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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

TD 9479

RIN 1545-BJ05

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210-AB30

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

CMS-4140-IFC

45 CFR Part 146

RIN 0938-AP65

Interim Final Rules under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008

AGENCIES: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Interim final rules with request for comments.

SUMMARY: This document contains interim final rules implementing the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, which requires parity between mental health or substance use disorder benefits and medical/surgical benefits with respect to financial requirements and treatment limitations under group health plans and health insurance coverage offered in connection with a group health plan.

DATES: Effective date. These interim final regulations are effective on [insert date 60 days after publication in the **Federal Register**].

Comment date. Comments are due on or before [insert date 90 days after publication in the **Federal Register**].

Applicability date. These interim final regulations generally apply to group health plans and group health insurance issuers for plan years beginning on or after July 1, 2010.

ADDRESSES: Written comments may be submitted to any of the addresses specified below. Any comment that is submitted to any Department will be shared with the other Departments. Please do not submit duplicates.

All comments will be made available to the public. **WARNING**: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are posted on the Internet exactly as received, and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

Department of Labor. Comments to the Department of Labor, identified by RIN 1210-AB30, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

- Email: E-OHPSCA.EBSA@dol.gov.

- Mail or Hand Delivery: 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.

Comments received by the Department of Labor will be posted without change to www.regulations.gov and www.dol.gov/ebsa, and available for public inspection at the Public Disclosure Room, N-1513, Employee Benefits Security Administration, 200 Constitution Avenue, NW, Washington, DC 20210.

Department of Health and Human Services. In commenting, please refer to file code CMS-4140-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to http://www.regulations.gov. Follow the instructions under the "More Search Options" tab.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-4140-IFC,

P.O. Box 8016,

Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the

close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-4140-IFC,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW,

Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

7500 Security Boulevard,

Baltimore, MD 21244-1850

If you intend to deliver your comments to the Baltimore address, please call (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. EST. To schedule an appointment to view public comments, phone 1-800-743-3951.

Internal Revenue Service. Comments to the IRS, identified by REG-120692-09, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.
- Mail: CC:PA:LPD:PR (REG-120692-09), room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.
- Hand or courier delivery: Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG-120692-09), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW, Washington DC 20224.

All submissions to the IRS will be open to public inspection and copying in room 1621, 1111 Constitution Avenue, NW, Washington, DC from 9 a.m. to 4 p.m.

FOR FURTHER INFORMATION CONTACT: Amy Turner or Beth Baum, Employee Benefits Security Administration, Department of Labor, at (202) 693-8335; Russ Weinheimer, Internal Revenue Service, Department of the Treasury, at (202) 622-6080; Adam Shaw, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at (877) 267-2323, extension 61091.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws, including the mental health parity provisions, may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the Department of Labor's website (http://www.dol.gov/ebsa). In addition, information from HHS on private health insurance for consumers (such as mental health and substance use disorder parity) can be found on the Centers for Medicare & Medicaid Services (CMS) website (http://www.cms.hhs.gov/HealthInsReformforConsume/01_Overview.asp).

SUPPLEMENTARY INFORMATION:

I. Background

The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) was enacted on October 3, 2008 as sections 511 and 512 of the Tax Extenders and Alternative Minimum Tax Relief Act of 2008 (Division C of Public Law 110-343).[1] MHPAEA amends the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Service Act (PHS Act), and the Internal Revenue Code of 1986 (Code). In 1996, Congress enacted the Mental Health Parity Act of 1996 (MHPA 1996), which required parity in aggregate lifetime and annual dollar limits for mental health benefits and medical and surgical benefits. Those mental health parity provisions were codified in section 712 of ERISA, section 2705 of the PHS Act, and section 9812 of the Code, which apply to employment-related group health plans and health insurance coverage offered in connection with a group health plan. The changes made by MHPAEA are codified in these same sections and consist of new requirements as well as amendments to the existing mental health parity provisions. The changes made by MHPAEA are generally effective for plan years beginning after October 3, 2009.

On April 28, 2009, the Departments of the Treasury, Labor, and HHS (collectively, the Departments) published in the **Federal Register** (74 FR 19155) a request for information (RFI) soliciting comments on the requirements of MHPAEA. After consideration of the comments received in response to the RFI, the Departments are publishing these interim final regulations. These regulations generally become applicable to plans and issuers for plan years beginning on or after July 1, 2010.

II. Overview of the Regulations

[1] A technical correction to the effective date for collectively bargained plans was made by Public Law 110-460, enacted on December 23, 2008.

These interim final regulations replace regulations published on December 22, 1997 at 62 FR 66932 implementing MHPA 1996. These regulations also make conforming changes to reflect modifications MHPAEA made to the original MHPA 1996 definitions and provisions regarding parity in aggregate lifetime and annual dollar limits, and incorporate new parity standards.

A. Meaning of Terms (26 CFR 54.9812-1T(a), 29 CFR 2590.712(a), and 45 CFR 146.136(a))

The paragraph with the heading "definitions" in the MHPA 1996 regulations has been renamed "meaning of terms" under these regulations because some of the terms added by MHPAEA are not comprehensively defined. The change in heading reflects the fact that if a term is described as including a list of examples, the term may have a broader meaning than the illustrative list of examples.

1. Aggregate Lifetime and Annual Dollar Limits

The word "dollar" has been added to the terms "aggregate lifetime limit" and "annual limit" under the MHPA 1996 regulations to distinguish them from lifetime and annual limits expressed in terms of days or visits which are subject to new requirements under MHPAEA.

2. Coverage Unit

Paragraph (a) in these regulations cross-references the definition of coverage unit in paragraph (c)(1). Paragraph (c)(1) clarifies the term for purposes of the new MHPAEA rules and is discussed later in this preamble.

3. Cumulative Financial Requirements

These regulations add a definition for the term "cumulative financial requirements". Under this definition, a cumulative financial requirement is a financial requirement that typically operates as a threshold amount that, once satisfied, will determine whether, or to what extent,

benefits are provided. A common example of a cumulative financial requirement is a deductible that must be satisfied before a plan will start paying for benefits. However, aggregate lifetime and annual dollar limits are excluded from being cumulative financial requirements (because the statutory term financial requirements excludes aggregate lifetime and annual dollar limits).

4. Cumulative Quantitative Treatment Limitations

These regulations add a definition for the term "cumulative quantitative treatment limitations". Similar to the definition for cumulative financial requirements, a cumulative quantitative treatment limitation is defined as a treatment limitation that will determine whether, or to what extent, benefits are provided based on an accumulated amount. A common example of a cumulative quantitative treatment limitation is a visit limit (whether imposed annually or on a lifetime basis).

5. Financial Requirements

These regulations repeat the statutory language that provides the term "financial requirements" includes deductibles, copayments, coinsurance, and out-of-pocket maximums. The statute and these regulations exclude aggregate lifetime and annual dollar limits from the meaning of financial requirements; these limits are subject to separate provisions originally enacted as part of MHPA 1996 that remain in paragraph (b).

6. Medical/Surgical Benefits, Mental Health Benefits, and Substance Use Disorder Benefits

Among the changes enacted by MHPAEA is an expansion of the parity requirements for aggregate lifetime and annual dollar limits to include protections for substance use disorder benefits. Prior law specifically excluded substance abuse or chemical dependency benefits[2] from

[2] The terms "substance abuse," "chemical dependency, " and "substance use disorder" are variously used to refer to substance use disorders. Although they mean essentially the same thing, the term used in MHPAEA is "substance use disorder".

those requirements. Consequently, these regulations amend the meanings of medical/surgical benefits and mental health benefits (and add a definition for substance use disorder benefits). Under these regulations, medical/surgical benefits are benefits for medical or surgical services, as defined under the terms of the plan or health insurance coverage, but do not include mental health or substance use disorder benefits. Mental health benefits and substance use disorder benefits are benefits with respect to services for mental health conditions and substance use disorders, as defined under the terms of the plan and in accordance with applicable Federal and State law. These regulations further provide that the plan terms defining whether the benefits are mental health or substance use disorder benefits must be consistent with generally recognized independent standards of current medical practice. This requirement is included to ensure that a plan does not misclassify a benefit in order to avoid complying with the parity requirements.

The word "generally" in the requirement "to be consistent with generally recognized independent standards of current medical practice" is not meant to imply that the standard must be a national standard; it simply means that a standard must be generally accepted in the relevant medical community. There are many different sources that would meet this requirement. For example, a plan may follow 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. All of these would be considered acceptable resources to determine whether benefits for a particular condition are classified as medical/surgical, mental health, or substance use disorder benefits.

7. Treatment Limitations

These regulations repeat the statutory language with respect to the term "treatment limitation" and also distinguish between a quantitative and a nonquantitative treatment limitation. These regulations provide that the parity requirements in the statute apply to both quantitative and nonquantitative treatment limitations. A quantitative treatment limitation is a limitation that is expressed numerically, such as an annual limit of 50 outpatient visits. A nonquantitative treatment limitation is a limitation that is not expressed numerically, but otherwise limits the scope or duration of benefits for treatment. A non-exhaustive list of nonquantitative treatment limitations is included in these regulations in paragraph (c)(4). This list, as well as the application of these regulations to nonquantitative treatment limitations, is further discussed later in this preamble. However, these regulations provide that a permanent exclusion of all benefits for a specific condition or disorder is not a treatment limitation.

B. Conforming Amendments to Parity Requirements With Respect To Aggregate Lifetime and Annual Dollar Limits (26 CFR 54.9812-1T(b), 29 CFR 2590.712(b), and 45 CFR 146.136(b))

Paragraph (b) of these regulations addresses the parity requirements with respect to aggregate lifetime and annual dollar limits. The mechanics of these requirements generally remain the same as under the MHPA 1996 regulations, except that MHPAEA expanded the scope of the parity provisions to apply also to substance use disorder benefits. Accordingly, these regulations make conforming changes to reflect this expansion. Certain examples illustrating the application of MHPA 1996 to benefits for substance abuse and chemical dependency were deleted (as they are no longer accurate); other provisions were modified to include references to substance use disorder benefits as within the scope of the parity requirements for aggregate lifetime and annual dollar limits.

C. Parity Requirements With Respect To Financial Requirements and Treatment Limitations (26 CFR 54.9812-1T(c), 29 CFR 2590.712(c), and 45 CFR 146.136(c))

Paragraph (c) of these regulations implements the core of MHPAEA's new rules, which require parity with respect to financial requirements and treatment limitations.

1. Clarification of Terms

In addition to the meaning of terms in paragraph (a), paragraph (c)(1) of these regulations clarifies certain terms that have been given specific meanings for purposes of MHPAEA.

a. Classification of benefits. Paragraph (c)(1) cross-references the term "classification of benefits" in paragraph (c)(2)(ii). Paragraph (c)(2)(ii) describes the six benefit classifications and their application, which are discussed later in this preamble. These regulations provide that the parity requirements for financial requirements and treatment limitations are applied on a classification-by-classification basis.

b. Type. These regulations use the term "type" to refer to financial requirements and treatment limitations of the same nature. Different types include copayments, coinsurance, annual visit limits, and episode visit limits. Plans often apply more than one financial requirement or treatment limitation to benefits. These regulations specify that a financial requirement or treatment limitation must be compared only to financial requirements or treatment limitations of the same type within a classification. For example, copayments are compared only to other copayments, and annual visit limits are compared only to other annual visit limits; copayments are not compared to coinsurance, and annual visit limits are not compared to episode visit limits.

c. Level. A type of financial requirement or treatment limitation may vary in magnitude. For example, a plan may impose a $20 copayment or a $30 copayment depending on the

medical/surgical benefit. In these regulations, a "level" of a type of financial requirement or treatment limitation refers to the magnitude (such as the dollar, percentage, day, or visit amount) of the financial requirement or treatment limitation.

d. Coverage unit. Plans typically distinguish between coverage for a single participant, for a participant plus a spouse, for a family, and so forth. Coverage unit is the term used in these regulations to refer to how a plan groups individuals for purposes of determining benefits, or premiums or contributions. These regulations provide that the general parity requirement of MHPAEA for financial requirements and treatment limitations is applied separately for each coverage unit.

2. General Parity Requirement for Financial Requirements and Treatment Limitations

The general parity requirement of paragraph (c)(2) of these regulations prohibits a plan (or health insurance coverage) from applying any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation applied to substantially all medical/surgical benefits in the same classification. For this purpose, the general parity requirement of MHPAEA applies separately for each type of financial requirement or treatment limitation (that is, for example, copayments are compared to copayments, and deductibles to deductibles). The test is applied somewhat differently to nonquantitative treatment limitations, as discussed later in this preamble.

a. Classifications of benefits. Plans often vary the financial requirements and treatment limitations imposed on benefits based on whether a treatment is provided on an inpatient, outpatient, or emergency basis; whether a provider is a member of the plan's network; or whether the benefit is specifically for a prescription drug. Therefore, determining the

predominant financial requirements and treatment limitations for the entire plan without taking these distinctions into account could potentially lead to absurd results. For example, if a plan generally requires a $100 copayment on inpatient medical/surgical benefits and a $10 copayment on outpatient medical/surgical benefits, and most services (as measured by plan costs) are provided on an inpatient basis, the plan theoretically could charge a $100 copayment for outpatient mental health and substance use disorder benefits. Similarly, if most benefits are provided on an outpatient basis, the plan would only be able to charge a $10 copayment for inpatient mental health and substance use disorder benefits. Commenters generally agreed that the statute should be applied within several broad classifications of benefits.

These regulations specify, in paragraph (c)(2)(ii), six classifications of benefits: inpatient, in-network; inpatient, out-of-network; outpatient, in-network; outpatient, out-of-network; emergency care; and prescription drugs. If a plan does not have a network of providers for inpatient or outpatient benefits, all benefits in the classification are characterized as out-of-network. These regulations provide that the parity requirements for financial requirements and treatment limitations are generally applied on a classification-by-classification basis and these are the only classifications used for purposes of satisfying the parity requirements of MHPAEA. Moreover, these classifications must be used for all financial requirements and treatment limitations to the extent that a plan (or health insurance coverage) provides benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment limitation) for benefits in the classification. Examples illustrate the application of this rule.

Commenters noted that a common plan design imposes lower copayments for treatment from a primary care provider (for example, an internist or a pediatrician) as compared to higher

copayments for treatment from a specialist (such as a cardiologist or an orthopedist). Some of these commenters requested that this distinction be permitted in applying the parity requirements by recognizing a separate classification for specialists; others of these commenters opposed allowing this distinction. Some plans (or health insurance coverage) identify a large range of mental health and substance use disorder providers as specialists. Allowing plans to provide less favorable benefits with respect to services by these providers than for services by providers of medical/surgical care that are classified by the plan as primary care providers would undercut the protections that the statute was intended to provide. These regulations, therefore, do not allow the separate classification of generalists and specialists in determining the predominant financial requirement that applies to substantially all medical/surgical benefits.

Under these regulations, if a plan provides any benefits for a mental health condition or substance use disorder, benefits must be provided for that condition or disorder in each classification for which any medical/surgical benefits are provided. This follows from the statutory requirement that any treatment limitations applied to mental health or substance use disorder benefits may be no more restrictive than the predominant treatment limitations applied to substantially all medical/surgical benefits. Treatment limitation is not comprehensively defined under the statute. The statute describes the term as including limits on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment, but it is not limited to such types of limits. Indeed, these regulations make a distinction between quantitative treatment limitations (such as day limits, visit limits, frequency of treatment limits) and non-quantitative treatment limitations (such as medical management, formulary design, step therapy). If a plan provides benefits for a mental health condition or substance use disorder in one or more classifications but excludes benefits for that condition or

disorder in a classification (such as outpatient, in-network) in which it provides medical/surgical benefits, the exclusion of benefits in that classification for a mental health condition or substance use disorder otherwise covered under the plan is a treatment limitation. It is a limit, at a minimum, on the type of setting or context in which treatment is offered.

This rule does not require an expansion of the range of mental health conditions or substance use disorders covered under the plan; it merely requires, for those conditions or disorders covered under the plan, that coverage also be provided for them in each classification in which medical/surgical coverage is provided. If a plan does not offer, for instance, any benefits for medical/surgical services on an outpatient basis by an out-of-network provider, then there is no requirement to provide benefits for mental health conditions or substance use disorders on an outpatient, out-of-network basis. Although this rule follows from the general parity requirement added by MHPAEA, the statute includes a specific provision in the case of out-of-network benefits.[3] The rule for out-of-network benefits is stated separately in these regulations to reflect the separate statutory provision, but the application of the general rule requires the same result with respect to all classifications.

These regulations do not define inpatient, outpatient, or emergency care. These terms are subject to plan design and their meanings may differ from plan to plan. Additionally, State health insurance laws may define these terms. A plan must apply these terms uniformly for both medical/surgical benefits and mental health or substance use disorder benefits. However, the manner in which they apply may differ from plan to plan. For example, a plan may treat a hospital stay of more than 12 hours as inpatient care for medical/surgical benefits; in such case, it must also treat a hospital stay of more than 12 hours as inpatient care for mental health and

[3] See sections 9812(a)(5) of the Code, 712(a)(5) of ERISA, 2705(a)(5) of the PHS Act.

substance use disorder benefits. However, another plan may treat a hospital stay that includes midnight as inpatient care for medical/surgical benefits; in such a case the plan must also treat a hospital stay that includes midnight as inpatient care for mental health or substance use disorder benefits.

b. Applying the general parity requirement to financial requirements and quantitative treatment limitations. Paragraph (c)(3) of these regulations addresses the application of the general parity requirement of MHPAEA to plan financial requirements and quantitative treatment limitations.

(1) Measuring plan benefits. In order to apply the substantive rules, these regulations first establish standards for measuring plan benefits. These regulations, similar to the MHPA 1996 regulations, provide that 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/surgical benefits in the classification expected to be paid under the plan for the plan year. Also similar to the MHPA 1996 regulations, any reasonable method may be used to determine the dollar amount expected to be paid under the plan for medical/surgical benefits subject to a financial requirement or quantitative treatment limitation.

Some cumulative financial requirements, such as deductibles and out-of-pocket maximums, involve a threshold amount that causes the amount of a plan payment to change. These regulations clarify that, for purposes of deductibles, the dollar amount of plan payments includes all payments with respect to claims that would be subject to the deductible if it had not been satisfied. For purposes of out-of-pocket maximums, the dollar amount of plan payments includes all plan payments associated with out-of-pocket payments that were taken into account towards the out-of-pocket maximum as well as all plan payments associated with out-of-pocket

payments that would have been made towards the out-of-pocket maximum if it had not been satisfied. Other threshold requirements are treated similarly.

(2) "Substantially all". The first step of these regulations in applying the general parity requirement of MHPAEA is to determine whether a financial requirement or quantitative treatment limitation applies to substantially all medical/surgical benefits in a classification. Regulations issued under MHPA 1996 interpreted the term "substantially all" to mean at least two-thirds. Under these regulations, a financial requirement or quantitative treatment limitation applies to substantially all medical/surgical benefits in a classification if it applies to at least two-thirds of the benefits in that classification. In determining whether a financial requirement or quantitative treatment limitation applies to substantially all medical/surgical benefits in a classification, benefits expressed as subject to a zero level of a type of financial requirement are treated the same as benefits that are not subject to that type of requirement, and benefits expressed as subject to an unlimited quantitative treatment limitation are treated the same as benefits that are not subject to that type of limitation. For example, in the classification of outpatient, in-network medical/surgical benefits, a plan could reduce the normal copayment amount of $15 to $0 for well baby care or routine physical examinations, while a copayment is not imposed on office visits for allergy shots. For purposes of this analysis, both of these benefits are treated as not subject to a copayment.

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, that type of requirement or limitation cannot be applied to mental health or substance use disorder benefits in that classification. If a single level of a type of financial requirement or quantitative treatment limitation applies to at least two-thirds of medical/surgical benefits in a classification, then it is

also the predominant level and that is the end of the analysis. However, if the financial requirement or quantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits in a classification but has multiple levels and no single level applies to at least two-thirds of all medical/surgical benefits in the classification, then additional analysis is required. In such a case, the next step is to determine which level of the financial requirement or quantitative treatment limitation is considered predominant.

(3) "Predominant". MHPAEA provides that a financial requirement or treatment limitation is predominant if it is the most common or frequent of a type of limit or requirement. Under these regulations, 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/surgical benefits subject to the financial requirement or quantitative treatment limitation in that classification. If a single level of a type of financial requirement or quantitative treatment limitation applies to more than one-half of medical/surgical benefits subject to the financial requirement or quantitative treatment limitation in a classification (based on plan costs, as discussed earlier in this preamble), the plan may not apply that particular financial requirement or quantitative treatment limitation to mental health or substance use disorder benefits at a level that is more restrictive than the level that has been determined to be predominant.

If no single level applies to more than one-half of medical/surgical benefits subject to a financial requirement or quantitative treatment limitation in a classification, plan payments for multiple levels of the same type of financial requirement or quantitative treatment limitation can be combined by the plan (or health insurance issuer) until the portion of plan payments subject to the financial requirement or quantitative treatment limitation exceeds one-half. For any combination of levels that exceeds one-half of medical/surgical benefits subject to the financial

requirement or quantitative treatment limitation in a classification, the plan may not apply that particular financial requirement or quantitative treatment limitation to mental health and substance use disorder benefits at a level that is more restrictive than the least restrictive level within the combination. The plan may combine plan payments for the most restrictive levels first, with each less restrictive level added to the combination until the combination applies to more than one-half of the benefits subject to the financial requirement or treatment limitation. Examples in these regulations illustrate the application of this rule.

