatment limitation. If the type of financial requirement (*e.g.*, a co-pay) or quantitative treatment limitation applies to at least two-thirds of medical and surgical benefits in a classification, but there are multiple levels (*e.g.*, $10, $25, $75) and no single level applies to at least two-thirds of all medical and surgical benefits within the classification, then additional analysis is required to determine which level of the financial requirement or quantitative

treatment limitation is considered predominant. In that case, the predominant level of a type of financial requirement or quantitative treatment limitation is the level that applies to more than one-half of medical and surgical benefits subject to the requirement or limitation within the particular classification, based on projected plan costs. Additional aggregation rules are provided if no limit applies to more than one-half of the medical and surgical benefits. 29 C.F.R. §2590.712(c)(3)(i)(B).

C. Defining and Excluding Mental Health/Substance Use disorder Conditions, Treatments and Treatment Settings

The Regulations do not require group health plans to cover mental health and substance use disorder benefits at all. The Regulations further recognize that a plan may permanently exclude all benefits for a specific mental health or substance use condition or disorder without violating the parity requirements. But, if a mental health or substance use disorder benefit is covered, it must be offered in parity with medical/surgical benefits. Moreover, if mental health or substance use benefits are provided in any category of benefits (*e.g.*, outpatient in-network), they must be offered in all categories where medical benefits are provided. 29 C.F.R. §2590.712(c)(2)(ii)(A).

The Regulations also recognize that mental health and substance use disorder benefits may be defined by the plan (in accordance with applicable Federal and state law), but require that those benefits be categorized consistent with generally recognized independent standards of current medical practice. As such, the Regulations provide that categorizing mental health and substance use benefits consistent with the DSM, the International Classification of Diseases or a state guideline would all meet this requirement. 29 C.F.R. §2590.712(a) (definitions of Mental health benefits and Substance use disorder benefits).

One of the key issues under the Act was the extent to which a plan may restrict the treatment or treatment setting available for a particular mental health or substance use condition that is otherwise covered by the plan (e.g., whether counseling or non-hospital residential treatment could be excluded). The Regulations do not specifically address this issue. Restrictions on treatments and treatment settings nevertheless should continue to be permitted. This is because the scope of the Regulations is limited such that nothing in the Regulations is supposed to affect the terms and conditions relating to the amount, duration or scope of mental health or substance use disorder benefits under the plan, except as specifically required under the parity requirements with regard to aggregate lifetime and annual limits, financial requirements and treatment limitations. 29 C.F.R. §§2590.712(e)(3)(ii). The preamble, however, recognizes that not all treatments or treatment settings for mental health or substance use disorder conditions correspond to those for medical and surgical conditions, and invites comments on whether and to what extent the Act addresses the scope of services or continuum of care provided by a group health plan or health insurance coverage.

D. New "Single Group Health Plan" Rule for Employers

Under the Regulations, employers must now combine *all* group health plan options offered by an employer into one group health plan for parity purposes. In fact, the new Regulations are very specific that all medical and surgical and mental health and substance use disorder benefits provided by an employer or employee organization constitute a single group health plan for purposes of the parity requirements. Additionally, the parity requirements apply to any and all combinations of benefits under the single "group health plan." This will have a significant impact on employers who sponsor carve-out mental health and substance use disorder plans. 29 C.F.R. §2590.712(e).

Where plans offer different levels of medical coverage (e.g., indemnity, PPO, HMO) and one mental health and substance use disorder benefit (a "carve out"), the parity rules must be applied option by option – and must include the mental health and substance use disorder benefit with each option. This will require significant programming so that the mental health/substance use disorder vendor can match up all of the medical plan options. We believe that an employer could still match up the mental health/substance use disorder benefit to the medical option with the lowest cost-sharing if the employer sought to have only one mental health/substance use disorder design. But, this rule makes clear that an employer cannot avoid using the parity requirements by providing mental health and substance use disorder benefits through a "carve-out" plan.