These regulations provide an alternative, simpler method for compliance when a type of financial requirement or quantitative treatment limitation applies to at least two-thirds of medical surgical benefits in a classification but no single level applies to more than one-half of the medical/surgical benefits subject to the financial requirement or quantitative treatment limitation in that classification. In such a situation, a plan is permitted to treat the least restrictive level of the financial requirement or quantitative treatment limitation applied to medical/surgical benefits in that classification as the predominant level.

If a plan provides benefits for more than one coverage unit and applies different levels of financial requirements or quantitative treatment limitations to these coverage units within a classification of benefits, determining the predominant level of a particular financial requirement or quantitative treatment limitation must be done separately for each coverage unit. Thus, for example, a plan with different deductibles for self-only and family coverage units would not determine the predominant level of a deductible applied for benefits across both the self-only and family coverage units. Instead, the plan would determine the predominant level of the deductible for self-only coverage independently from the predominant level for family coverage.

c. Special rule for prescription drug benefits with multiple levels of financial requirements. These regulations include, in paragraph (c)(3)(iii), a special rule for applying the general parity requirement of MHPAEA to prescription drug benefits. Although applying the general parity requirement to a prescription drug program with a single level of a type of financial requirement would be relatively uncomplicated, the analysis becomes more difficult if different financial requirements are imposed for different tiers of drugs. The placement of a drug in a tier is generally based on factors (such as cost and efficacy) unrelated to whether the drug is usually prescribed for the treatment of a medical/surgical condition or a mental health condition or substance use disorder. To the extent such a program does not distinguish between drugs as medical/surgical benefits or mental health or substance use disorder benefits, requiring the program to make that distinction solely for the purpose of determining the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in a classification might impose significant burdens without ensuring any greater parity for mental health and substance use disorder benefits.

Consequently, these regulations provide that if a plan imposes different levels of financial requirements on different tiers of prescription drugs based on reasonable factors (such as cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up), determined in accordance with the requirements for nonquantitative treatment limitations, and without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or mental health or substance use disorder benefits, the plan satisfies the parity requirements with respect to the prescription drug classification of benefits. The special rule for prescription drugs, in effect, allows a plan or issuer to subdivide the prescription drug classification into tiers and apply the general parity requirement separately to each tier of prescription drug benefits. For any tier, the

financial requirements and treatment limitations imposed with respect to the drugs prescribed for medical/surgical conditions are the same as (and thus not more restrictive than) the financial requirements and treatment limitations imposed with respect to the drugs prescribed for mental health conditions and substance use disorders in the tier. Moreover, because the financial requirements and treatment limitations apply to 100 percent of the medical/surgical drug benefits in the tier, they are the predominant financial requirements and treatment limitations that apply to substantially all of the medical/surgical drug benefits in the tier.

d. Cumulative financial requirements and quantitative treatment limitations, including deductibles. While financial requirements such as copayments and coinsurance generally apply separately to each covered expense, other financial requirements (in particular, deductibles) accumulate across covered expenses. In the case of deductibles, generally an amount of otherwise covered expenses must be accumulated before the plan pays benefits. Financial requirements and quantitative treatment limitations that determine whether and to what extent benefits are provided based on accumulated amounts are defined in these regulations as cumulative financial requirements and cumulative quantitative treatment limitations.

In response to the RFI, the Departments received a number of comments regarding how to apply the parity requirements to cumulative financial requirements, in particular to deductibles (although some also referred to out-of-pocket maximums). The comments reflect two opposing views. One view is that a plan can have deductibles that accumulate separately for medical/surgical benefits on the one hand, and mental health or substance use disorder benefits on the other, as long as the level of the two deductibles is the same (separately accumulating deductibles). The opposing view is that expenses for both mental health or substance use disorder benefits and medical/surgical benefits must accumulate to satisfy a single combined

deductible before the plan provides either medical/surgical benefits or mental health or substance use disorder benefits (combined deductible).

The provisions of the statute imposing parity on financial requirements and treatment limitations do not specifically address this issue; the language of the statute can be interpreted to support either position. The comments that supported allowing separately accumulating deductibles maintained that it is commonplace for plans to have such deductibles, and that the projected cost of converting systems to permit unified deductibles would be extremely high for the many plans that use a separate managed behavioral health organization (MBHO).[4]

By contrast, comments that supported requiring combined deductibles argued that allowing separately accumulating deductibles undermines a central goal of parity legislation, to affirm that mental health and substance use disorder benefits are integral components of comprehensive health care and generally should not be distinguished from medical/surgical benefits. Distinguishing between the two requires individuals who need both kinds of care to satisfy a deductible that is greater than that required for individuals needing only medical/surgical care. Other comments that supported requiring combined deductibles noted that mental health and substance use disorder benefits typically comprise only 2 to 5 percent of a plan's costs, so that even using identical levels for separately accumulating deductibles imposes a greater barrier to mental health and substance use disorder benefits.

[4] Several commenters stated that the estimated cost to develop interfaces between MBHOs and the entity administering medical/surgical claims would be $420,000-$750,000 per interface, and that in some cases multiple interfaces per MBHO (as many as 40-50) would be necessary. In response to these cost concerns, the Departments performed an independent analysis, which indicated that the initial cost per interface could be as low as $35,000. The Departments' lower estimated cost reflects, in part, the use of less expensive interface systems (for example, batch processing rather than real-time), and the ability to model new interfaces on existing systems used to interface with pharmacy benefit managers and dental insurers. In addition, many MBHOs already have developed interfaces, because their clients requested combined deductibles. This should result in reduced costs, because interface development costs are incremental and should decrease after the first interface is created. For a further discussion of this issue, see section IV. Economic Impact and Paperwork Burden later in this preamble.

The Departments carefully considered the positions advanced by both groups of comments regarding separately accumulating and combined deductibles. Given that the statutory language does not preclude either interpretation, the Departments' view is that prohibiting separately accumulating financial restrictions and quantitative treatment limitations is more consistent with the policy goals that led to the enactment of MHPAEA. Consequently, these regulations provide, in paragraph (c)(3)(v), that a plan may not apply cumulative financial requirements or cumulative quantitative treatment limitations to mental health or substance use disorder benefits in a classification that accumulate separately from any such cumulative financial requirements or cumulative quantitative treatment limitations established for medical/surgical benefits in the same classification.[5] Examples in these regulations illustrate the application of this rule.

e. Application to nonquantitative treatment limitations. Plans impose a variety of limits affecting the scope or duration of benefits under the plan that are not expressed numerically. Nonetheless, such nonquantitative provisions are also treatment limitations affecting the scope or duration of benefits under the plan. These regulations provide an illustrative list of nonquantitative treatment limitations, including medical management standards; prescription drug formulary design; standards for provider admission to participate in a network; determination of usual, customary, and reasonable amounts; requirements for using lower-cost therapies before the plan will cover more expensive therapies (also known as fail-first policies or step therapy protocols); and conditioning benefits on completion of a course of treatment.

[5] This rule in the interim final regulations prohibiting separately accumulating financial requirements and quantitative treatment limitations does not apply with respect to aggregate lifetime and annual dollar limits. The statutory language of MHPA 1996 specifically permitted plans to impose aggregate lifetime or annual dollar limits that distinguish between mental health benefits and medical/surgical benefits. MHPAEA left the language of this statutory provision intact, modifying it only to expand its applicability to include substance use disorder benefits.

Paragraph (c)(4) of these regulations generally prohibits the imposition of any nonquantitative treatment limitation to mental health or substance use disorder benefits unless certain requirements are met. Any processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in a classification 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 classification. However, these requirements allow variations to the extent that recognized clinically appropriate standards of care may permit a difference. These requirements apply to the terms of the plan (or health insurance coverage) both as written and in operation.

The phrase, "applied no more stringently" was included to ensure that any processes, strategies, evidentiary standards, or other factors that are comparable on their face are applied in the same manner to medical/surgical benefits and to mental health or substance use disorder benefits. Thus, for example, assume a claims administrator has discretion to approve benefits for treatment based on medical necessity. If that discretion is routinely used to approve medical/surgical benefits while denying mental health or substance use disorder benefits and recognized clinically appropriate standards of care do not permit such a difference, the processes used in applying the medical necessity standard are considered to be applied more stringently to mental health or substance use disorder benefits. The use of discretion in this manner violates the parity requirements for nonquantitative treatment limitations.

Different types of illnesses or injuries may require different review, as well as different care. The acute versus chronic nature of a condition, the complexity of it or the treatment involved, and other factors may affect the review. Although the processes, strategies,

evidentiary standards, and other factors used in applying these limitations must generally be applied in a comparable manner to all benefits, the mere fact of disparate results does not mean that the treatment limitations do not comply with parity.

Examples in these regulations illustrate the operation of the requirements for nonquantitative treatment limitations. Medical management standards are implemented by processes such as preauthorization, concurrent review, retrospective review, case management, and utilization review; the examples feature the application of these requirements to some of these processes. The facts in the examples reflect simple situations for purposes of better illustrating the application of the rules rather than reflecting the realistic, complex facts that would typically be found in a plan. The Departments invite comments on whether additional examples would be helpful to illustrate the application of the nonquantitative treatment limitation rule to other features of medical management or general plan design.

Commenters asked if the MHPAEA requirements apply when eligibility for mental health and substance use disorder benefits under a major medical program is conditioned on exhausting some limited number of mental health and substance use disorder counseling sessions offered through an employee assistance program (EAP). Generally, the provision of mental health or substance use disorder benefits by an EAP in addition to the benefits offered by a major medical program that otherwise complies with the parity rules would not violate MHPAEA. However, requiring participants to exhaust the EAP benefits – making the EAP a gatekeeper – before an individual is eligible for the major medical program's mental health or substance use disorder benefits is a nonquantitative treatment limitation subject to the parity requirements. Consequently, if similar gatekeeping processes with a similar exhaustion requirement (whether or not through the EAP) are not applied to medical/surgical benefits, the requirement to exhaust

mental health or substance use disorder benefits available under the EAP would violate the rule that nonquantitative treatment limitations be applied comparably and not more stringently to mental health and substance use disorder benefits.

The Departments received many comments addressing an issue characterized as "scope of services" or "continuum of care". Some commenters requested, with respect to a mental health condition or substance use disorder that is otherwise covered, that the regulations clarify that a plan is not required to provide benefits for any particular treatment or treatment setting (such as counseling or non-hospital residential treatment) if benefits for the treatment or treatment setting are not provided for medical/surgical conditions. Other commenters requested that the regulations clarify that a participant or beneficiary with a mental health condition or substance use disorder have coverage for the full scope of medically appropriate services to treat the condition or disorder if the plan covers the full scope of medically appropriate services to treat medical/surgical conditions, even if some treatments or treatment settings are not otherwise covered by the plan. Other commenters requested that MHPAEA be interpreted to require that group health plans provide benefits for any evidence-based treatment.

The Departments recognize that not all treatments or treatment settings for mental health conditions or substance use disorders correspond to those for medical/surgical conditions. The Departments also recognize that MHPAEA prohibits plans and issuers from imposing treatment limitations on mental health and substance use disorder benefits that are more restrictive than those applied to medical/surgical benefits. These regulations do not address the scope of services issue. The Departments 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.

D. Availability of Plan Information (26 CFR 54.9812-1T(d), 29 CFR 2590.712(d), and 45 CFR 146.136(d))

MHPAEA includes two new disclosure provisions for group health plans (and health insurance coverage offered in connection with a group health plan). First, the criteria for medical necessity determinations made under a plan (or health insurance coverage) with respect to mental health or substance use disorder benefits must be made available by the plan administrator (or the health insurance issuer offering such coverage) in accordance with regulations to any current or potential participant, beneficiary, or contracting provider upon request. These regulations repeat the statutory language without substantive change. The Departments invite comments on what additional clarifications might be helpful to facilitate compliance with this disclosure requirement for medical necessity criteria.

MHPAEA also provides that the reason for any denial under a group health plan (or health insurance coverage) of reimbursement or payment for services with respect to mental health or substance use disorder benefits in the case of any participant or beneficiary must be made available, upon request or as otherwise required, by the plan administrator (or the health insurance issuer) to the participant or beneficiary in accordance with regulations. These regulations clarify that, in order for plans subject to ERISA (and health insurance coverage offered in connection with such plans) to satisfy this requirement, disclosures must be made in a form and manner consistent with the rules for group health plans in the ERISA claims procedure regulations,[6] which provide (among other things) that such disclosures must be provided automatically and free of charge. In the case of non-Federal governmental and church plans (which are not subject to ERISA), and health insurance coverage offered in connection with such plans, these regulations provide that compliance with the form and manner of the ERISA claims

[6] 29 CFR 2560.503-1.

procedure regulations for group health plans satisfies this disclosure requirement. The Departments invite comments regarding any additional clarifications that would be helpful to facilitate compliance with MHPAEA's disclosure requirements regarding denials of mental health or substance use disorder benefits.

E. General Applicability Provisions (26 CFR 54.9812-1T(e), 29 CFR 2590.712(e), and 45 CFR 146.136(e))

Paragraph (e) of these regulations addresses the applicability of these regulations to group health plans and health insurance issuers and clarifies the scope of these regulations.

1. Overview

These regulations make a number of changes to the general applicability provisions in the MHPA 1996 regulations (paragraphs (c) and (d) in those regulations). Amendments made by MHPAEA require some of these changes. For example, the MHPA 1996 rules of construction specifically excluded any plan provisions relating to cost sharing, limits on the number of visits or days of coverage, and requirements relating to medical necessity from the application of the parity requirements for aggregate lifetime and annual dollar limits. MHPAEA replaces these exclusions with a rule providing that the provisions should not be construed as affecting the terms and conditions of the plan or coverage relating to mental health and substance use disorder benefits except as provided in the rules relating to financial requirements and treatment limitations. These regulations make corresponding changes to the MHPA 1996 regulations.

These regulations also (1) establish a new rule with respect to the mental health and substance use disorder parity requirements for the determination of the number of plans that an employer or employee organization maintains, (2) combine what were in the MHPA 1996

regulations separate rules for group health plans and benefit packages, and (3) make additional clarifications.

a. Group health plans. In 2004, the Departments issued proposed regulations for a number of issues under Chapter 100 of the Code, Part 7 of ERISA, and Title XXVII of the PHS Act, including rules for determining the number of group health plans that an employer or employee organization is considered to maintain for purposes of those provisions.[7] Those proposed regulations generally would have respected the number of plans designated in the instruments governing the employer's or employee organization's arrangements to provide medical care benefits as long as the arrangements were operated pursuant to those instruments as separate plans. The 2004 proposed regulations included an anti-abuse clause, providing that, if a principal purpose of establishing separate plans was to evade any requirement of law, then the separate plans would be considered a single plan to the extent necessary to prevent the evasion.

The Departments recognized that under the 2004 proposed regulations, absent the anti-abuse clause, plan sponsors might attempt to provide mental health (and now substance use disorder) benefits under a plan that is separate from a plan that provides only medical/surgical benefits. Because the mental health (and now substance use disorder) parity requirements apply only to plans that provide both mental health or substance use disorder benefits and medical/surgical benefits, the absence of medical/surgical benefits in a plan providing mental health or substance use disorder benefits would have resulted in, absent the anti-abuse clause, the inapplicability of the parity requirements. The 2004 proposed regulations included the anti-abuse clause to avoid this kind of evasion of the parity requirements. Commenters raised problems of proof with the subjective intent element of the proposed anti-abuse clause. While the 2004 rule

[7] See 69 FR 78800 (December 30, 2004).

remains proposed, these interim final regulations include a rule for determining the number of plans that an employer or employee organization maintains for the mental health and substance use disorder parity requirements that operates irrespective of the intent of a plan sponsor. The rule is that all medical care benefits provided by an employer or employee organization constitute a single group health plan.

MHPAEA left unchanged the rule from MHPA 1996 requiring that the parity requirements be applied separately to each benefit package option under a group health plan. The MHPA 1996 regulations used the term "benefit package" rather than "benefit package option" and clarified that the parity requirements would apply separately to separate benefit packages also in situations in which the participants (or beneficiaries) had no choice between multiple benefit packages, such as where retirees are provided one benefit package and active employees a separate benefit package. Under these regulations, the statutory rule providing that the parity requirements apply separately to separate benefit package options (reflected in paragraph (c) of the MHPA 1996 regulations), the statutory rule providing that the parity requirements apply to a group health plan providing both mental health or substance use disorder benefits and medical/surgical benefits (reflected in paragraph (d) of the MHPA 1996 regulations), and the determination of how many plans an employer or employee organization maintains have been combined as a single rule in paragraph (e)(1).

The new combined rule in these regulations does not use the term benefit package. Instead, it provides that (1) the parity requirements apply to a group health plan offering both medical/surgical benefits and mental health or substance use disorder benefits, (2) the parity requirements apply separately with respect to each combination of medical/surgical coverage and mental health or substance use disorder coverage that any participant (or beneficiary) can

simultaneously receive from an employer's or employee organization's arrangement or arrangements to provide medical care benefits, and (3) all such combinations constitute a single group health plan for purposes of the parity requirements. This new combined rule clearly prohibits what might have been formerly viewed as a potential evasion of the parity requirements by allocating mental health or substance use disorder benefits to a plan or benefit package without medical/surgical benefits (when medical/surgical benefits are also otherwise available). For example, if an employer with a single benefit package for medical/surgical benefits also has a separately administered benefit package for mental health and substance use disorder benefits, the parity requirements apply to the combined benefit package and the combined benefit package is considered a single plan for purposes of the parity requirements.

Similarly, if an employer offered three medical/surgical benefit packages, A, B, and C, and a mental health and substance use disorder benefit package, D, that could be combined with each of A, B , and C, then the parity requirements must be satisfied with respect to each of AD, BD, and CD. If the A benefit package had a standard option and a high option, A_1 and A_2, then the parity requirements would have to be satisfied with respect to each of A_1D and A_2D.

b. Health insurance issuers. These regulations make a change regarding applicability with respect to health insurance issuers. Both the MHPA 1996 regulations and these regulations apply to an issuer offering health insurance coverage. The MHPA 1996 regulations provide that the health insurance coverage must be for both medical/surgical and mental health benefits in connection with a group health plan; the rule in these regulations provides that the health insurance coverage must be for mental health or substance use disorder benefits in connection with a group health plan subject to MHPAEA under paragraph (e)(1). Thus, under these regulations, an issuer offering health insurance coverage without any medical/surgical benefits is

nonetheless subject to the parity requirements if it offers health insurance coverage with mental health or substance use disorder benefits in connection with a group health plan subject to the parity requirements. In addition, under these regulations, the parity requirements do not apply to an issuer offering health insurance coverage to a group health plan not subject to the parity requirements.

c. Scope. Paragraph (e)(3) of these regulations provides that nothing in these regulations requires a plan or issuer to provide any mental health or substance use disorder benefits. Moreover, the provision of benefits for one or more mental health conditions or substance use disorders does not require the provision of benefits for any other condition or disorder.

2. Interaction with State Insurance Laws

Numerous comments requested guidance on how MHPAEA interacts with State insurance laws requiring parity for, or mandating coverage of, mental health or substance use disorder benefits. Some commenters sought clarification that MHPAEA does not preempt any State insurance law mandating a minimum level of coverage (such as a minimum dollar, day, or visit level) for mental health conditions or substance use disorders. Other commenters suggested that, while MHPAEA does not preempt State insurance parity and mandate laws to the extent that they do not prevent the application of MHPAEA, provisions in the State laws that are more restrictive than the requirements of MHPAEA are preempted.

The preemption provisions of section 731 of ERISA and section 2723 of the PHS Act (added by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the MHPAEA requirements are not to be "construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance

issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement" of MHPAEA. The HIPAA conference report indicates that this is intended to be the "narrowest" preemption of State laws. (See House Conf. Rep. No. 104-736, at 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018.)

A State law, for example, that mandates that an issuer offer a minimum dollar amount of mental health or substance use disorder benefits does not prevent the application of MHPAEA. Nevertheless, an issuer subject to MHPAEA may be required to provide mental health or substance use disorder benefits beyond the State law minimum in order to comply with MHPAEA.

F. Small Employer Exemption (26 CFR 54.9812-1T(f), 29 CFR 2590.712(f), and 45 CFR 146.136(f))

Paragraph (f) of these regulations amends the MHPA 1996 regulations to implement the exemption for a group health plan (or health insurance issuer offering coverage in connection with a group health plan) for a plan year of a small employer. For this purpose, a small employer is generally defined, in connection with a group health plan with respect to a calendar year and a plan year, as an employer who employed an average of not more than 50 employees on business days during the preceding calendar year.

G. Increased Cost Exemption (26 CFR 54.9812-1T(g), 29 CFR 2590.712(g), and 45 CFR 146.136(g))

Both MHPA 1996 and MHPAEA include an increased cost exemption under which, if certain requirements are met, plans that incur increased costs above a certain threshold as a result of the application of the parity requirements of both these laws can be exempt from the statutory parity requirements. MHPAEA changed the MHPA 1996 increased cost exemption in several

ways, including (1) raising the threshold for qualification from one percent to two percent for the first year for which the plan is subject to MHPAEA; (2) requiring certification by qualified and licensed actuaries who are members in good standing of the American Academy of Actuaries; and (3) revising the notice requirements. Under MHPAEA, plans that comply with the parity requirements for one full plan year and that satisfy the conditions for the increased cost exemption are exempt from the parity requirements for the following plan year, and the exemption lasts for one year. Thus, the increased cost exemption may only be claimed for alternating plan years.

These regulations withdraw the MHPA 1996 regulatory guidance on the increased cost exemption and reserve paragraph (g). The Departments intend to issue, in the near future, guidance implementing the new requirements for the increased cost exemption under MHPAEA. The Departments invite comments on implementing the new statutory requirements for the increased cost exemption under MHPAEA, as well as information on how many plans expect to use the exemption.

H. Sale of Nonparity Health Insurance Coverage (26 CFR 54.9812-1T(h), 29 CFR 2590.712(h), and 45 CFR 146.136(h))

These regulations make a few changes to what was paragraph (g) in the MHPA 1996 regulations. That paragraph included a paragraph (g)(2) relating to how long the increased cost exemption applies once its requirements have been satisfied. It has been deleted because MHPAEA provides a new rule for how long the increased cost exemption applies. In addition, minor changes have been made to the presentation in what was paragraph (g)(1) in the MHPA 1996 regulations. Both that paragraph and paragraph (h) in these regulations address the circumstances of health insurance coverage that does not comply with the parity requirements

being sold to a group health plan. The MHPA 1996 regulations refer to an issuer selling a policy; these regulations refer to an issuer selling a policy, certificate, or contract of insurance. The longer phrase in these regulations includes health insurance coverage sold in a form that might not always be described by the term "policy" and is the more typical formulation used throughout the regulations under Chapter 100 of the Code, Part 7 of ERISA, and Title XXVII of the PHS Act. An additional change shifts the emphasis by stating the rule in terms of an issuer not being able to sell except in the described circumstances, rather than in terms of an issuer being able to sell only in the described circumstances. Finally, the cross-reference contained in this paragraph to the parity requirements has been conformed to include the new requirements of MHPAEA.

I. Applicability Dates (26 CFR 54.9812-1T(i), 29 CFR 2590.712(i), and 45 CFR 146.136(i))

In general, the requirements of these regulations apply for plan years beginning on or after July 1, 2010. There is a special effective date for certain collectively-bargained plans, which provides that, for group health plans maintained pursuant to one or more collective bargaining agreements ratified before October 3, 2008, the requirements of these regulations do not apply to the plan (or health insurance coverage offered in connection with the plan) for plan years beginning before the later of either the date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension agreed to after October 3, 2008) or July 1, 2010. MHPAEA provides that any plan amendment made pursuant to a collective bargaining agreement solely to conform to the requirements of MHPAEA not be treated as a termination of the agreement.

Many commenters requested guidance on what percentage of employees covered by a plan must be union employees for the plan to be considered a plan maintained pursuant to one or

more collective bargaining agreements – some suggesting as low a percentage as 25 percent while others suggested 90 percent. This issue arises in a number of statutes that provide special rules for plans maintained pursuant to collective bargaining agreements. As such, the issue is beyond the scope of these regulations implementing the MHPAEA amendments and is not addressed in them.

Because the statutory MHPAEA provisions are self-implementing and are generally effective for plan years beginning after October 3, 2009, many commenters asked for a good faith compliance period from Departmental enforcement until plans (and health insurance issuers) have time to implement changes consistent with these regulations. For purposes of enforcement, 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 paragraph (i) of these regulations. However, this does not prevent participants or beneficiaries from bringing a private action.

III. Interim Final Regulations and Request for Comments

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of Chapter 100 of Subtitle K of the Code, Part 7 of Subtitle B of Title I of ERISA, and Part A of Title XXVII of the PHS Act, which include the provisions of MHPAEA.

Under Section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest.

These rules are being adopted on an interim final basis because the Secretaries have determined that without prompt guidance some members of the regulated community may not know what steps to take to comply with the requirements of MHPAEA, which may result in an adverse impact on participants and beneficiaries with regard to their health benefits under group health plans and the protections provided under MHPAEA. Moreover, MHPAEA's requirements will affect the regulated community in the immediate future.

The requirements of MHPAEA are generally effective for all group health plans and for health insurance issuers offering coverage in connection with such plans for plan years beginning after October 3, 2009. Plan administrators and sponsors, issuers, and participants and beneficiaries need guidance on how to comply with the new statutory provisions. As noted earlier, these regulations take into account comments received by the Departments in response to the request for information on MHPAEA published in the **Federal Register** on April 28, 2009 (74 FR 19155). For the foregoing reasons, the Departments find that the publication of a proposed regulation, for the purpose of notice and public comment thereon, would be impracticable, unnecessary, and contrary to the public interest.

IV. Economic Impact and Paperwork Burden

A. Summary--Department of Labor and Department of Health and Human Services

As discussed earlier in this preamble, MHPAEA requires group health plans and group health insurance issuers to ensure that financial requirements (e.g., copayments, deductibles) and treatment limitations (e.g., visit limits) applicable to mental health or substance use disorder benefits are no more restrictive than the predominant financial requirements or treatment limitations applied to substantially all medical/surgical benefits. Under MHPAEA, a financial requirement or treatment limitation is considered to be predominant if it is the most common or

frequent of such type of requirement or limitation. Additionally, there can be no separate cost-sharing requirements or treatment limitations applicable only with respect to mental health or substance use disorder benefits. The statute does not mandate coverage for either mental health or substance use disorder benefits. Thus, self-insured plans are free to choose whether to provide mental health or substance use disorder benefits; insured plans may have to provide these benefits under state laws. Either type of plan that provides mental health or substance use disorder benefits must do so in accordance with MHPAEA's parity provisions.

The Departments have crafted these regulations to secure the protections intended by Congress in as economically efficient a manner as possible. Although the Departments are unable to quantify the regulations' economic benefits, they have quantified some of the costs and have provided a qualitative discussion of some of the benefits and costs that may stem from these regulations.

B. Statement of Need for Regulatory Action

Congress directed the Departments to issue regulations implementing the MHPAEA provisions. In response to this Congressional directive, these interim final regulations clarify and interpret the MHPAEA provisions under section 712 of ERISA, section 2705 of the PHS Act, and section 9812 of the Code. These regulations are needed to secure and implement MHPAEA's provisions and ensure that the rights provided to participants, beneficiaries, and other individuals under MHPAEA are fully realized. The Departments' assessment of the expected economic effects of these regulations is discussed in detail below.

C. Executive Order 12866--Department of Labor and Department of Health and Human Services

Under Executive Order 12866 (58 FR 51735), the Department must determine whether a regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB). Section 3(f) of the Executive Order defines a "significant regulatory action" as an action that is likely to result in a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. The Departments have determined that this regulatory action is economically significant within the meaning of section 3(f)(1) of the Executive Order, because it is likely to have an effect on the economy of $100 million or more in any one year. Accordingly, the Departments provide the following assessment of its potential costs and benefits. As elaborated below, the Department believes that the benefits of the rule justify its costs.

Table 1, below, summarizes the costs associated with the rule. The estimates are explained in the following sections. Over the ten-year period of 2010 to 2019, the total undiscounted cost of the rule is estimated to be $115 million in 2010 Dollars. Columns E and F display the costs discounted at 3 percent and 7 percent respectively. Column G shows a transfer of $25.6 billion over the ten-year period. All other numbers included in the text are not discounted, except where noted.

TABLE 1.--*Total Costs of Rule (in Millions of 2010 Dollars)*

Year	General Review (A)	Medical Necessity Disclosure (B)	Single Deductible (C)	Total Undiscounted Costs A+B+C	Total 3% Discounted Costs (E)	Total 7% Discounted Costs (F)	Transfer (undiscounted) (G)
2010	$27.8	$1.2	$39.2	$68.2	$68.2	$68.2	$2,360.0

2011	$0	$1.2	$3.9	$5.2	$5.0	$4.8	$2,400.0
2012	$0	$1.2	$3.9	$5.2	$4.9	$4.5	$2,430.0
2013	$0	$1.2	$3.9	$5.2	$4.7	$4.2	$2,460.0
2014	$0	$1.2	$3.9	$5.2	$4.6	$3.9	$2,510.0
2015	$0	$1.2	$3.9	$5.2	$4.4	$3.7	$2,570.0
2016	$0	$1.2	$3.9	$5.2	$4.3	$3.4	$2,620.0
2017	$0	$1.2	$3.9	$5.2	$4.2	$3.2	$2,680.0
2018	$0	$1.2	$3.9	$5.2	$4.1	$3.0	$2,740.0
2019	$0	$1.2	$3.9	$5.2	$4.0	$2.8	$2,810.0
			Total	**$114.6**	**$108.4**	**$101.8**	**$25,600.0**

Note: The displayed numbers are rounded to the nearest thousand and therefore may not add up to the totals.

The Departments performed a comprehensive, unified analysis to estimate the costs and, to the extent feasible, provide a qualitative assessment of benefits attributable to the regulations for purposes of compliance with Executive Order 12866, the Regulatory Flexibility Act, and the Paperwork Reduction Act. The Departments' assessment and underlying analysis is set forth below.

1. Regulatory Alternatives

Section 6(a)(3)(C)(iii) of Executive Order 12866 requires an economically significant regulation to include an assessment of the costs and benefits of potentially effective and reasonable alternatives to the planned regulation, and an explanation of why the planned regulatory action is preferable to the potential alternatives. As discussed earlier in this preamble, the Departments considered the alternative of whether to require the same separately accumulating deductible for medical/surgical benefits and mental health or substance use disorder benefits or a combined deductible for such benefits.

The language of the statute can be interpreted to support either alternative. The comments that supported allowing separately accumulating deductibles maintained that it is commonplace for plans to have such deductibles, and that the projected cost of converting systems to permit unified deductibles would be extremely high for the many plans that use a

separate managed behavioral health organization (MBHO).[8] By contrast, comments that supported requiring combined deductibles argued that allowing separately accumulating deductibles undermines a central goal of parity legislation: to affirm that mental health and substance use disorder benefits are integral components of comprehensive health care and generally should not be distinguished from medical/surgical benefits. Distinguishing between the two requires individuals who need both kinds of care to satisfy a deductible that is greater than that required for individuals needing only medical/surgical care. Other comments that supported requiring combined deductibles noted that mental health and substance use disorder benefits typically comprise only 2 to 5 percent of a plan's costs, so that even using identical levels for separately accumulating deductibles imposes a greater barrier to mental health and substance use disorder benefits.

The Departments carefully considered the alternative of requiring separately accumulating or combined deductibles. Given that the statutory language does not preclude either interpretation, the Departments choose to require combined deductibles, because this position is more consistent with the policy goals that led to the enactment of MHPAEA.

2. Affected Entities and Other Assumptions

The Departments expect MHPAEA to benefit the approximately 111 million participants in 446,400 ERISA-covered employer group health plans, and an estimated 29 million participants in the approximately 20,300 public, non-Federal employer group health plans sponsored by state and local governments.[9] In addition, approximately 460 health insurance

[8] For a full discussion of the cost considerations involved with these alternatives, see section 4. b., below, Costs associated with cumulative financial requirements and quantitative treatment limitations, including deductibles.

[9] The Departments' estimates of the numbers of affected participants are based on DOL estimates using the 2008 CPS. ERISA plan counts are based on DOL estimates using the 2008 MEP-IC and Census Bureau statistics. The number of state and local government employer-sponsored plans was estimated using 2007 Census data and DOL

issuers providing mental health or substance use disorder benefits in the group health insurance market and at least 120 MBHOs providing mental health or substance use disorder benefits to group health plans are expected to be affected.[10]

3. Benefits

Congress first passed mental health parity legislation in 1996 with the enactment of MHPA 1996.[11] As discussed earlier in this preamble, this law requires health insurance issuers and group health plans that offer mental health benefits to have aggregate annual and lifetime dollar limits on mental health benefits that are no more restrictive than those for all medical/surgical benefits.

The impact of MHPA 1996 was limited, however, because it did not require parity with respect to day limits for inpatient or outpatient care, deductibles, co-payments or coinsurance, substance use disorder benefits, and prescription drug coverage.[12] While a large majority of plans complied with the MHPA 1996 parity requirement regarding annual and lifetime dollar limits, many employer-sponsored group health plans contained plan design features that were

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estimates. Please note that the estimates are based on survey data that is not broken down by the employer size covered by MHPAEA making it difficult to exclude from estimates those participants employed by employers who employed an average of at least 2 but no more than 50 employees on the first day of the plan year.

[10] The Departments' estimate of the number of insurers is based on industry trade association membership. Please note that these estimates could undercount small state regulated insurers.

[11] P.L. 104-204, title VII, 110 Stat. 2874, 2944-50.

[12] GAO/HEHS-00-95, *Implementation of the Mental Health Parity Act*. In the report, GAO found that 87 percent of compliant plans contained at least one more restrictive provision for mental health benefits with the most prevalent being limits on the number of outpatient office visits and hospital day limits. *Id*. at 5.

more restrictive for mental health benefits than for medical/surgical benefits. For example, data on private insurance arrangements from the pre-MHPAEA era show that after MHPA 1996, the most significant disparities in coverage for mental health substance use treatment involve limits on the number of covered days of inpatient care and the number of outpatient visits. Survey data from the Kaiser/HRET national employer survey shows that 64 percent of covered workers had more restrictive limits on the number of covered hospital days for mental health care and 74 percent had more restrictive limits on outpatient mental health visits. In addition, 22 percent of covered workers had higher cost-sharing imposed on mental health care benefits. Among those workers with more restrictive limits on inpatient days, 77 percent had limits of 30 days or less. [13] For these reasons, as discussed more fully below, the Departments expect that MHPAEA and these regulations will have their greatest impact on people needing the most intensive treatment and financial protection. The Departments do not have an estimate of the number of individuals who have exceeded the treatment limits. However, according to the FEHBP data used to analyze the FEHBP parity directive in the year before its implementation, the 90th percentile of the mental health spending distribution was corresponded to $2,134 in 1999 dollars. Among the people spending at the 90th percentile or higher, 12% had inpatient psychiatric stays and 20% of those above the 90th percentile had a diagnosis of schizophrenia or bipolar disorder, chronic conditions requiring prescription drugs and regular contact with mental health service providers. It is this group that experienced especially large declines in out of pocket payments after FEHBP implemented parity.

[13] Barry, Colleen, et al. "Design of Mental Health Benefits: Still Unequal After All These Years," *Health Affairs* Vol. 22, Number 5, 2003. Please note that the baseline data from the Kaiser HRET survey cited in this article are weighted by region, firm size and industry to reflect the national composition of employers. So the data cited establishing the baseline reflects the impact of state parity laws. It is important to realize that state parity laws frequently focus on a subset of diagnoses, e.g. biologically based disorders, and do not apply to self-funded insurance programs. Thus, in most states only a minority of insurance contracts is affected by state parity laws.

Treatment for alcohol abuse disorders showed a similar trend: Surveys indicate that 74 percent of private industry employees were covered by plans that imposed more restrictive limits for inpatient detoxification benefits than medical and surgical benefits, 88 imposed more restrictive limits for inpatient rehabilitation, and 89 percent imposed more restrictive limits for outpatient rehabilitation.[14]

After MHPA 1996, many states also passed mental health parity laws. Research focused on the impacts of parity laws found that similar to MHPA 1996, even the most comprehensive state laws resulted in little or no increase in access to and utilization of mental health services for covered individuals.[15]

To address these issues, Congress amended MHPA 1996 by enacting MHPAEA. One of Congress' primary objectives in enacting MHPAEA was to improve access to mental health and substance use disorder benefits by eliminating discrimination that existed with respect to these benefits after MHPA 1996. Congress' intent in enacting MHPAEA was articulated in a floor statement from Representative Patrick Kennedy (D-RI), one of the chief sponsors of the legislation, who said "[a]ccess to mental health services is one of the most important and most neglected civil rights issues facing the Nation. For too long, persons living with mental disorders have suffered discriminatory treatment at all levels of society." [16] In a similar statement, Representative James Ramstad (R-MN) said, "[i]t's time to end the discrimination against people

[14] Morton, John D. and Patricia Aleman. "Trends in Employer-provided Mental Health and Substance Abuse Benefits." *Monthly Labor Review*, April 2005.

[15] *Id.*, at 9. The state mental health parity laws varied significantly with most of differences related the following areas: the type of mental health mandate, definition of mental illness, the inclusion of substance abuse coverage, small employers' coverage, and cost increase exceptions. Few state laws provide as extensive coverage as MHPAEA, particularly with regard to its prohibition of visit limitations.

[16] 153 *Cong. Rec. S1864-5 (daily ed., February 12, 2007).*

who need treatment for mental illness and addition. It's time to prohibit health insurers from placing discriminatory barriers on treatment." [17]

The Departments expect that the largest benefit associated with MHPAEA and these regulations will be derived from applying parity to cumulative quantitative treatment limitations such as annual or lifetime day or visit limits (visit limitations). As discussed above, a large percentage of plans imposed visit limitations pre-MHPAEA, and the GAO found that a major shortcoming of MHPA 1996 was its failure to apply parity to visit limitations. Applying parity to visit limitations will help ensure that vulnerable populations – those accessing substantial amounts of mental health and substance use disorder services – have better access to appropriate care. The Departments cannot estimate how large this benefit will be, because sufficient data is not available to estimate the number of covered individuals that had their benefits terminated because they reached their coverage limit. Though difficult to estimate, the number of beneficiaries who have a medical necessity for substantial amount of care are likely to be relatively small. Severe mental health disorders account for 2-3 percent of people in private health insurance plans and a substantially larger share of mental health spending. Evidenced-based treatments for severe and persistent mental illnesses like schizophrenia, bipolar disorder and chronic major depression requires prolonged (possibly lifetime) maintenance treatment that consists of pharmacotherapy, supportive counseling and often rehabilitation services.[18] The most common visit limits under current insurance arrangements are those for 20 visits per year. That means assuming a minimal approach to treatment of one visit per week, people with severe and persistent mental disorders will exhaust their coverage in about five months. This often results in

[17] 154 *Cong. Rec. H8619 (daily ed., September 23, 2008).*

[18] See, Lehman AF "Quality of care in mental health: the case of schizophrenia" Health Affairs 18(5): 52-65.

people foregoing outpatient treatment and a higher likelihood of non-adherence to treatment regimes that produce poor outcomes and the potential for increased hospitalization costs.

Increased coverage also should provide enhanced financial protection for this group by reducing out-of-pocket expenses for services that previously were needed but uncovered. This should help prevent bankruptcy and financial distress for these individuals and families and reduce cost-shifting of care to the public sector, both of which occur when covered benefits are exhausted. In addition, increased coverage for those seeking substantial amounts of care potentially could reduce emergency room use by ensuring that benefits for individuals with serious conditions are not terminated. Finally, reduced entry into disability programs may result from having more complete insurance coverage for mental health and substance use disorder treatment.

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[19] 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

[19] Sturm R, "Tracking changes in behavioral health services: How carve-outs changed care?" Journal of Behavioral Health Services and Research 26(4): 360-371, 1999. Frank RG and Garfield RL; "Managed Behavioral Health Carve-Outs: Past Performance and Future Prospects" Annual Reviews of Public Health 2007, 28:11; 1-18. Frank RG and Garfield RL; "Managed Behavioral Health Carve-Outs: Past Performance and Future Prospects" Annual Reviews of Public Health 2007, 28:11; 1-18.

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.

The OPM encouraged its insurers to consider carve-out arrangements when implementing the parity directive in 2000 for the FEHBP. This is because of the ability of behavioral health carve-outs to use utilization management tools to control utilization and spending in the face of reductions in cost-sharing and elimination of limits. 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.

Another potential benefit associated with MHPAEA and these regulations is that use of mental health and substance use disorder benefits could improve.[20] Untreated or under treated mental health conditions and substance use disorders are detrimental to individuals and the entire economy. Day and visit limits can interfere with appropriate treatment thereby reducing the impact of care for workers seeking treatment. Many people with mental health conditions and substance use disorders are employed and these debilitating conditions have a devastating impact on employee attendance and productivity, which results in lost productivity for employers and lost earnings for employees. For example, studies have shown that the high prevalence of depression and the low productivity it causes have cost employers $31 billion to $51 billion

[20] While studies have shown that state parity laws have increased access only marginally, most state laws still allowed disparate treatment limits for mental health conditions and substance use disorders, which limited access for those needing significant amounts of treatment. As discussed above, MHPAEA and these regulations prohibit the imposition of such disparate limits, which could increase access for those individuals. Nine states have treatment limit requirements similar to MHPAEA for mental health benefits, while 10 states have similar requirements for substance abuse disorder benefits.

annually in lost productivity in the United States.[21] More days of work loss and work impairment are caused by mental illness than by various other chronic conditions, including diabetes and lower back pain.[22]

Moreover, studies have consistently found that workers who report symptoms of mental disorders have lower earnings than other similarly-situated coworkers. For example, a recent study funded by the National Institutes of Health's National Institute of Mental Health[23] found that mental disorders cost employees at least $193 billion annually in lost earnings alone, a staggering number that probably is a conservative estimate because it did not include the costs associated with people in hospitals and prisons, and included very few participants with autism, schizophrenia and other chronic illnesses that are known to greatly affect a person's ability to work. The study also noted that individuals suffering from depression earn 40 percent less than non-depressed individuals.

Although accurately determining cause and effect can be difficult, studies have attempted to estimate the beneficial impact of treating mental disorders. One study found that treating individuals suffering from mental disorders helped close the gap in productivity between those

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[21] Stewart, W.F., Ricci, J.A., Chee, E., Hahn, S.R. & Morgenstein, D. (2003, June 18). "Cost of lost productive work time among US workers with depression." *JAMA: Journal of the American Medical Association.* 289, *23*, 3135-3144.