E. Small Employer and Cost Exemptions

The parity rules apply to employers who employed an average of more than 50 employees on business days during the preceding calendar year. 29 C.F.R. §2590.712(f). The Regulations do not, however, address how to count employees for purposes of the small employer exemption.

The Act changed the requirements for a plan to meet the cost exemption. The cost exemption in the Act permits plans to apply for a one year cost exception, if, after six months, the plan can show that the application of the parity requirements resulted in an increase in total plan costs of 2% in the first year and 1 % in subsequent plan years. ERISA § 712(c)(2). The agencies intend to issue guidance on the cost exemption in the near future and state in the preamble that they are seeking comments on implementing the new statutory requirements for the cost exemption, and information on how plans expect to use the exemption.

F. New Disclosure Requirements

The Regulations require plans to comply with new disclosure requirements. Specifically, upon request by a current or potential participant, beneficiary or contracting provider, the plan administrator or health insurance issuer must provide the criteria for medical necessity determinations made under the plan with respect to mental health or substance use disorder benefits. Similar to the rules for denied claims under ERISA, the plan administrator or health insurance issuer must also make available upon request, or as otherwise required, the reason for

any denial of reimbursement or payment for services with respect to mental health or substance use disorder benefits in the case of any participant or beneficiary. 29 C.F.R. §2590.712(d).

The Regulations provide that both ERISA and non-ERISA plans that satisfy the requirements of the ERISA claims regulations will also satisfy the claims denial notice requirement under these Regulations. The agencies are seeking comments concerning the medical necessity disclosure and any additional clarifications that would be helpful to facilitate compliance with the Act's disclosure requirements regarding denials of mental health or substance use disorder benefits.

G. Applicability Date and Good Faith Nonenforcement Period

In general, the Regulations are effective for plan years beginning on or after July 1, 2010 (*e.g.*, January 1, 2011 for calendar year plans). There is a special rule for collectively bargained plans. For group health plans maintained pursuant to a collective bargaining agreement that was ratified before October 3, 2008, the Regulations do not apply for plan years beginning before the later of the termination date of the last collective bargaining agreement relating to the plan or July 1, 2010. 29 C.F.R. §2590.712(i).

The preamble to the Regulations indicates that the agencies did not provide guidance on whether the general applicability date or the special rule should be used when a plan covers both union and non-union employees because other labor laws address these issues.

For purposes of enforcement, the preamble to the Regulations indicates that the agencies charged with enforcing the Act (IRS, DOL, and CMS) will take into account good faith efforts to comply with a reasonable interpretation of the Act's statutory requirements with respect to a violation that occurs before the applicability date. However, the preamble notes that this does not prevent participants or beneficiaries from bringing a private lawsuit under ERISA.

As noted above, comments regarding the Regulations are due on or before May 3, 2010.

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Authors: Jon W. Breyfogle, Cheryl Risley Hughes, Tammy Killion and Kimberly Dahm.

If you have any questions, please contact your regular Groom contact or any of the Health and Welfare practice group attorneys listed below:

Jon W. Breyfogle	jwb@groom.com	(202) 861-6641
Jenifer A. Cromwell	jac@groom.com	(202) 861-6329
Kimberly M. Dahm	kdahm@groom.com	(202) 861-2606
Thomas F. Fitzgerald	tff@groom.com	(202) 861-6621
Cheryl Risley Hughes	chughes@groom.com	(202) 861-0167
Christine L. Keller	clk@groom.com	(202) 861-9371

Tamara S. Killion	tkillion@groom.com	(202) 861-6328
William F. Sweetnam	wfs@groom.com	(202) 861-5427
Christy A. Tinnes	cat@groom.com	(202) 861-6603
Donald G. Willis	dgw@groom.com	(202) 861-6332
Brigen L. Winters	blw@groom.com	(202) 861-6618