Kessler, R.C., Akiskal, H.S., Ames, M., Birnbaum, H., Greenberg, P., Hirschfeld, H.M.A. et al. (2006). "Prevalence and effects of mood disorders on work performance in a nationally representative sample of U.S. workers." *American Journal of Psychiatry*, 163, 1561-1568.

[22] Stewart, W.F., Ricci, J.A., Chee, E., Hahn, S.R. & Morgenstein, D. (2003, June 18). "Cost of lost productive work time among US workers with depression." *JAMA: Journal of the American Medical Association.* 289, *23*, 3135-3144.

[23] Kessler, Ronald C., Steven Heeringa, Matthew D. Lakoma, Maria Petukhova, Agnes E. Rupp, Michael Schoenbaum, Philip S. Wang, and Alan M. Zaslavsky. "Individual and Societal Effects of Mental Disorders on Earnings in the United States: Results From the National Comorbidity Survey Replication." *The American Journal of Psychiatry;* June 2008; 165, 6; Research Library pg. 703.

with mental disorders and those who did not have a mental disorder.[24] The finding that treatment can help increase the productivity of those suffering from mental illness suggests that increasing access to treatment of mental disorders could have a beneficial impact on lost productivity cost and lost earnings that stem from untreated and under treated mental health conditions and substance use disorders. The Departments, however, do not have sufficient data to determine whether this result will occur, and, if it does, the extent to which lost productivity cost and lost earnings could improve.

As noted above the combination of reduced cost sharing and the elimination of day and visit limits have the effect of making coverage more complete. The dominant role of managed behavioral health care in the market and the evidence about it success in controlling costs means that the moral hazard problem can be controlled (the evidence on this is discussed in more detail below). The implication is that more complete financial protection can be offered to people without a significant increase in social costs. This implies improved efficiency in the insurance market since more efficient risk spreading would occur without much welfare loss due to moral hazard.

In order to comply with MHPAEA and these regulations, cost-sharing requirements for mental health and substance use disorder benefits cannot be any more restrictive than the predominant cost-sharing requirement applied to substantially all medical/surgical benefits. Because expenditures on mental health and substance use disorder benefits only comprise 3-6 percent of the total benefits covered by a group health plan and 8 percent of overall healthcare

[24] Hilton, Michael F., Paul A. Schuffham, Judith Sheridan, Catherine M. Clearly, Neria Vecchio, and Harvey A. Whiteford. "The Association Between Mental Disorders and Productivity in Treated and Untreated Employees." *Journal of Occupational and Environmental Medicine.* Volume 51, Number 9, September 2009.

costs,[25] the Departments expect that group health plans will lower cost-sharing on mental health and substance use disorder benefits instead of raising cost-sharing on medical/surgical benefits.

MHPAEA and these interim final regulations could have a positive impact on the delivery system of mental health services. Currently, approximately half of mental health care is delivered solely by primary care physicians.[26] This trend is likely due in part to the large discrepancies between insurance cost-sharing for services delivered by mental health professionals and primary care physicians. Historically, the cost-sharing associated with primary care physician visits is lower than cost-sharing for mental health professional visits. This difference in the relative price encouraged patients suffering from mental illness to visit primary care physicians for mental health-related conditions. If MHPAEA and these regulations result in lowering the relative price of mental health care, more individuals suffering from mental illness could visit and receive care from mental health professionals. One study[27] found that only 12.7 percent of individuals treated in the general medical sector received at least minimally adequate mental health care compared to 48.3 percent of patients treated in the specialty mental health sector.[28] A shift in source of treatment from primary care physicians to mental health

[25] Finch R.A., Phillips K.. Center for Prevention and Health Services. "An Employer's Guide to Behavioral Health Services: A Roadmap and Recommendations for Evaluating Designing, and Implementing Behavioral Health Services." National Business Group on Health 2005.

[26] Wang, P.S., Lane, M., Olfson, M., Pincus, H.A., Wells, K.B., and Kessler, R.C. (2005, June). "Twelve month use of mental health services in the United States." *Archives of General Psychiatry*, 62, 629-640. The study found that 40 percent of people reporting mental health and substance use disorders receive some treatment in a year.

[27] Wang, P.S., Lane, M., Olfson, M., Pincus, H.A., Wells, K.B., and Kessler, R.C. (2005, June). "Twelve month use of mental health services in the United states." *Archives of General Psychiatry*, 62, 629-640.

[28] Another analysis demonstrating poor adherence to evidence-based treatment for mental disorders is: Wang PS, Berglund P, Kessler RC, *Journal of General Internal Medicine*. 2000; 15:284-292. Recent care of common mental disorders in the United States: prevalence and conformance with evidence-based recommendations. This study finds that only 57.3 percent of people with major depression receive treatment during a year and less than one-third of those who receive treatment receive effective treatment.

professionals could lead to more appropriate care, and thus, better health outcomes.[29] The Departments, however, do not have sufficient data to estimate how large this shift in treatment could be or determine whether it will occur.

Mental health and physical health are interrelated, and individuals with poor mental health are more likely to have physical health problems as well. Increased access and utilization of mental health and substance use disorder benefits could result in a reduction of medical/surgical costs for individuals afflicted with mental health conditions and substance use disorders. The decrease in medical/surgical costs could be significant; however, the Departments do not have sufficient data to estimate how large these health care spending offsets could be or determine whether they will occur.

There is disagreement among experts as to whether depression is an important antecedent risk factor for physical illness or whether the causal relationship acts in the opposite direction. Regardless, there is evidence that comorbid depression worsens the prognosis, prolongs recovery and may increase the risk of mortality associated with physical illness. In addition, comorbid depression has been shown to increase the costs of medical care, over and above the costs of treating the depression itself.[30]

Based on expert opinion, Normand et al. rated the likely effectiveness of combinations of general medical visits, specialty visits (with psychotherapy) and drug treatment to demonstrate the correlation between adequate treatment for depression and the probability of remission. For patients with no anti-depressant medication, the probability of remission increased as the number of specialty visits increased from one or less during a year to ten or more. The probability of remission was greater for patients with antidepressant medication and improved with more specialty visits during the year. Normand SLT, Frank RG, McGuire, TG. "Using elicitation techniques to estimate the value of ambulatory treatments for depression." Medical Decision Making, 2001; 22: 245-261.

[29] The Healthcare Effectiveness Data and Information Set report card for 2007 produced by National Center for Quality Assurance shows that for treatment of depression, only 20 percent of patients get appropriate levels of provider contacts; about 45 percent receive appropriate maintenance level medications and 62 percent obtain adequate medication doses and duration during the acute phase of illness.

[30] Conti R, Berndt ER, Frank RG. "Early retirement and DI/SSI applications: exploring the impact of depression", in Culter DM, Wise DA. *Health in Older Ages: The causes and consequences of declining disability among the elderly,* (Chicago: National Bureau of Economic Research, 2008).

The returns on investment from treatment of substance use disorders can be large.[31] Studies in Washington state clinics demonstrated that each dollar invested in inpatient and outpatient substance abuse treatment yielded returns of about 10 and 23 times their initial investments, respectively.[32] California and Oregon state treatment systems demonstrated a sevenfold return in their investments.[33] Other studies show effects ranging from a return of one and a half times the cost in a large study of a treatment clinic in Chicago to a return of 5 times the initial investment for a treatment for mentally ill chemical abusers,[34] resulting in a net benefit of about $85,000 per client for an investment of nearly $20,000. [35]

4. Costs

a. Cost associated with increased utilization of mental health and substance use disorder benefits. As discussed in the Benefits section earlier in this preamble, one of Congress' primary objectives in enacting MPHAEA was to eliminate barriers that impede access to and utilization of mental health and substance use disorder benefits. This has raised concerns among some that increased access and utilization of mental health and substance use disorder benefits will result in increases in associated payments and plan expenditures, which could lead to large premium

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[31] The Office of National Drug Control Policy has information on effective treatment and cost savings at www.whitehousedrugpolicy.gov.

[32] French, M. T., H. J. Salome, A. Krupski, J. R. McKay, D. M. Donovan, A. T. McLellan, and J. Durrell. (2000). "Benefit-cost analysis of residential and outpatient addiction treatment in the State of Washington." *Evaluation Review, 24(6),* 609-634.

[33] Ettner, S. L., D. Huang, E. Evans, D. R. Ash, M. Hardy, M. Jourabchi, and Y. Hser. (2006). "Benefit-Cost in the California Treatment Outcome Project: Does Substance Abuse Treatment 'Pay for Itself?'" *Health Services Research,* 41(1), 192-213.

[34] French, M.T., K. E. McCollister, S. Sacks, K. McKendrick, & G. De Leon. (2002). "Benefit cost analysis of a modified therapeutic community for mentally ill chemical abusers." *Evaluation and Program Planning, 25*, 137-148.

[35] The returns are the ratio of benefits to costs. Benefits include personal as well as societal benefits including increased employment and reduced crime.

increases that will make mental health and substance use disorder benefits unaffordable. The Departments are uncertain regarding the level of increased costs and premium increases that will result from MHPAEA and these regulations, but there is evidence that any increases will not be large.

One theory for increased costs resulting from parity is based on the fact that cost-sharing for mental health and substance use disorder benefits will decrease. A frequent justification for higher cost-sharing of mental health and substance use disorder benefits is the greater extent of moral hazard for these benefits; individuals will utilize more mental health and substance use disorder benefits at a higher rate when they are not personally required to pay the cost. To support this assumption, many have cited the RAND Health Insurance Experiment, conducted in 1977-1982, which demonstrated that individuals are more likely to increase their mental health care usage when their personal cost-sharing for mental health care services fall than they are to increase their physical health care usage when their personal cost-sharing for physical health care services decreases. Because this experiment was conducted nearly thirty years ago, researchers recently tested to determine whether this result held true.[36] Their results indicate that individuals' sensitivity to changes in cost-sharing may have changed significantly over time. These changes are explained at least in part due to the expansion of managed behavioral health care (described earlier). The authors found that individuals' price responsiveness of ambulatory mental health treatment is now slightly lower than physical health treatment. These results indicate that if

[36] Meyerhoefer, Chad D. and Samuel Zuvekas, 2006. "New Estimates of the Demand for Physical and Mental Health Treatment." Agency for Healthcare Research and Quality Working Paper No. 06008

plans lower the cost-sharing associated with mental health services, costs will not rise as much as would be expected using the results from the RAND Experiment.[37]

When the RAND Experiment was conducted, managed care was not nearly as prevalent as it is today. Health care economists have studied the impact of using cost control techniques associated with managed care to reduce the quantity of mental health and substance use disorder benefits utilized so that lowered cost sharing may result in only a small increase in spending.[38] This research concluded that "comprehensive parity implemented in the context of managed care would have little impact on total spending."[39]

These findings were similar to those of a recent study published in the New England Journal of Medicine examining the Federal Employees Health Benefits Program (FEHBP), which implemented parity for mental health and substance use disorder benefits in 2001.[40] The primary concern has been that the existence of parity in the FEHBP would result in large increases in the use of mental health and substance-abuse services and spending on these services. However, the 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,

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[37] Another paper showing a similar result to the Myerhoefer paper cited above is: Lu CL, Frank, RG and McGuire TG. "Demand Response Under Managed Care." *Contemporary Economic Policy*, 27(1):1-15, 2009.

[38] Barry, Frank, and McGuire. "The Costs of Mental Health Parity: Still an Impediment?" *Health Affairs*, no. 3:623 (2006).

[39] *Id.*

[40] Goldman, et al., "Behavioral Health Insurance Parity for Federal Employees," New England Journal of Medicine (March 30, 2006) Vol. 354, No. 13. In 1999, President Clinton directed the Office of Personnel Management (OPM) to equalize benefits coverage in the FEHBP, and parity was implemented in 2001. Parity under the FEHBP is very similar to MHPAEA. It requires benefits coverage for plan mental health, substance abuse, medical, surgical, and hospital providers to have the same limitations and cost-sharing such as deductibles, coinsurance, and co-pays. When patients use plan providers and follow a treatment regime approved by their plan, all diagnostic categories of mental health and substance abuse conditions listed in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM IV) are covered.

is feasible and can accomplish its objectives of greater fairness and improved insurance protection without adverse consequences for health care costs."[41] The study found average per user declines in out patient cost sharing of between zero and $87 depending on the plan. The reductions were largest for high users of mental health care. The study also found that insurers were not likely to drop out of the FEHBP pool due to the implementation of parity.

The experience of states that have enacted mental health parity laws with appropriate managed care also suggests that minimal increased cost results from implementing parity. One study found that "with the implementation of mental health parity at the same time as managed behavioral health care, many states have discovered that overall health care costs increased minimally and in some cases even were reduced."[42] For example, at least nine states – California, Maine, Maryland, Minnesota, North Carolina, Pennsylvania, Rhode Island, South Carolina, and Vermont – have actually documented experience that implementing mental health parity including cost controls through managed care resulted in lower costs and lowered premiums (or at most, very modest cost increases of less than one percent) within the first year of implementation.[43]

Similarly, the Departments expect medical management and managed care techniques will help control any major cost impact resulting from MHPAEA and these regulations. As discussed earlier in this preamble, these regulations provide that medical management can be applied to mental health and substance use disorder benefits by plans as long as any processes,

[41] *Id.*

[42] Melek, Steve, "The Costs of Mental Health Parity," *Health Section News* (March 2005).

[43] Bachman, Ronald, *Mental Health Parity – Just the Facts* (2000).

strategies, evidentiary standards, or other factors used in applying medical management are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying medical management to medical/surgical benefits.

Although the increase in per plan costs associated with parity is not likely to be substantial, there may be plans that decide to drop coverage for mental health and substance use disorder benefits in response to higher costs, or individuals may decide to drop coverage even if it is offered. The Departments do not have an estimate of the number of plans that will drop coverage or the number of individuals that will lose benefits. Currently 98 percent of covered workers have some form of mental health benefits.[44] The lack of coverage for mental health and substance use disorder benefits for these people may lead to many of the typical costs associated with uninsured individuals: lack of access, decreased health, and increased financial burden. The Departments are not able to quantify these costs. Research on the introduction of state parity laws suggests few plans or individuals will drop insurance coverage due to parity.[45]

b. Costs associated with cumulative financial requirements and quantitative treatment limitations, including deductibles. As discussed earlier in this preamble, paragraph (c)(3)(v) of these regulations provide that a group health plan may not apply cumulative financial requirements, such as deductibles, for mental health and substance use disorder benefits in a classification that accumulate separately from any such requirements or limitations established for medical/surgical benefits in the same classification. Some group health plans and health insurance issuers "carve-out" the administration and management of mental health and substance

[44] Kaiser Family Foundation and Health Research & Educational Trust. *Employer Health Benefits 2008 Annual Survey*.

[45] Cseh, Attila. "Labor Market Consequences of State Mental Health Parity Mandates," Forum for Health Economics & Policy, Vol. 11, issue 2, 2008.

use disorder benefits to MBHOs. These entities obtain cost savings for plan sponsors by providing focused case management and directing care to a broad network of mental and behavioral health specialists (with whom they negotiate lower fees) who ensure that appropriate care for mental health conditions and substance use disorders is provided.[46]

When a group health plan or health insurance issuer uses a carve-out arrangement, at least two entities are involved in separately managing and administering medical/surgical and mental health and substance use disorder benefits.[47] The imposition of a single deductible requires entities providing medical/surgical and mental health and substance use disorder benefits to develop and program a communication network often referred to as an "interface" or an "accumulator" that will allow them to exchange the data necessary to make timely and accurate determinations of when participants have incurred sufficient combined medical/surgical and mental health and substance use disorder expenses to satisfy the single deductible.

Two comments received in response to the RFI indicate that MBHOs would confront significant costs to develop real-time interfaces that could range from $420,000-$750,000 with an additional $40,000-$70,000 required for annual maintenance.[48] The Departments held discussions with the regulated community which indicated that interface development costs may not be as high as stated in the RFI comments. For example, the Departments have learned that

[46] Research papers have indicated that carve-out arrangements have reduced the cost of proving mental health and substance use disorder benefits by an estimated 25-40 percent. Frank, Richard G. and Thomas G. McGuire, "Savings from a Carve-Out Program for Mental Health and Substance Abuse in Massachusetts Medicaid" Psychiatric Services 48(9); 1147-1152, 1997; Ma, Ching-to Albert and Thomas G. McGuire, "Costs and Incentives in a Behavioral Health Carve-out. *Health Affairs* March/April 1998.

[47] This can create a coordination issue that has cost implications that otherwise do not exist when a single vendor is used.

[48] RFI comments. MHPAEA RFI comments can be viewed at http://www.dol.gov/ebsa/regs/cmt-MHPAEA.html.

MBHOs could develop less costly "batch process" interfaces that exchange data on a daily or weekly basis rather than real-time for as low as approximately $35,000 per interface.[49]

It also appears that some plan sponsors using carve-out arrangements already are implementing a unified, single deductible, and MBHOs have created interfaces to service these clients. For example, the Departments' discussions found that one MBHO already has established 10-15 accumulators, because its plan sponsor clients requested a single deductible. The MBHO reported that another 10-15 accumulators were being implemented for the current benefit year, because plan sponsors wanted to ensure that they were compliant with MHPAEA. This finding suggests that while costly, putting these accumulators in place is not cost prohibitive for the MBHOs and plan sponsors. Moreover, plans and issuers have created and used interfaces with separate pharmacy benefit managers and dental insurers for years. Interface development costs should decrease after the first interface is created. The experience and lessons learned from creating these interfaces should reduce the cost associated with designing and implementing interfaces with MBHOs.

While the RFI comment letters suggested that MBHOs would have to create 40-50 interfaces each, this number most likely only relates to the largest MBHOs. The smallest MBHOs would need to create fewer interfaces. The Departments assume that a significant number of smaller MBHOs exist; therefore, the Departments estimate that, on average, seven

[49] An additional undetermined expense would be required to reconcile and make adjustments in instances when two claims are received on the same day satisfying the unified deductible. While this alternative would produce a much lower cost than real-time interfaces, the costs remain significant. A low-end estimate of the first year cost for MBHOs and insurers to create, on average, at least 20 new interfaces would be $700,000 per insurer. There is uncertainty regarding the total cost, because the number of entities that would need to create interfaces is unclear. The Departments are aware of 460 health insurance issuers and at least 120 MBHOs that could be affected.

interfaces would have to be created per insurer. The Departments acknowledge that there is uncertainty in this estimate due to incomplete information about the MBHO industry.

For purposes of this analysis, the Departments have used an estimated interface development cost of $35,000 per interface, because the Departments were not able to substantiate the higher estimated costs provided in the RFI comment letters, and the propensity of the evidence leads to the conclusion that the cost could be significantly less. Based on the foregoing, the Departments estimate total interface development costs of approximately $39.2 million.[50]

Once the interfaces are created, ongoing annual maintenance costs will be incurred. One industry source suggested that ongoing maintenance costs could be one-tenth of the development costs, and based on this information, the Departments estimate that maintenance cost of $3.9 million will be incurred annually after the interfaces are created.

While the total interface development and maintenance costs are large, a useful measure to examine is the per-participant cost impact. While reliable estimates of the number of participants enrolled in plans utilizing MBHOs are not available, based on the best available information, the Departments estimate that at least 70 million participants are covered by MBHOs. Based on this count, the per-participant first year interface development costs would be $0.60, and the maintenance costs in subsequent years would be less than one cent.

Comments from health insurance issuers have suggested that the costs of creating these interfaces would be passed on to participants in the form of higher premiums; however, no independent information has been found to corroborate this assertion.

[50] Please note that using the $420,000 per interface estimate cited in the RFI comment letters would result in total interface development costs of $470 million, with annual maintenance costs of $47 million. Based on this estimate, the per-participant first year interface development costs would be $7, and the annual maintenance costs in subsequent years would be $.06 cents per participant per month.

c. Compliance review costs. The Departments expect that group health plans and health insurance issuers will conduct a compliance review to ensure that their plan documents, summary plan descriptions, and any associated policies and procedures comply with the requirements of MHPAEA and these regulations. While the Departments do not know the total number of issuers that will be affected by the regulations, the Departments estimate that there are approximately 460 issuers operating in the group market. In addition, the Departments are aware of at least 120 MBHOs.[51] The Departments believe smaller MBHOs exist but were unable to obtain a count.

The Departments assume that insured plans will rely on the issuers providing coverage to ensure compliance, and that self-insured plans will rely on third-party administrators to ensure compliance. The per-plan compliance costs are expected to be low, because vendors and issuers will be able to spread these costs across multiple client plans. These regulations provide examples illustrating the application of the rules to specific situations, which are intended to reduce the compliance burden.

The Departments assume that the average burden per plan will be one-half hour of a legal professional's time at an hourly labor rate of $120 to conduct the compliance review and make the needed changes to the plan and related documents. This results in a total cost of $27.8 million in the first year. The Departments welcome public comments on this estimate.

d. Costs associated with MHPAEA disclosures. MHPAEA and these regulations contain two new disclosure provisions for group health plans and health insurance coverage offered in connection with a group health plan that are addressed in paragraph (d) of the rules.

[51] There are about 460 issuers in the group market; this is an average of 1,000 plans per issuers. In addition, there are at least 120 MBHOs.

(1) Medical necessity disclosure. The first disclosure requires plan administrators to make the plan's medical necessity determination criteria available upon request to potential participants, beneficiaries, or contracting providers. The Departments are unable to estimate with certainty the number of requests that will be received by plan administrators based on this requirement. However, the Departments have assumed that, on average, each plan affected by the rule will receive one request. For purposes of this estimate, the Departments assume that it will take a medically trained clerical staff member five minutes to respond to each request at a labor rate of $26.85 per hour resulting in an annual cost of approximately $1,044,000.[52]

The Departments also estimated the cost to deliver the requested criteria for medical necessity determinations. Many insurers already have the information prepared in electronic form, and the Departments assume that 38 percent[53] of requests will be delivered electronically resulting in a de minimis cost. The Departments estimate that the cost associated with distributing the approximately 290,000 requests sent by paper will be approximately $192,000.[54]

(2) Claims denial disclosure. MHPAEA and these regulations also provide that the reason for any denial under a group health plan (or health insurance coverage) of reimbursement or payment for services with respect to mental health or substance use disorder benefits in the case of any participant or beneficiary must be made available upon request or as otherwise required by the plan administrator (or the health insurance issuer offering such coverage) to the

[52] EBSA estimates of labor rates include wages, other benefits, and overhead based on the National Occupational Employment Survey (May 2008, Bureau of Labor Statistics) and the Employment Cost Index (June 2009, Bureau of Labor Statistics).

[53] For purposes of this burden estimate, the Departments assume that 38 percent of the disclosures will be provided through electronic means in accordance with the Department's standards for electronic communication of required information provided under 29 CFR 2520.104b-1(c).

[54] This estimate is based on an average document size of four pages, $.05 cents per page material and printing costs, $.44 cent postage costs.

participant or beneficiary. The Department of Labor's ERISA claims procedure regulation (29 CFR 2560.503-1) requires, among other things, such disclosures to be provided automatically to participants and beneficiaries free of charge. Although non-ERISA covered plans, such as plans sponsored by state and local governments that are subject to the PHS Act, are not required to comply with the ERISA claims procedure regulation, these regulations provide that such plans (and health insurance coverage offered in connection with such plans) will be deemed to satisfy the MHPAEA claims denial disclosure requirement if they comply with the ERISA claims procedure regulation.

For purposes of this cost analysis, the Departments assume that non-Federal governmental plans will satisfy the safe harbor, because the same third-party administrators and insurers are hired by ERISA- and non-ERISA-covered plans, and these entities provide the same claims denial notifications to participants covered by ERISA- and non-ERISA-covered plans. Therefore, based on the foregoing, the Departments have not included a cost for plans to provide the claims denial disclosures.

5. Transfer resulting for premium increase due to MHPAEA

The evaluation of mental health and substance use disorder parity in the Federal Employees Health Benefit Program (FEHBP) estimated the overall impact of parity on total spending for mental health and substance use disorder services relative to a set of control plans that did not experience any increase in mental health coverage.[55] That evaluation also assessed changes in out-of-pocket spending. The overall results on total mental health and substance use disorder (MH/SUD) spending (health plan spending plus out of pocket spending) showed

[55] Goldman, et al., "Behavioral Health Insurance Parity for Federal Employees," New England Journal of Medicine (March 30, 2006) Vol. 354, No. 13.

essentially no significant increase in total MH/SUD spending. The evaluation also showed that in general parity resulted in a statistically significant decrease in out-of-pocket spending. This means that while there was no increase in the total spending on MH/SUD services there was a significant shift in the final responsibility for paying for these services. In other words, health plan spending expanded due to parity. The magnitude of the change implies an estimated increase in total health care premiums of 0.4 percent.[56] Thus the 0.4 percent increase derived from the FEHBP evaluation is due entirely to a shift in final responsibility for payment.

The Congressional Budget Office[57] estimated the direct and indirect costs to the private and public sector of implementing MHPAEA and similarly found that health insurance premiums would go up by approximately 0.4 percent. The FEHBP estimate contrasts with the CBO estimate, because the CBO estimate appears to include some shift in final payment along with an increase in service utilization.

The Departments estimate that total health care premiums will rise 0.4 percent due to MHPAEA based on data and analysis from the FEHBP evaluation. The premium increase is a transfer from those not using MH/SUD benefits to those who do, because given the size of the estimated impacts and the known changes in coverage from baseline discussed earlier in this Regulatory Impact Analysis, any change in utilization must be very small again suggesting that premium changes were primarily due to a shift in responsibility for final payments for MH/SUD care.

[56] The estimated .04 percent increase was derived from an authors' final calculation based on data from the report cited in the previous footnote.

[57] Congressional Budget Office Cost Estimate on H.R. 1424—Paul Wellstone Mental Health and Addiction Equity Act of 2007, 21 November 2007.

Using data on private health insurance premiums from the National Health Expenditure Projections[58] and data on premiums for individual insurance[59] from the National Association of Insurance Commissioners, the Departments estimate that the dollar amount of the 0.4 percent premium increases attributable to MHPAEA would be approximately $25.6 billion over the ten-year period 2010-2019. The ten-year value using a discount rate of seven percent is $19.0 billion, and it is $22.4 billion using a three percent discount rate. Yearly estimates are reported in Table 1, column G. Due to the magnitude of this transfer, this regulatory action is economically significant pursuant to section 3(f)(1) of Executive Order 12866.

D. Regulatory Flexibility Act--Department of Labor and Department of Health and Human Services

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) (RFA) imposes certain requirements with respect to federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 et seq.) and that are likely to have a significant economic impact on a substantial number of small entities. Under Section 553(b) of the Administrative Procedures Act (APA), a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. These interim final regulations are exempt from APA, because the Departments made a good cause finding that a general notice of proposed rulemaking is not necessary earlier in this preamble.

[58] National Health Expenditures Projections 2008-2018, Centers for Medicare & Medicaid Services, Office of the Actuary, http://www.cms.hhs.gov/NationalHealthExpendData/.

[59] The National Health Expenditure estimate of total spending on private health insurance includes premiums for purchases made in the individual market, which is not affected by MHPAEA. Therefore it needs to be subtracted from the total. The NAIC data does not contain information from California; therefore, an adjustment based on the number of lives covered in California and average premiums was used to impute a value for California.

Therefore, the RFA does not apply and the Departments are not required to either certify that the rule would not have a significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis.

Nevertheless, the Departments carefully considered the likely impact of the rule on small entities in connection with their assessment under Executive Order 12866. The Departments expect the rules to reduce the compliance burden imposed on plans and insurers by clarifying definitions and terms contained in the statute and providing examples of acceptable methods to comply with specific provisions. The Departments believe that the rule's impact on small entities will be minimized by the fact that MHPAEA does not apply to small employers who have between two and 50 employees.

E. Special Analyses—Department of the Treasury

Notwithstanding the determinations of the Department of Labor and Department of Health and Human Services, for purposes of the Department of the Treasury, it has been determined that this Treasury decision is not a significant regulatory action for purposes of Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. For the applicability of the RFA, refer to the Special Analyses section in the preamble to the cross-referencing notice of proposed rulemaking published elsewhere in this issue of the **Federal Register**. Pursuant to section 7805(f) of the Code, these temporary regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small businesses.

F. Paperwork Reduction Act

1. Departments of Labor and the Treasury

As part of their continuing efforts to reduce paperwork and respondent burden, the Departments conduct a preclearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

As discussed earlier in this preamble, MHPAEA includes two new disclosure provisions for group health plans and health insurance coverage offered in connection with a group health plan. First, the criteria for medical necessity determinations made under a group health plan with respect to mental health or substance use disorder benefits (or health insurance coverage offered in connection with the plan with respect to such benefits) must be made available in accordance with regulations by the plan administrator (or the health insurance issuer offering such coverage) to any current or potential participant, beneficiary, or contracting provider upon request ("medical necessity disclosure").

MHPAEA also requires the reason for any denial under a group health plan (or health insurance coverage) of reimbursement or payment for services with respect to mental health or substance use disorder benefits in the case of any participant or beneficiary must be made available upon request or as otherwise required by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary in accordance with regulations ("claims denial notice").

The MHPAEA disclosures are information collection requests (ICRs) subject to the PRA. The Departments are not soliciting comments concerning an ICR pertaining to the claims denial

notice, because the Department of Labor's ERISA claims procedure regulation (29 CFR 2560.503-1) requires (among other things) ERISA-covered group health plans to provide such disclosures automatically to participants and beneficiaries free of charge. Although non-ERISA covered plans, such as certain church plan under Treasury/IRS jurisdiction and plans sponsored by state and local governments that are subject to the PHS Act and under HHS jurisdiction (these plans are discussed under the HHS ICR discussion below) are not required to comply with the ERISA claims procedure regulation, these regulations provide that such plans (and health insurance coverage offered in connection with such plans) will be deemed to satisfy the MHPAEA claims denial disclosure requirement if they comply with the ERISA claims procedure regulation. For purposes of this PRA analysis, the Departments assume that non-ERISA plans will satisfy the safe harbor, because the same third-party administrators and insurers are hired by ERISA- and non-ERISA-covered plans, and these entities provide the same claims denial notifications to participants covered by ERISA- and non-ERISA-covered plans. Therefore, the Departments hereby determine that the hour and cost burden associated with the claims denial notice already is accounted for in the ICR for the ERISA claims procedure regulation that is approved under OMB Control Number 1210-0053.

Currently, the Departments are soliciting comments concerning the medical necessity disclosure. The Departments have submitted a copy of these interim final regulations to OMB in accordance with 44 U.S.C. 3507(d) for review of the information collections. The Departments and OMB are particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

- Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, for example, by permitting electronic submission of responses.

Comments should be sent to the Office of Information and Regulatory Affairs, Attention: Desk Officer for the Employee Benefits Security Administration either by fax to (202) 395-7285 or by email to oira_submission@omb.eop.gov. Although comments may be submitted through **[insert date that is 60 days after publication in the Federal Register]**, OMB requests that comments be received within 30 days of publication of these interim final regulations to ensure their consideration. A copy of the ICR may be obtained by contacting the PRA addressee: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue, NW, Room N-5718, Washington, DC 20210. Telephone: (202) 693-8410; Fax: (202) 219-4745. These are not toll-free numbers. E-mail: ebsa.opr@dol.gov. ICRs submitted to OMB also are available at reginfo.gov (http://www.reginfo.gov/public/do/ PRAMain).

The Departments are unable to estimate with certainty the number of requests for medical necessity criteria disclosures that will be received by plan administrators; however, the Departments have assumed that, on average, each plan affected by the rule will receive one request. The Departments estimate that approximately 93 percent of large plans and all small plans administer claims using service providers; therefore, 5.1 percent of the medical necessity

criteria disclosures will be done in-house. For PRA purposes, plans using service providers will report the costs as a cost burden, while plans administering claims in-house will report the burden as an hour burden.

The Departments assume that it will take a medically trained clerical staff member five minutes to respond to each request at a wage rate of $27 per hour. This results in an annual hour burden of nearly 1,900 hours and an associated equivalent cost of nearly $51,000 for the approximately 23,000 requests done in-house by plans. The remaining 424,000 medical necessity criteria disclosures will be provided through service providers resulting in a cost burden of approximately $950,000.

The Departments also calculated the cost to deliver the requested medical necessity criteria disclosures. Many insurers and plans already may have the information prepared in electronic form, and the Departments assume that 38 percent of requests will be delivered electronically resulting in a de minimis cost. The Departments estimate that the cost burden associated with distributing the approximately 277,000 medical necessity criteria disclosures sent by paper will be approximately $177,000.[60] The Departments note that persons are not required to respond to, and generally are not subject to any penalty for failing to comply with, an ICR unless the ICR has a valid OMB control number.[61]

These paperwork burden estimates are summarized as follows:

Type of Review: New collection.

Agencies: Employee Benefits Security Administration, Department of Labor; Internal Revenue Service, U.S. Department of the Treasury,

[60] This estimate is based on an average document size of four pages, $.05 cents per page material and printing costs, $.44 cent postage costs.

[61] 5 CFR 1320.1 through 1320.18.

Title: Notice of Medical Necessity Criteria under the Mental Health Parity and Addition Equity Act of 2008.

OMB Number: 1210–NEW; 1545–NEW.

Affected Public: Business or other for-profit; not-for-profit institutions.

Total Respondents: 446,400.

Total Responses: 446,400.

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours: 950 hours (Employee Benefits Security Administration); 950 hours (Internal Revenue Service).

Estimated Total Annual Burden Cost: $562,500 (Employee Benefits Security Administration); $562,500 (Internal Revenue Service).

2. Department of Health and Human Services

Under the PRA, we are required to provide 30-days notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

ICRs Regarding Parity in Mental Health and Substance Use Disorder Benefits. (45 CFR §146.136(d))

As discussed above, MHPAEA includes two new disclosure provisions for group health plans and health insurance coverage offered in connection with a group health plan. First, the criteria for medical necessity determinations made under a group health plan with respect to mental health or substance use disorder benefits (or health insurance coverage offered in connection with the plan with respect to such benefits) must be made available in accordance with regulations by the plan administrator (or the health insurance issuer offering such coverage) to any current or potential participant, beneficiary, or contracting provider upon request ("medical necessity disclosure").

MHPAEA also requires the reason for any denial under a group health plan (or health insurance coverage) of reimbursement or payment for services with respect to mental health or substance use disorder benefits in the case of any participant or beneficiary must be made available upon request or as otherwise required by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary in accordance with regulations ("claims denial disclosure").

Medical Necessity Disclosure

The Department estimates that there are 29.1 million participants covered by 20,300 state and local public plans that are subject to the MHPAEA disclosure requirements that are employed by employers with more than 50 employees.[62]

The Department is unable to estimate with certainty the number of requests for medical necessity criteria disclosures that will be received by plan administrators; however, the Department has assumed that, on average, each plan affected by the rule will receive one request. CMS estimates that approximately 93 percent of large plans administer claims using third party providers. Furthermore the vast majority of all smaller employers usually are fully insured such that issuers will be administering their claims. Therefore 5.1 percent of claims are administered in-house. For plans that use issuers or third party providers the costs are reported as cost burden while for plans that administer claims in-house the burden is reported as an hour burden. For purposes of this estimate, the Department assumes that it will take a medically trained clerical staff member five minutes to respond to each request at a wage rate of $26.85 per hour. This results in an annual hour burden of 86 hours and an associated equivalent cost of about $2,300 for the approximately 1,000 requests handled by plans. The remaining 19,300 claims (94.9 percent) are provided through a third-party provider or an issuer and results in a cost burden of approximately $43,000.

Claims Denial Disclosure

MHPAEA requires plans to disclose to participants and beneficiaries upon request the reason for any denial under the plan (or coverage) of reimbursement or payment for services

[62] Non-Federal governmental plans may opt-out of MHPAEA and certain other requirements under Section 2721 of the PHS Act. Since past experience has shown that the number of non-Federal governmental plans that opt-out is small, the impact of the opt-out election should be immaterial on the Department's estimates.

with respect to mental health or substance use disorder benefits. The Department of Labor's ERISA claims procedure regulation (29 CFR 2560.503-1) requires, among other things, such disclosures to be provided automatically to participants and beneficiaries free of charge. Although non-ERISA covered plans, such as plans sponsored by state and local governments that are subject to the PHS Act, are not required to comply with the ERISA claims procedure regulation, the interim final regulations provide that these plans (and health insurance coverage offered in connection with such plans) will be deemed to satisfy the MHPAEA claims denial disclosure requirement if they comply with the ERISA claims procedure regulation.

Using assumptions similar to those used for the ERISA claims procedure regulation, the Department estimates that there will be approximately 29.7 million claims for mental health or substance use disorder benefits with approximately 4.45 million denials that could result in a request for an explanation of reason for denial. The Department has no data on the percent of denials that will result in a request for an explanation, but assumed that ten percent of denials will result in a request for an explanation (445,000 requests).

The Department estimates that a medically trained clerical staff member may require five minutes to respond to each request at a labor rate of $27 per hour. This results in an annual hour burden of nearly 1,900 hours and an associated equivalent cost of nearly $51,000 for the approximately 22,700 requests completed by plans. The remaining 422,300 are provided through an issuer or a third-party provider, which results in a cost burden of approximately $945,000.

In association with the explanation of denial, participants may request a copy of the medical necessity criteria. While the Department does not know how many notices of denial will result in a request for the criteria of medical necessity, the Department assumes that ten percent

of those requesting an explanation of the reason for denial will also request the criteria of medical necessity, resulting in 44,500 requests, 2,300 of which will be completed in-house with an hour burden of 190 hours and equivalent cost of $5,000 and 42,000requests handled by issuers or third-party providers with a cost burden of $95,000.

The Department also calculated the cost to deliver the requested information. Many insurers or plans may already have the information prepared in electronic format, and the Department assumes that requests will be delivered electronically resulting in a de minimis cost.[63] The Department estimates that the cost burden associated with distributing the approximately 135,000 disclosures sent by paper will be approximately $86,000.[64] The Department notes that persons are not required to respond to, and generally are not subject to any penalty for failing to comply with, an ICR unless the ICR has a valid OMB control number.[65] These paperwork burden estimates are summarized as follows:

Type of Review: New collection.

Agency: Department of Health and Human Services.

Title: Required Disclosures Under the Mental Health Parity and Addition Equity Act of 2008.

OMB Number: 0938–NEW.

Affected Public: State, Local, or Tribal Governments.

Respondents: 20,300.

Responses: 510,000.

[63] Following the assumption in the ERISA claims regulation, it was assumed 75 percent of the explanation of denials disclosures would be delivered electronically, while it was assumed that 38 percent of non-denial related requests for the medical necessity criteria would be delivered electronically.

[64] This estimate is based on an average document size of four pages, $.05 cents per page material and printing costs, $.44 cent postage costs.

[65] 5 CFR 1320.1 through 1320.18.

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours: 2,200 hours.

Estimated Total Annual Burden Cost: $1,169,000.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the ADDRESSES section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, 4140-IFC

Fax: (202) 395-6974; or

Email: OIRA_submission@omb.eop.gov

G. Congressional Review Act

These regulations are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.) and have been transmitted to Congress and the Comptroller General for review.

H. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires agencies to prepare several analytic statements before proposing any rules that may result in annual expenditures of $100 million (as adjusted for inflation) by state, local and tribal governments or the private sector. These rules are not subject to the Unfunded Mandates Reform Act because they are being issued as interim final rules. However, consistent with the policy embodied in the Unfunded Mandates Reform Act, the regulation has been designed to be the least burdensome

alternative for state, local and tribal governments, and the private sector, while achieving the objectives of MHPAEA.

I. Federalism Statement--Department of Labor and Department of Health and Human Services

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by federal agencies in the process of their formulation and implementation of policies that have "substantial direct effects" on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with State and local officials, and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the regulation.

In the Departments' view, these regulations have federalism implications, because they have direct effects on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among various levels of government. However, in the Departments' view, the federalism implications of these regulations are substantially mitigated because, with respect to health insurance issuers, the Departments expect that the majority of States have enacted or will enact laws or take other appropriate action resulting in their meeting or exceeding the federal MHPAEA standards.

In general, through section 514, ERISA supersedes State laws to the extent that they relate to any covered employee benefit plan, and preserves State laws that regulate insurance, banking, or securities. While ERISA prohibits States from regulating a plan as an insurance or investment company or bank, the preemption provisions of section 731 of ERISA and section 2723 of the PHS Act (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so

that the MHPAEA requirements are not to be "construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement" of MHPAEA. The conference report accompanying HIPAA indicates that this is intended to be the "narrowest" preemption of State laws. (See House Conf. Rep. No. 104-736, at 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018.)

States may continue to apply State law requirements except to the extent that such requirements prevent the application of the MHPAEA requirements that are the subject of this rulemaking. State insurance laws that are more stringent than the federal requirements are unlikely to "prevent the application of"' MHPAEA, and be preempted. Accordingly, States have significant latitude to impose requirements on health insurance issuers that are more restrictive than the federal law.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the States, the Departments have engaged in numerous efforts to consult with and work cooperatively with affected State and local officials. It is expected that the Departments will act in a similar fashion in enforcing the MHPAEA requirements.

Throughout the process of developing these regulations, to the extent feasible within the specific preemption provisions of HIPAA as it applies to MHPAEA, the Departments have attempted to balance the States' interests in regulating health insurance issuers, and Congress' intent to provide uniform minimum protections to consumers in every State. By doing so, it is the Departments' view that they have complied with the requirements of Executive Order 13132.

Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to these regulations, the Departments certify that the Employee Benefits Security Administration and the Centers for Medicare & Medicaid Services have complied with the requirements of Executive Order 13132 for the attached regulations in a meaningful and timely manner.

V. Statutory Authority

The Department of the Treasury temporary and final regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor interim final regulations are adopted pursuant to the authority contained in 29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104-191, 110 Stat. 1936; sec. 401(b), Public Law 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110-343, 122 Stat. 3765; Public Law 110-460, 122 Stat. 5123; Secretary of Labor's Order 6-2009, 74 FR 21524 (May 7, 2009).

The Department of Health and Human Services interim final regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 USC 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 146

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

Internal Revenue Service

26 CFR Chapter 1

Accordingly, 26 CFR Parts 54 and 602 are amended as follows:

PART 54--PENSION EXCISE TAXES

Paragraph 1. The authority citation for part 54 continues to read in part as follows:

Authority: 26 U.S.C. 7805. * * *

Par. 2. Section 54.9812-1T is revised to read as follows:

§54.9812 Parity in mental health and substance use disorder benefits (temporary).

(a) Meaning of terms. For purposes of this section, except where the context clearly indicates otherwise, the following terms have the meanings indicated:

Aggregate lifetime dollar limit means a dollar limitation on the total amount of specified benefits that may be paid under a group health plan for any coverage unit.

Annual dollar limit means a dollar limitation on the total amount of specified benefits that may be paid in a 12-month period under a group health plan for any coverage unit.

Coverage unit means coverage unit as described in paragraph (c)(1)(iv) of this section.

Cumulative financial requirements are financial requirements that determine whether or to what extent benefits are provided based on accumulated amounts and include deductibles and out-of-pocket maximums. (However, cumulative financial requirements do not include aggregate lifetime or annual dollar limits because these two terms are excluded from the meaning of financial requirements.)

Cumulative quantitative treatment limitations are treatment limitations that determine whether or to what extent benefits are provided based on accumulated amounts, such as annual or lifetime day or visit limits.

Financial requirements include deductibles, copayments, coinsurance, or out-of-pocket maximums. Financial requirements do not include aggregate lifetime or annual dollar limits.

Medical/surgical benefits means benefits for medical or surgical services, as defined under the terms of the plan, but does not include mental health or substance use disorder benefits. Any condition defined by the plan as being or as not being a medical/surgical condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the International Classification of Diseases (ICD) or State guidelines).

Mental health benefits means benefits with respect to services for mental health conditions, as defined under the terms of the plan and in accordance with applicable Federal and State law. Any condition defined by the plan as being or as not being a mental health condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), the most current version of the ICD, or State guidelines).

Substance use disorder benefits means benefits with respect to services for substance use disorders, as defined under the terms of the plan and in accordance with applicable Federal and State law. Any disorder defined by the plan as being or as not being a substance use disorder must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the DSM, the most current version of the ICD, or State guidelines).

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations,

which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under a plan. (See paragraph (c)(4)(ii) of this section for an illustrative list of nonquantitative treatment limitations.) A permanent exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation.

(b) Parity requirements with respect to aggregate lifetime and annual dollar limits--(1)--General--(i) General parity requirement. A group health plan that provides both medical/surgical benefits and mental health or substance use disorder benefits must comply with paragraph (b)(2), (b)(3), or (b)(6) of this section.

(ii) Exception. The rule in paragraph (b)(1)(i) of this section does not apply if a plan satisfies the requirements of paragraph (f) or (g) of this section (relating to exemptions for small employers and for increased cost).

(2) Plan with no limit or limits on less than one-third of all medical/surgical benefits. If a plan does not include an aggregate lifetime or annual dollar limit on any medical/surgical benefits or includes an aggregate lifetime or annual dollar limit that applies to less than one-third of all medical/surgical benefits, it may not impose an aggregate lifetime or annual dollar limit, respectively, on mental health or substance use disorder benefits.

(3) Plan with a limit on at least two-thirds of all medical/surgical benefits. If a plan includes an aggregate lifetime or annual dollar limit on at least two-thirds of all medical/surgical benefits, it must either--

(i) Apply the aggregate lifetime or annual dollar limit both to the medical/surgical benefits to which the limit would otherwise apply and to mental health or substance use disorder

benefits in a manner that does not distinguish between the medical/surgical benefits and mental health or substance use disorder benefits; or

(ii) Not include an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is less than the aggregate lifetime or annual dollar limit, respectively, on medical/surgical benefits. (For cumulative limits other than aggregate lifetime or annual dollar limits, see paragraph (c)(3)(v) of this section prohibiting separately accumulating cumulative financial requirements or cumulative quantitative treatment limitations.)

(4) Examples. The rules of paragraphs (b)(2) and (b)(3) of this section are illustrated by the following examples:

Example 1. (i) Facts. A group health plan has no annual limit on medical/surgical benefits and a $10,000 annual limit on mental health and substance use disorder benefits. To comply with the requirements of this paragraph (b), the plan sponsor is considering each of the following options:

(A) Eliminating the plan's annual dollar limit on mental health and substance use disorder benefits;

(B) Replacing the plan's annual dollar limit on mental health and substance use disorder benefits with a $500,000 annual limit on all benefits (including medical/surgical and mental health and substance use disorder benefits); and

(C) Replacing the plan's annual dollar limit on mental health and substance use disorder benefits with a $250,000 annual limit on medical/surgical benefits and a $250,000 annual limit on mental health and substance use disorder benefits.

(ii) Conclusion. In this Example 1, each of the three options being considered by the plan sponsor would comply with the requirements of this paragraph (b).

Example 2. (i) Facts. A plan has a $100,000 annual limit on medical/surgical inpatient benefits and a $50,000 annual limit on medical/surgical outpatient benefits. To comply with the parity requirements of this paragraph (b), the plan sponsor is considering each of the following options:

(A) Imposing a $150,000 annual limit on mental health and substance use disorder benefits; and

(B) Imposing a $100,000 annual limit on mental health and substance use disorder inpatient benefits and a $50,000 annual limit on mental health and substance use disorder outpatient benefits.

(ii) Conclusion. In this Example 2, each option under consideration by the plan sponsor would comply with the requirements of this section.

(5) Determining one-third and two-thirds of all medical/surgical benefits. For purposes of this paragraph (b), the determination of whether the portion of medical/surgical benefits subject to an aggregate lifetime or annual dollar limit represents one-third or two-thirds of all medical/surgical benefits is based on the dollar amount of all plan payments for medical/surgical benefits expected to be paid under the plan for the plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the aggregate lifetime or annual dollar limits). Any reasonable method may be used to determine whether the dollar amount expected to be paid under the plan will constitute one-third or two-thirds of the dollar amount of all plan payments for medical/surgical benefits.

(6) Plan not described in paragraph (b)(2) or (b)(3) of this section--(i) In general. A group health plan that is not described in paragraph (b)(2) or (b)(3) of this section with respect to aggregate lifetime or annual dollar limits on medical/surgical benefits, must either--

(A) Impose no aggregate lifetime or annual dollar limit, as appropriate, on mental health or substance use disorder benefits; or

(B) Impose an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is no less than an average limit calculated for medical/surgical benefits in the following manner. The average limit is calculated by taking into account the weighted average of the aggregate lifetime or annual dollar limits, as appropriate, that are applicable to the categories of medical/surgical benefits. Limits based on delivery systems, such as

inpatient/outpatient treatment or normal treatment of common, low-cost conditions (such as treatment of normal births), do not constitute categories for purposes of this paragraph (b)(6)(i)(B). In addition, for purposes of determining weighted averages, any benefits that are not within a category that is subject to a separately-designated dollar limit under the plan are taken into account as a single separate category by using an estimate of the upper limit on the dollar amount that a plan may reasonably be expected to incur with respect to such benefits, taking into account any other applicable restrictions under the plan.

(ii) Weighting. For purposes of this paragraph (b)(6), the weighting applicable to any category of medical/surgical benefits is determined in the manner set forth in paragraph (b)(5) of this section for determining one-third or two-thirds of all medical/surgical benefits.

(iii) Example. The rules of this paragraph (b)(6) are illustrated by the following example:

Example. (i) Facts. A group health plan that is subject to the requirements of this section includes a $100,000 annual limit on medical/surgical benefits related to cardio-pulmonary diseases. The plan does not include an annual dollar limit on any other category of medical/surgical benefits. The plan determines that 40 percent of the dollar amount of plan payments for medical/surgical benefits are related to cardio-pulmonary diseases. The plan determines that $1,000,000 is a reasonable estimate of the upper limit on the dollar amount that the plan may incur with respect to the other 60 percent of payments for medical/surgical benefits.

(ii) Conclusion. In this Example, the plan is not described in paragraph (b)(3) of this section because there is not one annual dollar limit that applies to at least two-thirds of all medical/surgical benefits. Further, the plan is not described in paragraph (b)(2) of this section because more than one-third of all medical/surgical benefits are subject to an annual dollar limit. Under this paragraph (b)(6), the plan sponsor can choose either to include no annual dollar limit on mental health or substance use disorder benefits, or to include an annual dollar limit on mental health or substance use disorder benefits that is not less than the weighted average of the annual dollar limits applicable to each category of medical/surgical benefits. In this example, the minimum weighted average annual dollar limit that can be applied to mental health or substance use disorder benefits is $640,000 (40% x $100,000 + 60% x $1,000,000 = $640,000).

(c) Parity requirements with respect to financial requirements and treatment limitations--

(1) Clarification of terms--(i) Classification of benefits. When reference is made in this

paragraph (c) to a classification of benefits, the term "classification" means a classification as described in paragraph (c)(2)(ii) of this section.

(ii) Type of financial requirement or treatment limitation. When reference is made in this paragraph (c) to a type of financial requirement or treatment limitation, the reference to type means its nature. Different types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations include annual, episode, and lifetime day and visit limits. See paragraph (c)(4)(ii) of this section for an illustrative list of nonquantitative treatment limitations.

(iii) Level of a type of financial requirement or treatment limitation. When reference is made in this paragraph (c) to a level of a type of financial requirement or treatment limitation, level refers to the magnitude of the type of financial requirement or treatment limitation. For example, different levels of coinsurance include 20 percent and 30 percent; different levels of a copayment include $15 and $20; different levels of a deductible include $250 and $500; and different levels of an episode limit include 21 inpatient days per episode and 30 inpatient days per episode.

(iv) Coverage unit. When reference is made in this paragraph (c) to a coverage unit, coverage unit refers to the way in which a plan groups individuals for purposes of determining benefits, or premiums or contributions. For example, different coverage units include self-only, family, and employee-plus-spouse.

(2) General parity requirement--(i) General rule. A group health plan that provides both medical/surgical benefits and mental health or substance use disorder benefits may not apply any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or

treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification. Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial requirement or treatment limitation. The application of the rules of this paragraph (c)(2) to financial requirements and quantitative treatment limitations is addressed in paragraph (c)(3) of this section; the application of the rules of this paragraph (c)(2) to nonquantitative treatment limitations is addressed in paragraph (c)(4) of this section.

(ii) Classifications of benefits used for applying rules--(A) In general. If a plan provides mental health or substance use disorder benefits in any classification of benefits described in this paragraph (c)(2)(ii), mental health or substance use disorder benefits must be provided in every classification in which medical/surgical benefits are provided. In determining the classification in which a particular benefit belongs, a plan must apply the same standards to medical/surgical benefits and to mental health or substance use disorder benefits. To the extent that a plan provides benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment limitation) for benefits in the classification, the rules of this paragraph (c) apply separately with respect to that classification for all financial requirements or treatment limitations. The following classifications of benefits are the only classifications used in applying the rules of this paragraph (c):

(1) Inpatient, in-network. Benefits furnished on an inpatient basis and within a network of providers established or recognized under a plan.

(2) Inpatient, out-of-network. Benefits furnished on an inpatient basis and outside any network of providers established or recognized under a plan. This classification includes inpatient benefits under a plan that has no network of providers.

(3) Outpatient, in-network. Benefits furnished on an outpatient basis and within a network of providers established or recognized under a plan.

(4) Outpatient, out-of-network. Benefits furnished on an outpatient basis and outside any network of providers established or recognized under a plan. This classification includes outpatient benefits under a plan that has no network of providers.

(5) Emergency care. Benefits for emergency care.

(6) Prescription drugs. Benefits for prescription drugs. See special rules for multi-tiered prescription drug benefits in paragraph (c)(3)(iii) of this section.

(B) Application to out-of-network providers. See paragraph (c)(2)(ii)(A) of this section, under which a plan that provides mental health or substance use disorder benefits in any classification of benefits must provide mental health or substance use disorder benefits in every classification in which medical/surgical benefits are provided, including out-of-network classifications.

(C) Examples. The rules of this paragraph (c)(2)(ii) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

Example 1. (i) Facts. A group health plan offers inpatient and outpatient benefits and does not contract with a network of providers. The plan imposes a $500 deductible on all benefits. For inpatient medical/surgical benefits, the plan imposes a coinsurance requirement. For outpatient medical/surgical benefits, the plan imposes copayments. The plan imposes no other financial requirements or treatment limitations.

(ii) Conclusion. In this Example 1, because the plan has no network of providers, all benefits provided are out-of-network. Because inpatient, out-of-network medical/surgical benefits are subject to separate financial requirements from outpatient, out-of-network medical/surgical benefits, the rules of this paragraph (c) apply separately with respect to any financial requirements and treatment limitations, including the deductible, in each classification.

Example 2. (i) Facts. A plan imposes a $500 deductible on all benefits. The plan has no network of providers. The plan generally imposes a 20 percent coinsurance requirement with respect to all benefits, without distinguishing among inpatient, outpatient, emergency, or prescription drug benefits. The plan imposes no other financial requirements or treatment limitations.

(ii) Conclusion. In this Example 2, because the plan does not impose separate financial requirements (or treatment limitations) based on classification, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance across all benefits.

Example 3. (i) Facts. Same facts as Example 2, except the plan exempts emergency care benefits from the 20 percent coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(ii) Conclusion. In this Example 3, because the plan imposes separate financial requirements based on classifications, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance separately for--

(A) Benefits in the emergency classification; and

(B) All other benefits.

Example 4. (i) Facts. Same facts as Example 2, except the plan also imposes a preauthorization requirement for all inpatient treatment in order for benefits to be paid. No such requirement applies to outpatient treatment.

(ii) Conclusion. In this Example 4, because the plan has no network of providers, all benefits provided are out-of-network. Because the plan imposes a separate treatment limitation based on classifications, the rules of this paragraph (c) apply with respect to the deductible and coinsurance separately for--

(A) Inpatient, out-of-network benefits; and

(B) All other benefits.

(3) Financial requirements and quantitative treatment limitations--(i) Determining "substantially all" and "predominant"--(A) Substantially all. For purposes of this paragraph (c),

a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification of benefits if it applies to at least two-thirds of all medical/surgical benefits in that classification. (For this purpose, benefits expressed as subject to a zero level of a type of financial requirement are treated as benefits not subject to that type of financial requirement, and benefits expressed as subject to a quantitative treatment limitation that is unlimited are treated as benefits not subject to that type of quantitative treatment limitation.) If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that type cannot be applied to mental health or substance use disorder benefits in that classification.

(B) Predominant--(1) If a type of financial requirement or quantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits in a classification as determined under paragraph (c)(3)(i)(A) of this section, the level of the financial requirement or quantitative treatment limitation that is considered the predominant level of that type in a classification of benefits is the level that applies to more than one-half of medical/surgical benefits in that classification subject to the financial requirement or quantitative treatment limitation.

(2) If, with respect to a type of financial requirement or quantitative treatment limitation that applies to at least two-thirds of all medical/surgical benefits in a classification, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to the financial requirement or quantitative treatment limitation, the plan may combine levels until the combination of levels applies to more than one-half of medical/surgical benefits subject to the financial requirement or quantitative treatment limitation in the classification. The

least restrictive level within the combination is considered the predominant level of that type in the classification. (For this purpose, a plan may combine the most restrictive levels first, with each less restrictive level added to the combination until the combination applies to more than one-half of the benefits subject to the financial requirement or treatment limitation.)

(C) Portion based on plan payments. For purposes of this paragraph (c), the determination of the portion of medical/surgical benefits in a classification of benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation) is based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan for the plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the financial requirement or quantitative treatment limitation).

(D) Clarifications for certain threshold requirements. For any deductible, the dollar amount of plan payments includes all plan payments with respect to claims that would be subject to the deductible if it had not been satisfied. For any out-of-pocket maximum, the dollar amount of plan payments includes all plan payments associated with out-of-pocket payments that are taken into account towards the out-of-pocket maximum as well as all plan payments associated with out-of-pocket payments that would have been made towards the out-of-pocket maximum if it had not been satisfied. Similar rules apply for any other thresholds at which the rate of plan payment changes.

(E) Determining the dollar amount of plan payments. Subject to paragraph (c)(3)(i)(D) of this section, any reasonable method may be used to determine the dollar amount expected to be paid under a plan for medical/surgical benefits subject to a financial requirement or

quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation).

(ii) Application to different coverage units. If a plan applies different levels of a financial requirement or quantitative treatment limitation to different coverage units in a classification of medical/surgical benefits, the predominant level that applies to substantially all medical/surgical benefits in the classification is determined separately for each coverage unit.

(iii) 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 determined in accordance with the rules in paragraph (c)(4)(i) of this section (relating to requirements for nonquantitative treatment limitations) and without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits, the plan satisfies the parity requirements of this paragraph (c) with respect to prescription drug benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up.

(iv) Examples. The rules of paragraphs (c)(3)(i), (c)(3)(ii), and (c)(3)(iii) of this section are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

Example 1. (i) Facts. For inpatient, out-of-network medical/surgical benefits, a group health plan imposes five levels of coinsurance. Using a reasonable method, the plan projects its payments for the upcoming year as follows:

Coinsurance rate	0 %	10%	15%	20%	30%	Total
Projected payments	$200x	$100x	$450x	$100x	$150x	$1,000x
Percent of total plan costs	20%	10%	45%	10%	15%	
Percent subject to coinsurance level	N/A	12.5% (100x/800x)	56.25% (450x/800x)	12.5% (100x/800x)	18.75% (150x/800x)	

The plan projects plan costs of $800x to be subject to coinsurance ($100x + $450x + $100x + $150x = $800x). Thus, 80 percent ($800x/$1,000x) of the benefits are projected to be subject to coinsurance, and 56.25 percent of the benefits subject to coinsurance are projected to be subject to the 15 percent coinsurance level.

(ii) Conclusion. In this Example 1, the two-thirds threshold of the substantially all standard is met for coinsurance because 80 percent of all inpatient, out-of-network medical/surgical benefits are subject to coinsurance. Moreover, the 15 percent coinsurance is the predominant level because it is applicable to more than one-half of inpatient, out-of-network medical/surgical benefits subject to the coinsurance requirement. The plan may not impose any level of coinsurance with respect to inpatient, out-of-network mental health or substance use disorder benefits that is more restrictive than the 15 percent level of coinsurance.

Example 2. (i) Facts. For outpatient, in-network medical/surgical benefits, a plan imposes five different copayment levels. Using a reasonable method, the plan projects payments for the upcoming year as follows:

Copayment amount	$0	$10	$15	$20	$50	Total
Projected payments	$200x	$200x	$200x	$300x	$100x	$1,000x
Percent of total plan costs	20%	20%	20%	30%	10%	
Percent subject to copayments	N/A	25% (200x/800x)	25% (200x/800x)	37.5% (300x/800x)	12.5% (100x/800x)	

The plan projects plan costs of $800x to be subject to copayments ($200x + $200x +$300x + $100x = $800x). Thus, 80 percent ($800x/$1,000x) of the benefits are projected to be subject to a copayment.

(ii) Conclusion. In this Example 2, the two-thirds threshold of the substantially all standard is met for copayments because 80 percent of all outpatient, in-network medical/surgical benefits are subject to a copayment. Moreover, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to a copayment (for the $10 copayment, 25 percent; for the $15 copayment, 25 percent; for the $20 copayment, 37.5 percent; and for the $50 copayment, 12.5 percent). The plan can combine any levels of copayment, including the highest levels, to determine the predominant level that can be applied to mental health or substance use disorder benefits. If the plan combines the highest levels of copayment, the combined projected payments for the two highest copayment levels, the $50 copayment and the $20 copayment, are not more than one-half of the outpatient, in-network medical/surgical benefits subject to a copayment because they are exactly one-half ($300x + $100x = $400x; $400x/$800x = 50%). The combined projected payments for the three highest copayment levels -- the $50 copayment, the $20 copayment, and the $15 copayment -- are more than one-half of the outpatient, in-network medical/surgical benefits subject to the copayments ($100x + $300x + $200x = $600x; $600x/$800x = 75%). Thus, the plan may not impose any copayment on

outpatient, in-network mental health or substance use disorder benefits that is more restrictive than the least restrictive copayment in the combination, the $15 copayment.

Example 3. (i) Facts. A plan imposes a $250 deductible on all medical/surgical benefits for self-only coverage and a $500 deductible on all medical/surgical benefits for family coverage. The plan has no network of providers. For all medical/surgical benefits, the plan imposes a coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(ii) Conclusion. In this Example 3, because the plan has no network of providers, all benefits are provided out-of-network. Because self-only and family coverage are subject to different deductibles, whether the deductible applies to substantially all medical/surgical benefits is determined separately for self-only medical/surgical benefits and family medical/surgical benefits. Because the coinsurance is applied without regard to coverage units, the predominant coinsurance that applies to substantially all medical/surgical benefits is determined without regard to coverage units.

Example 4. (i) Facts. A plan applies the following financial requirements for prescription drug benefits. The requirements are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits. Moreover, the process for certifying a particular drug as "generic", "preferred brand name", "non-preferred brand name", or "specialty" complies with the rules of paragraph (c)(4)(i) of this section (relating to requirements for nonquantitative treatment limitations).

	Tier 1	Tier 2	Tier 3	Tier 4
Tier description	Generic drugs	Preferred brand name drugs	Non-preferred brand name drugs (which may have Tier 1 or Tier 2 alternatives)	Specialty drugs
Percent paid by plan	90%	80%	60%	50%

(ii) Conclusion. In this Example 4, the financial requirements that apply to prescription drug benefits are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits; the process for certifying drugs in different tiers complies with paragraph (c)(4) of this section; and the bases for establishing different levels or types of financial requirements are reasonable. The financial requirements applied to prescription drug benefits do not violate the parity requirements of this paragraph (c)(3).

(v) No separate cumulative financial requirements or cumulative quantitative treatment limitations. (A) A group health plan may not apply any cumulative financial requirement or cumulative quantitative treatment limitation for mental health or substance use disorder benefits

in a classification that accumulates separately from any established for medical/surgical benefits in the same classification.

(B) The rules of this paragraph (c)(3)(v) are illustrated by the following examples:

Example 1. (i) Facts. A group health plan imposes a combined annual $500 deductible on all medical/surgical, mental health, and substance use disorder benefits.

(ii) Conclusion. In this Example 1, the combined annual deductible complies with the requirements of this paragraph (c)(3)(v).

Example 2. (i) Facts. A plan imposes an annual $250 deductible on all medical/surgical benefits and a separate annual $250 deductible on all mental health and substance use disorder benefits.

(ii) Conclusion. In this Example 2, the separate annual deductible on mental health and substance use disorder benefits violates the requirements of this paragraph (c)(3)(v).

Example 3. (i) Facts. A plan imposes an annual $300 deductible on all medical/surgical benefits and a separate annual $100 deductible on all mental health or substance use disorder benefits.

(ii) Conclusion. In this Example 3, the separate annual deductible on mental health and substance use disorder benefits violates the requirements of this paragraph (c)(3)(v).

Example 4. (i) Facts. A plan generally imposes a combined annual $500 deductible on all benefits (both medical/surgical benefits and mental health and substance use disorder benefits) except prescription drugs. Certain benefits, such as preventive care, are provided without regard to the deductible. The imposition of other types of financial requirements or treatment limitations varies with each classification. Using reasonable methods, the plan projects its payments for medical/surgical benefits in each classification for the upcoming year as follows:

Classification	Benefits Subject to Deductible	Total Benefits	Percent Subject to Deductible
Inpatient, in-network	$1,800x	$2,000x	90%
Inpatient, out-of-network	$1,000x	$1,000x	100%
Outpatient, in-network	$1,400x	$2,000x	70%
Outpatient, out-of-network	$1,880x	$2,000x	94%
Emergency care	$300x	$500x	60%

(ii) Conclusion. In this Example 4, the two-thirds threshold of the substantially all standard is met with respect to each classification except emergency care because in each of those other classifications at least two-thirds of medical/surgical benefits are subject to the $500

deductible. Moreover, the $500 deductible is the predominant level in each of those other classifications because it is the only level. However, emergency care mental health and substance use disorder benefits cannot be subject to the $500 deductible because it does not apply to substantially all emergency care medical/surgical benefits.

(4) Nonquantitative treatment limitations--(i) General rule. A group health plan may not impose a nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation with respect to medical surgical/benefits in the classification, except to the extent that recognized clinically appropriate standards of care may permit a difference.

(ii) Illustrative list of nonquantitative treatment limitations. Nonquantitative treatment limitations include--

(A) Medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;

(B) Formulary design for prescription drugs;

(C) Standards for provider admission to participate in a network, including reimbursement rates;

(D) Plan methods for determining usual, customary, and reasonable charges;

(E) Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols); and

(F) Exclusions based on failure to complete a course of treatment.

(iii) Examples. The rules of this paragraph (c)(4) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

Example 1. (i) Facts. A group health plan limits benefits to treatment that is medically necessary. The plan requires concurrent review for inpatient, in-network mental health and substance use disorder benefits but does not require it for any inpatient, in-network medical/surgical benefits. The plan conducts retrospective review for inpatient, in-network medical/surgical benefits.

(ii) Conclusion. In this Example 1, the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation – medical necessity – applies to both mental health and substance use disorder benefits and to medical/surgical benefits for inpatient, in-network services, the concurrent review process does not apply to medical/surgical benefits. The concurrent review process is not comparable to the retrospective review process. While such a difference might be permissible in certain individual cases based on recognized clinically appropriate standards of care, it is not permissible for distinguishing between all medical/surgical benefits and all mental health or substance use disorder benefits.

Example 2. (i) Facts. A plan requires prior approval that a course of treatment is medically necessary for outpatient, in-network medical/surgical, mental health, and substance use disorder benefits. For mental health and substance use disorder treatments that do not have prior approval, no benefits will be paid; for medical/surgical treatments that do not have prior approval, there will only be a 25 percent reduction in the benefits the plan would otherwise pay.

(ii) Conclusion. In this Example 2, the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation – medical necessity – is applied both to mental health and substance use disorder benefits and to medical/surgical benefits for outpatient, in-network services, the penalty for failure to obtain prior approval for mental health and substance use disorder benefits is not comparable to the penalty for failure to obtain prior approval for medical/surgical benefits.

Example 3. (i) Facts. A plan generally covers medically appropriate treatments. For both medical/surgical benefits and mental health and substance use disorder benefits, evidentiary standards used in determining whether a treatment is medically appropriate (such as the number of visits or days of coverage) are based on recommendations made by panels of experts with appropriate training and experience in the fields of medicine involved. The evidentiary standards are applied in a manner that may differ based on clinically appropriate standards of care for a condition.

(ii) Conclusion. In this Example 3, the plan complies with the rules of this paragraph (c)(4) because the nonquantitative treatment limitation – medical appropriateness – is the same for both medical/surgical benefits and mental health and substance use disorder benefits, and the processes for developing the evidentiary standards and the application of them to mental health and substance use disorder benefits are comparable to and are applied no more stringently than for medical/surgical benefits. This is the result even if, based on clinically appropriate standards of care, the application of the evidentiary standards does not result in similar numbers of visits, days of coverage, or other benefits utilized for mental health conditions or substance use disorders as it does for any particular medical/surgical condition.

Example 4. (i) Facts. A plan generally covers medically appropriate treatments. In determining whether prescription drugs are medically appropriate, the plan automatically excludes coverage for antidepressant drugs that are given a black box warning label by the Food and Drug Administration (indicating the drug carries a significant risk of serious adverse effects). For other drugs with a black box warning (including those prescribed for other mental health conditions and substance use disorders, as well as for medical/surgical conditions), the plan will provide coverage if the prescribing physician obtains authorization from the plan that the drug is medically appropriate for the individual, based on clinically appropriate standards of care.

(ii) Conclusion. In this Example 4, the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation – medical appropriateness – is applied to both mental health and substance use disorder benefits and medical/surgical benefits, the plan's unconditional exclusion of antidepressant drugs given a black box warning is not comparable to the conditional exclusion for other drugs with a black box warning.

Example 5. (i) Facts. An employer maintains both a major medical program and an employee assistance program (EAP). The EAP provides, among other benefits, a limited number of mental health or substance use disorder counseling sessions. Participants are eligible for mental health or substance use disorder benefits under the major medical program only after exhausting the counseling sessions provided by the EAP. No similar exhaustion requirement applies with respect to medical/surgical benefits provided under the major medical program.

(ii) Conclusion. In this Example 5, limiting eligibility for mental health and substance use disorder benefits only after EAP benefits are exhausted is a nonquantitative treatment limitation subject to the parity requirements of this paragraph (c). Because no comparable requirement applies to medical/surgical benefits, the requirement may not be applied to mental health or substance use disorder benefits.

(5) Exemptions. The rules of this paragraph (c) do not apply if a group health plan satisfies the requirements of paragraph (f) or (g) of this section (relating to exemptions for small employers and for increased cost).

(d) Availability of plan information--(1) Criteria for medical necessity determinations. The criteria for medical necessity determinations made under a group health plan with respect to mental health or substance use disorder benefits must be made available by the plan administrator to any current or potential participant, beneficiary, or contracting provider upon request.

(2) Reason for denial. The reason for any denial under a group health plan of reimbursement or payment for services with respect to mental health or substance use disorder benefits in the case of any participant or beneficiary must be made available by the plan administrator to the participant or beneficiary in accordance with this paragraph (d)(2).

(i) Plans subject to ERISA. If a plan is subject to ERISA, it must provide the reason for the claim denial in a form and manner consistent with the requirements of 29 CFR 2560.503-1 for group health plans.

(ii) Plans not subject to ERISA. If a plan is not subject to ERISA, upon the request of a participant or beneficiary the reason for the claim denial must be provided within a reasonable time and in a reasonable manner. For this purpose, a plan that follows the requirements of 29 CFR 2560.503-1 for group health plans complies with the requirements of this paragraph (d)(2)(ii).

(e) Applicability--(1) Group health plans. The requirements of this section apply to a group health plan offering medical/surgical benefits and mental health or substance use disorder benefits. If, under an arrangement or arrangements to provide health care benefits by an employer or employee organization (including for this purpose a joint board of trustees of a multiemployer trust affiliated with one or more multiemployer plans), any participant (or beneficiary) can simultaneously receive coverage for medical/surgical benefits and coverage for

mental health or substance use disorder benefits, then the requirements of this section (including the exemption provisions in paragraph (g) of this section) apply separately with respect to each combination of medical/surgical benefits and of mental health or substance use disorder benefits that any participant (or beneficiary) can simultaneously receive from that employer's or employee organization's arrangement or arrangements to provide health care benefits, and all such combinations are considered for purposes of this section to be a single group health plan.

(2) Health insurance issuers. See 29 CFR 2590.712(e)(2) and 45 CFR 146.136(e)(2), under which a health insurance issuer offering health insurance coverage for mental health or substance use disorder benefits is subject to requirements similar to those applicable to group health plans under this section if the health insurance coverage is offered in connection with a group health plan subject to requirements under 29 CFR 2590.712 or 45 CFR 146.136 similar to those applicable to group health plans under this section.

(3) Scope. This section does not--

(i) Require a group health plan to provide any mental health benefits or substance use disorder benefits, and the provision of benefits by a plan for one or more mental health conditions or substance use disorders does not require the plan under this section to provide benefits for any other mental health condition or substance use disorder; or

(ii) 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 provided in paragraphs (b) and (c) of this section.

(f) Small employer exemption--(1) In general. The requirements of this section do not apply to a group health plan for a plan year of a small employer. For purposes of this paragraph (f), the term small employer means, in connection with a group health plan with respect to a

calendar year and a plan year, an employer who employed an average of at least two (or one in the case of an employer residing in a state that permits small groups to include a single individual) but not more than 50 employees on business days during the preceding calendar year. See section 9831(a)(2) and §54.9831-1(b), which provide that this section (and certain other sections) does not apply to any group health plan for any plan year if, on the first day of the plan year, the plan has fewer than two participants who are current employees.

(2) Rules in determining employer size. For purposes of paragraph (f)(1) of this section--

(i) All persons treated as a single employer under subsections (b), (c), (m), and (o) of section 414 are treated as one employer;

(ii) If an employer was not in existence throughout the preceding calendar year, whether it is a small employer is determined based on the average number of employees the employer reasonably expects to employ on business days during the current calendar year; and

(iii) Any reference to an employer for purposes of the small employer exemption includes a reference to a predecessor of the employer.

(g) Increased cost exemption—[Reserved].

(h) Sale of nonparity health insurance coverage. See 29 CFR 2590.712(h) and 45 CFR 146.136(h), under which a health insurance issuer may not sell a policy, certificate, or contract of insurance that fails to comply with requirements similar to those under paragraph (b) or (c) of this section, except to a plan for a year for which the plan is exempt from requirements similar to those under paragraph (b) or (c) of this section because the plan meets requirements under paragraph (f) or (g) of 29 CFR 2590.712 or 45 CFR 146.136 similar to those under paragraph (f) or (g) of this section.

(i) Effective/applicability dates--(1) In general. Except as provided in paragraph (i)(2) of this section, the requirements of this section are applicable for plan years beginning on or after July 1, 2010.

(2) Special effective date for certain collectively-bargained plans. For a group health plan maintained pursuant to one or more collective bargaining agreements ratified before October 3, 2008, the requirements of this section do not apply to the plan for plan years beginning before the later of either--

(i) The date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension agreed to after October 3, 2008); or

(ii) July 1, 2010.

(j) Expiration date. This section expires on or before January 29, 2013.

PART 602--OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

Par. 3. The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

Par. 4. In §602.101, paragraph (b) is amended by adding the following entry in numerical order to the table:

§602.101 OMB Control numbers.

* * * * *

(b) * * *

CFR part or section where identified and described	Current OMB control No.
* * * * * * *	
54.9812-1T	1545-2165
* * * * * * *	

Steven T. Miller
Deputy Commissioner for Services and Enforcement,
Internal Revenue Service.

Approved: January 27, 2010

Michael F. Mundaca
Acting Assistant Secretary of the Treasury (Tax Policy).

Employee Benefits Security Administration

29 CFR Chapter XXV

29 CFR Part 2590 is amended as follows:

PART 2590—RULES AND REGULATIONS FOR HEALTH INSURANCE PORTABILITY AND RENEWABILITY FOR GROUP HEALTH PLANS

1. The authority citation for Part 2590 is revised to read as follows:

Authority: Secs. 29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104-191, 110 Stat. 1936; sec. 401(b), Public Law 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110-343, 122 Stat. 3765; Public Law 110-460, 122 Stat. 5123; Secretary of Labor's Order 6-2009, 74 FR 21524 (May 7, 2009).

Subpart C—Other Requirements

2. Section 2590.712 is revised to read as follows:

§ 2590.712 Parity in mental health and substance use disorder benefits.

(a) Meaning of terms. For purposes of this section, except where the context clearly indicates otherwise, the following terms have the meanings indicated:

Aggregate lifetime dollar limit means a dollar limitation on the total amount of specified benefits that may be paid under a group health plan (or health insurance coverage offered in connection with such a plan) for any coverage unit.

Annual dollar limit means a dollar limitation on the total amount of specified benefits that may be paid in a 12-month period under a group health plan (or health insurance coverage offered in connection with such a plan) for any coverage unit.

Coverage unit means coverage unit as described in paragraph (c)(1)(iv) of this section.

Cumulative financial requirements are financial requirements that determine whether or to what extent benefits are provided based on accumulated amounts and include deductibles and out-of-pocket maximums. (However, cumulative financial requirements do not include aggregate lifetime or annual dollar limits because these two terms are excluded from the meaning of financial requirements.)

Cumulative quantitative treatment limitations are treatment limitations that determine whether or to what extent benefits are provided based on accumulated amounts, such as annual or lifetime day or visit limits.

Financial requirements include deductibles, copayments, coinsurance, or out-of-pocket maximums. Financial requirements do not include aggregate lifetime or annual dollar limits.

Medical/surgical benefits means benefits for medical or surgical services, as defined under the terms of the plan or health insurance coverage, but does not include mental health or substance use disorder benefits. Any condition defined by the plan as being or as not being a medical/surgical condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the International Classification of Diseases (ICD) or State guidelines).

Mental health benefits means benefits with respect to services for mental health conditions, as defined under the terms of the plan and in accordance with applicable Federal and State law. Any condition defined by the plan as being or as not being a mental health condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), the most current version of the ICD, or State guidelines).

Substance use disorder benefits means benefits with respect to services for substance use disorders, as defined under the terms of the plan and in accordance with applicable Federal and State law. Any disorder defined by the plan as being or as not being a substance use disorder must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the DSM, the most current version of the ICD, or State guidelines).

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under a plan. (See paragraph (c)(4)(ii) of this section for an illustrative list of nonquantitative treatment limitations.) A permanent exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation.

(b) Parity requirements with respect to aggregate lifetime and annual dollar limits—(1)—General—(i) General parity requirement. A group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that provides both medical/surgical benefits and mental health or substance use disorder benefits must comply with paragraph (b)(2), (b)(3), or (b)(6) of this section.

(ii) Exception. The rule in paragraph (b)(1)(i) of this section does not apply if a plan (or health insurance coverage) satisfies the requirements of paragraph (f) or (g) of this section (relating to exemptions for small employers and for increased cost).

(2) Plan with no limit or limits on less than one-third of all medical/surgical benefits. If a plan (or health insurance coverage) does not include an aggregate lifetime or annual dollar limit on any medical/surgical benefits or includes an aggregate lifetime or annual dollar limit that applies to less than one-third of all medical/surgical benefits, it may not impose an aggregate lifetime or annual dollar limit, respectively, on mental health or substance use disorder benefits.

(3) Plan with a limit on at least two-thirds of all medical/surgical benefits. If a plan (or health insurance coverage) includes an aggregate lifetime or annual dollar limit on at least two-thirds of all medical/surgical benefits, it must either—

(i) Apply the aggregate lifetime or annual dollar limit both to the medical/surgical benefits to which the limit would otherwise apply and to mental health or substance use disorder benefits in a manner that does not distinguish between the medical/surgical benefits and mental health or substance use disorder benefits; or

(ii) Not include an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is less than the aggregate lifetime or annual dollar limit, respectively, on medical/surgical benefits. (For cumulative limits other than aggregate lifetime or annual dollar limits, see paragraph (c)(3)(v) of this section prohibiting separately accumulating cumulative financial requirements or cumulative quantitative treatment limitations.)

(4) Examples. The rules of paragraphs (b)(2) and (b)(3) of this section are illustrated by the following examples:

Example 1. (i) Facts. A group health plan has no annual limit on medical/surgical benefits and a $10,000 annual limit on mental health and substance use disorder benefits. To comply with the requirements of this paragraph (b), the plan sponsor is considering each of the following options –

(A) Eliminating the plan's annual dollar limit on mental health and substance use disorder benefits;

(B) Replacing the plan's annual dollar limit on mental health and substance use disorder benefits with a $500,000 annual limit on all benefits (including medical/surgical and mental health and substance use disorder benefits); and

(C) Replacing the plan's annual dollar limit on mental health and substance use disorder benefits with a $250,000 annual limit on medical/surgical benefits and a $250,000 annual limit on mental health and substance use disorder benefits.

(ii) Conclusion. In this Example 1, each of the three options being considered by the plan sponsor would comply with the requirements of this paragraph (b).

Example 2. (i) Facts. A plan has a $100,000 annual limit on medical/surgical inpatient benefits and a $50,000 annual limit on medical/surgical outpatient benefits. To comply with the parity requirements of this paragraph (b), the plan sponsor is considering each of the following options –

(A) Imposing a $150,000 annual limit on mental health and substance use disorder benefits; and

(B) Imposing a $100,000 annual limit on mental health and substance use disorder inpatient benefits and a $50,000 annual limit on mental health and substance use disorder outpatient benefits.

(ii) Conclusion. In this Example 2, each option under consideration by the plan sponsor would comply with the requirements of this section.

(5) Determining one-third and two-thirds of all medical/surgical benefits. For purposes of this paragraph (b), the determination of whether the portion of medical/surgical benefits subject to an aggregate lifetime or annual dollar limit represents one-third or two-thirds of all medical/surgical benefits is based on the dollar amount of all plan payments for medical/surgical benefits expected to be paid under the plan for the plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the aggregate lifetime or annual dollar limits). Any reasonable method may be used to determine whether the dollar amount expected to be paid under the plan will constitute one-third or two-thirds of the dollar amount of all plan payments for medical/surgical benefits.

(6) Plan not described in paragraph (b)(2) or (b)(3) of this section—(i) In general. A group health plan (or health insurance coverage) that is not described in paragraph (b)(2) or (b)(3) of this section with respect to aggregate lifetime or annual dollar limits on medical/surgical benefits, must either—

(A) Impose no aggregate lifetime or annual dollar limit, as appropriate, on mental health or substance use disorder benefits; or

(B) Impose an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is no less than an average limit calculated for medical/surgical benefits in the following manner. The average limit is calculated by taking into account the weighted average of the aggregate lifetime or annual dollar limits, as appropriate, that are applicable to the categories of medical/surgical benefits. Limits based on delivery systems, such as inpatient/outpatient treatment or normal treatment of common, low-cost conditions (such as treatment of normal births), do not constitute categories for purposes of this paragraph (b)(6)(i)(B). In addition, for purposes of determining weighted averages, any benefits that are not within a category that is subject to a separately-designated dollar limit under the plan are taken into account as a single separate category by using an estimate of the upper limit on the dollar amount that a plan may reasonably be expected to incur with respect to such benefits, taking into account any other applicable restrictions under the plan.

(ii) Weighting. For purposes of this paragraph (b)(6), the weighting applicable to any category of medical/surgical benefits is determined in the manner set forth in paragraph (b)(5) of this section for determining one-third or two-thirds of all medical/surgical benefits.

(iii) Example. The rules of this paragraph (b)(6) are illustrated by the following example:

Example. (i) Facts. A group health plan that is subject to the requirements of this section includes a $100,000 annual limit on medical/surgical benefits related to cardio-pulmonary diseases. The plan does not include an annual dollar limit on any other category of medical/surgical benefits. The plan determines that 40% of the dollar amount of plan payments for medical/surgical benefits are related to cardio-pulmonary diseases. The plan determines that $1,000,000 is a reasonable estimate of the upper limit on the dollar amount that the plan may incur with respect to the other 60% of payments for medical/surgical benefits.

(ii) Conclusion. In this Example, the plan is not described in paragraph (b)(3) of this section because there is not one annual dollar limit that applies to at least two-thirds of all medical/surgical benefits. Further, the plan is not described in paragraph (b)(2) of this section because more than one-third of all medical/surgical benefits are subject to an annual dollar limit. Under this paragraph (b)(6), the plan sponsor can choose either to include no annual dollar limit on mental health or substance use disorder benefits, or to include an annual dollar limit on mental health or substance use disorder benefits that is not less than the weighted average of the annual dollar limits applicable to each category of medical/surgical benefits. In this example, the minimum weighted average annual dollar limit that can be applied to mental health or substance use disorder benefits is $640,000 (40% x $100,000 + 60% x $1,000,000 = $640,000).

(c) Parity requirements with respect to financial requirements and treatment limitations -- (1) Clarification of terms -- (i) Classification of benefits. When reference is made in this paragraph (c) to a classification of benefits, the term “classification” means a classification as described in paragraph (c)(2)(ii) of this section.

(ii) Type of financial requirement or treatment limitation. When reference is made in this paragraph (c) to a type of financial requirement or treatment limitation, the reference to type means its nature. Different types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations include annual, episode, and lifetime day and visit limits. See paragraph (c)(4)(ii) of this section for an illustrative list of nonquantitative treatment limitations.

(iii) Level of a type of financial requirement or treatment limitation. When reference is made in this paragraph (c) to a level of a type of financial requirement or treatment limitation, level refers to the magnitude of the type of financial requirement or treatment limitation. For

example, different levels of coinsurance include 20 percent and 30 percent; different levels of a copayment include $15 and $20; different levels of a deductible include $250 and $500; and different levels of an episode limit include 21 inpatient days per episode and 30 inpatient days per episode.

(iv) Coverage unit. When reference is made in this paragraph (c) to a coverage unit, coverage unit refers to the way in which a plan (or health insurance coverage) groups individuals for purposes of determining benefits, or premiums or contributions. For example, different coverage units include self-only, family, and employee-plus-spouse.

(2) General parity requirement – (i) General rule. A group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that provides both medical/surgical benefits and mental health or substance use disorder benefits may not apply any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification. Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial requirement or treatment limitation. The application of the rules of this paragraph (c)(2) to financial requirements and quantitative treatment limitations is addressed in paragraph (c)(3) of this section; the application of the rules of this paragraph (c)(2) to nonquantitative treatment limitations is addressed in paragraph (c)(4) of this section.

(ii) Classifications of benefits used for applying rules – (A) In general. If a plan (or health insurance coverage) provides mental health or substance use disorder benefits in any

classification of benefits described in this paragraph (c)(2)(ii), mental health or substance use disorder benefits must be provided in every classification in which medical/surgical benefits are provided. In determining the classification in which a particular benefit belongs, a plan (or health insurance issuer) must apply the same standards to medical/surgical benefits and to mental health or substance use disorder benefits. To the extent that a plan (or health insurance coverage) provides benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment limitation) for benefits in the classification, the rules of this paragraph (c) apply separately with respect to that classification for all financial requirements or treatment limitations. The following classifications of benefits are the only classifications used in applying the rules of this paragraph (c):

(1) Inpatient, in-network. Benefits furnished on an inpatient basis and within a network of providers established or recognized under a plan or health insurance coverage.

(2) Inpatient, out-of-network. Benefits furnished on an inpatient basis and outside any network of providers established or recognized under a plan or health insurance coverage. This classification includes inpatient benefits under a plan (or health insurance coverage) that has no network of providers.

(3) Outpatient, in-network. Benefits furnished on an outpatient basis and within a network of providers established or recognized under a plan or health insurance coverage.

(4) Outpatient, out-of-network. Benefits furnished on an outpatient basis and outside any network of providers established or recognized under a plan or health insurance coverage. This classification includes outpatient benefits under a plan (or health insurance coverage) that has no network of providers.

(5) Emergency care. Benefits for emergency care.

(6) Prescription drugs. Benefits for prescription drugs. See special rules for multi-tiered prescription drug benefits in paragraph (c)(3)(iii) of this section.

(B) Application to out-of-network providers. See paragraph (c)(2)(ii)(A) of this section, under which a plan (or health insurance coverage) that provides mental health or substance use disorder benefits in any classification of benefits must provide mental health or substance use disorder benefits in every classification in which medical/surgical benefits are provided, including out-of-network classifications.

(C) Examples. The rules of this paragraph (c)(2)(ii) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

Example 1. (i) Facts. A group health plan offers inpatient and outpatient benefits and does not contract with a network of providers. The plan imposes a $500 deductible on all benefits. For inpatient medical/surgical benefits, the plan imposes a coinsurance requirement. For outpatient medical/surgical benefits, the plan imposes copayments. The plan imposes no other financial requirements or treatment limitations.

(ii) Conclusion. In this Example 1, because the plan has no network of providers, all benefits provided are out-of-network. Because inpatient, out-of-network medical/surgical benefits are subject to separate financial requirements from outpatient, out-of-network medical/surgical benefits, the rules of this paragraph (c) apply separately with respect to any financial requirements and treatment limitations, including the deductible, in each classification.

Example 2. (i) Facts. A plan imposes a $500 deductible on all benefits. The plan has no network of providers. The plan generally imposes a 20 percent coinsurance requirement with respect to all benefits, without distinguishing among inpatient, outpatient, emergency, or prescription drug benefits. The plan imposes no other financial requirements or treatment limitations.

(ii) Conclusion. In this Example 2, because the plan does not impose separate financial requirements (or treatment limitations) based on classification, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance across all benefits.

Example 3. (i) Facts. Same facts as Example 2, except the plan exempts emergency care benefits from the 20 percent coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(ii) Conclusion. In this Example 3, because the plan imposes separate financial requirements based on classifications, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance separately for –

(A) Benefits in the emergency classification; and

(B) All other benefits.

Example 4. (i) Facts. Same facts as Example 2, except the plan also imposes a preauthorization requirement for all inpatient treatment in order for benefits to be paid. No such requirement applies to outpatient treatment.

(ii) Conclusion. In this Example 4, because the plan has no network of providers, all benefits provided are out-of-network. Because the plan imposes a separate treatment limitation based on classifications, the rules of this paragraph (c) apply with respect to the deductible and coinsurance separately for –

(A) Inpatient, out-of-network benefits; and

(B) All other benefits.

(3) Financial requirements and quantitative treatment limitations – (i) Determining "substantially all" and "predominant" – (A) Substantially all. For purposes of this paragraph (c), a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification of benefits if it applies to at least two-thirds of all medical/surgical benefits in that classification. (For this purpose, benefits expressed as subject to a zero level of a type of financial requirement are treated as benefits not subject to that type of financial requirement, and benefits expressed as subject to a quantitative treatment limitation that is unlimited are treated as benefits not subject to that type of quantitative treatment limitation.) If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification,

then that type cannot be applied to mental health or substance use disorder benefits in that classification.

(B) Predominant – (1) If a type of financial requirement or quantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits in a classification as determined under paragraph (c)(3)(i)(A) of this section, the level of the financial requirement or quantitative treatment limitation that is considered the predominant level of that type in a classification of benefits is the level that applies to more than one-half of medical/surgical benefits in that classification subject to the financial requirement or quantitative treatment limitation.

(2) If, with respect to a type of financial requirement or quantitative treatment limitation that applies to at least two-thirds of all medical/surgical benefits in a classification, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to the financial requirement or quantitative treatment limitation, the plan (or health insurance issuer) may combine levels until the combination of levels applies to more than one-half of medical/surgical benefits subject to the financial requirement or quantitative treatment limitation in the classification. The least restrictive level within the combination is considered the predominant level of that type in the classification. (For this purpose, a plan may combine the most restrictive levels first, with each less restrictive level added to the combination until the combination applies to more than one-half of the benefits subject to the financial requirement or treatment limitation.)

(C) Portion based on plan payments. For purposes of this paragraph (c), the determination of the portion of medical/surgical benefits in a classification of benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial

requirement or quantitative treatment limitation) is based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan for the plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the financial requirement or quantitative treatment limitation).

(D) Clarifications for certain threshold requirements. For any deductible, the dollar amount of plan payments includes all plan payments with respect to claims that would be subject to the deductible if it had not been satisfied. For any out-of-pocket maximum, the dollar amount of plan payments includes all plan payments associated with out-of-pocket payments that are taken into account towards the out-of-pocket maximum as well as all plan payments associated with out-of-pocket payments that would have been made towards the out-of-pocket maximum if it had not been satisfied. Similar rules apply for any other thresholds at which the rate of plan payment changes.

(E) Determining the dollar amount of plan payments. Subject to paragraph (c)(3)(i)(D) of this section, any reasonable method may be used to determine the dollar amount expected to be paid under a plan for medical/surgical benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation).

(ii) Application to different coverage units. If a plan (or health insurance coverage) applies different levels of a financial requirement or quantitative treatment limitation to different coverage units in a classification of medical/surgical benefits, the predominant level that applies to substantially all medical/surgical benefits in the classification is determined separately for each coverage unit.

(iii) Special rule for multi-tiered prescription drug benefits. If a plan (or health insurance coverage) applies different levels of financial requirements to different tiers of prescription drug benefits based on reasonable factors determined in accordance with the rules in paragraph (c)(4)(i) of this section (relating to requirements for nonquantitative treatment limitations) and without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits, the plan (or health insurance coverage) satisfies the parity requirements of this paragraph (c) with respect to prescription drug benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up.

(iv) Examples. The rules of paragraphs (c)(3)(i), (c)(3)(ii), and (c)(3)(iii) of this section are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

Example 1. (i) Facts. For inpatient, out-of-network medical/surgical benefits, a group health plan imposes five levels of coinsurance. Using a reasonable method, the plan projects its payments for the upcoming year as follows:

Coinsurance rate	0 %	10%	15%	20%	30%	Total
Projected payments	$200x	$100x	$450x	$100x	$150x	$1,000x
Percent of total plan costs	20%	10%	45%	10%	15%	
Percent subject to coinsurance level	N/A	12.5% (100x/800x)	56.25% (450x/800x)	12.5% (100x/800x)	18.75% (150x/800x)	

The plan projects plan costs of $800x to be subject to coinsurance ($100x + $450x + $100x + $150x = $800x). Thus, 80 percent ($800x/$1,000x) of the benefits are projected to be subject to coinsurance, and 56.25 percent of the benefits subject to coinsurance are projected to be subject to the 15 percent coinsurance level.

(ii) Conclusion. In this Example 1, the two-thirds threshold of the substantially all standard is met for coinsurance because 80 percent of all inpatient, out-of-network medical/surgical benefits are subject to coinsurance. Moreover, the 15 percent coinsurance is the predominant level because it is applicable to more than one-half of inpatient, out-of-network

medical/surgical benefits subject to the coinsurance requirement. The plan may not impose any level of coinsurance with respect to inpatient, out-of-network mental health or substance use disorder benefits that is more restrictive than the 15 percent level of coinsurance.

Example 2. (i) Facts. For outpatient, in-network medical/surgical benefits, a plan imposes five different copayment levels. Using a reasonable method, the plan projects payments for the upcoming year as follows:

Copayment amount	$0	$10	$15	$20	$50	Total
Projected payments	$200x	$200x	$200x	$300x	$100x	$1,000x
Percent of total plan costs	20%	20%	20%	30%	10%	
Percent subject to copayments	N/A	25% (200x/800x)	25% (200x/800x)	37.5% (300x/800x)	12.5% (100x/800x)	

The plan projects plan costs of $800x to be subject to copayments ($200x + $200x +$300x + $100x = $800x). Thus, 80 percent ($800x/$1,000x) of the benefits are projected to be subject to a copayment.

(ii) Conclusion. In this Example 2, the two-thirds threshold of the substantially all standard is met for copayments because 80 percent of all outpatient, in-network medical/surgical benefits are subject to a copayment. Moreover, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to a copayment (for the $10 copayment, 25%; for the $15 copayment, 25%; for the $20 copayment, 37.5%; and for the $50 copayment, 12.5%). The plan can combine any levels of copayment, including the highest levels, to determine the predominant level that can be applied to mental health or substance use disorder benefits. If the plan combines the highest levels of copayment, the combined projected payments for the two highest copayment levels, the $50 copayment and the $20 copayment, are not more than one-half of the outpatient, in-network medical/surgical benefits subject to a copayment because they are exactly one-half ($300x + $100x = $400x; $400x/$800x = 50%). The combined projected payments for the three highest copayment levels – the $50 copayment, the $20 copayment, and the $15 copayment – are more than one-half of the outpatient, in-network medical/surgical benefits subject to the copayments ($100x + $300x + $200x = $600x; $600x/$800x = 75%). Thus, the plan may not impose any copayment on outpatient, in-network mental health or substance use disorder benefits that is more restrictive than the least restrictive copayment in the combination, the $15 copayment.

Example 3. (i) Facts. A plan imposes a $250 deductible on all medical/surgical benefits for self-only coverage and a $500 deductible on all medical/surgical benefits for family coverage. The plan has no network of providers. For all medical/surgical benefits, the plan imposes a coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(ii) Conclusion. In this Example 3, because the plan has no network of providers, all benefits are provided out-of-network. Because self-only and family coverage are subject to

different deductibles, whether the deductible applies to substantially all medical/surgical benefits is determined separately for self-only medical/surgical benefits and family medical/surgical benefits. Because the coinsurance is applied without regard to coverage units, the predominant coinsurance that applies to substantially all medical/surgical benefits is determined without regard to coverage units.

Example 4. (i) Facts. A plan applies the following financial requirements for prescription drug benefits. The requirements are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits. Moreover, the process for certifying a particular drug as "generic", "preferred brand name", "non-preferred brand name", or "specialty" complies with the rules of paragraph (c)(4)(i) of this section (relating to requirements for nonquantitative treatment limitations).

	Tier 1	Tier 2	Tier 3	Tier 4
Tier description	Generic drugs	Preferred brand name drugs	Non-preferred brand name drugs (which may have Tier 1 or Tier 2 alternatives)	Specialty drugs
Percent paid by plan	90%	80%	60%	50%

(ii) Conclusion. In this Example 4, the financial requirements that apply to prescription drug benefits are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits; the process for certifying drugs in different tiers complies with paragraph (c)(4) of this section; and the bases for establishing different levels or types of financial requirements are reasonable. The financial requirements applied to prescription drug benefits do not violate the parity requirements of this paragraph (c)(3).

(v) No separate cumulative financial requirements or cumulative quantitative treatment limitations – (A) A group health plan (or health insurance coverage offered in connection with a group health plan) may not apply any cumulative financial requirement or cumulative quantitative treatment limitation for mental health or substance use disorder benefits in a classification that accumulates separately from any established for medical/surgical benefits in the same classification.

(B) The rules of this paragraph (c)(3)(v) are illustrated by the following examples:

Example 1. (i) Facts. A group health plan imposes a combined annual $500 deductible on all medical/surgical, mental health, and substance use disorder benefits.

(ii) Conclusion. In this Example 1, the combined annual deductible complies with the requirements of this paragraph (c)(3)(v).

Example 2. (i) Facts. A plan imposes an annual $250 deductible on all medical/surgical benefits and a separate annual $250 deductible on all mental health and substance use disorder benefits.

(ii) Conclusion. In this Example 2, the separate annual deductible on mental health and substance use disorder benefits violates the requirements of this paragraph (c)(3)(v).

Example 3. (i) Facts. A plan imposes an annual $300 deductible on all medical/surgical benefits and a separate annual $100 deductible on all mental health or substance use disorder benefits.

(ii) Conclusion. In this Example 3, the separate annual deductible on mental health and substance use disorder benefits violates the requirements of this paragraph (c)(3)(v).

Example 4. (i) Facts. A plan generally imposes a combined annual $500 deductible on all benefits (both medical/surgical benefits and mental health and substance use disorder benefits) except prescription drugs. Certain benefits, such as preventive care, are provided without regard to the deductible. The imposition of other types of financial requirements or treatment limitations varies with each classification. Using reasonable methods, the plan projects its payments for medical/surgical benefits in each classification for the upcoming year as follows:

Classification	Benefits Subject to Deductible	Total Benefits	Percent Subject to Deductible
Inpatient, in-network	$1,800x	$2,000x	90%
Inpatient, out-of-network	$1,000x	$1,000x	100%
Outpatient, in-network	$1,400x	$2,000x	70%
Outpatient, out-of-network	$1,880x	$2,000x	94%
Emergency care	$300x	$500x	60%

(ii) Conclusion. In this Example 4, the two-thirds threshold of the substantially all standard is met with respect to each classification except emergency care because in each of those other classifications at least two-thirds of medical/surgical benefits are subject to the $500 deductible. Moreover, the $500 deductible is the predominant level in each of those other classifications because it is the only level. However, emergency care mental health and substance use disorder benefits cannot be subject to the $500 deductible because it does not apply to substantially all emergency care medical/surgical benefits.

(4) Nonquantitative treatment limitations – (i) General rule. A group health plan (or health insurance coverage) may not impose a nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan (or health insurance coverage) as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation with respect to medical surgical/benefits in the classification, except to the extent that recognized clinically appropriate standards of care may permit a difference.

(ii) Illustrative list of nonquantitative treatment limitations. Nonquantitative treatment limitations include –

(A) Medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;

(B) Formulary design for prescription drugs;

(C) Standards for provider admission to participate in a network, including reimbursement rates;

(D) Plan methods for determining usual, customary, and reasonable charges;

(E) Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols); and

(F) Exclusions based on failure to complete a course of treatment.

(iii) Examples. The rules of this paragraph (c)(4) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

Example 1. (i) Facts. A group health plan limits benefits to treatment that is medically necessary. The plan requires concurrent review for inpatient, in-network mental health and substance use disorder benefits but does not require it for any inpatient, in-network medical/surgical benefits. The plan conducts retrospective review for inpatient, in-network medical/surgical benefits.

(ii) Conclusion. In this Example 1, the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation – medical necessity – applies to both mental health and substance use disorder benefits and to medical/surgical benefits for inpatient, in-network services, the concurrent review process does not apply to medical/surgical benefits. The concurrent review process is not comparable to the retrospective review process. While such a difference might be permissible in certain individual cases based on recognized clinically appropriate standards of care, it is not permissible for distinguishing between all medical/surgical benefits and all mental health or substance use disorder benefits.

Example 2. (i) Facts. A plan requires prior approval that a course of treatment is medically necessary for outpatient, in-network medical/surgical, mental health, and substance

use disorder benefits. For mental health and substance use disorder treatments that do not have prior approval, no benefits will be paid; for medical/surgical treatments that do not have prior approval, there will only be a 25 percent reduction in the benefits the plan would otherwise pay.

(ii) Conclusion. In this Example 2, the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation – medical necessity – is applied both to mental health and substance use disorder benefits and to medical/surgical benefits for outpatient, in-network services, the penalty for failure to obtain prior approval for mental health and substance use disorder benefits is not comparable to the penalty for failure to obtain prior approval for medical/surgical benefits.

Example 3. (i) Facts. A plan generally covers medically appropriate treatments. For both medical/surgical benefits and mental health and substance use disorder benefits, evidentiary standards used in determining whether a treatment is medically appropriate (such as the number of visits or days of coverage) are based on recommendations made by panels of experts with appropriate training and experience in the fields of medicine involved. The evidentiary standards are applied in a manner that may differ based on clinically appropriate standards of care for a condition.

(ii) Conclusion. In this Example 3, the plan complies with the rules of this paragraph (c)(4) because the nonquantitative treatment limitation – medical appropriateness – is the same for both medical/surgical benefits and mental health and substance use disorder benefits, and the processes for developing the evidentiary standards and the application of them to mental health and substance use disorder benefits are comparable to and are applied no more stringently than for medical/surgical benefits. This is the result even if, based on clinically appropriate standards of care, the application of the evidentiary standards does not result in similar numbers of visits, days of coverage, or other benefits utilized for mental health conditions or substance use disorders as it does for any particular medical/surgical condition.

Example 4. (i) Facts. A plan generally covers medically appropriate treatments. In determining whether prescription drugs are medically appropriate, the plan automatically excludes coverage for antidepressant drugs that are given a black box warning label by the Food and Drug Administration (indicating the drug carries a significant risk of serious adverse effects). For other drugs with a black box warning (including those prescribed for other mental health conditions and substance use disorders, as well as for medical/surgical conditions), the plan will provide coverage if the prescribing physician obtains authorization from the plan that the drug is medically appropriate for the individual, based on clinically appropriate standards of care.

(ii) Conclusion. In this Example 4, the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation – medical appropriateness – is applied to both mental health and substance use disorder benefits and medical/surgical benefits, the plan's unconditional exclusion of antidepressant drugs given a black box warning is not comparable to the conditional exclusion for other drugs with a black box warning.

Example 5. (i) Facts. An employer maintains both a major medical program and an employee assistance program (EAP). The EAP provides, among other benefits, a limited number of mental health or substance use disorder counseling sessions. Participants are eligible for mental health or substance use disorder benefits under the major medical program only after exhausting the counseling sessions provided by the EAP. No similar exhaustion requirement applies with respect to medical/surgical benefits provided under the major medical program.

(ii) Conclusion. In this Example 5, limiting eligibility for mental health and substance use disorder benefits only after EAP benefits are exhausted is a nonquantitative treatment limitation subject to the parity requirements of this paragraph (c). Because no comparable requirement applies to medical/surgical benefits, the requirement may not be applied to mental health or substance use disorder benefits.

(5) Exemptions. The rules of this paragraph (c) do not apply if a group health plan (or health insurance coverage) satisfies the requirements of paragraph (f) or (g) of this section (relating to exemptions for small employers and for increased cost).

(d) Availability of plan information – (1) Criteria for medical necessity determinations. The criteria for medical necessity determinations made under a group health plan with respect to mental health or substance use disorder benefits (or health insurance coverage offered in connection with the plan with respect to such benefits) must be made available by the plan administrator (or the health insurance issuer offering such coverage) to any current or potential participant, beneficiary, or contracting provider upon request.

(2) Reason for any denial. The reason for any denial under a group health plan (or health insurance coverage) of reimbursement or payment for services with respect to mental health or substance use disorder benefits in the case of any participant or beneficiary must be made available by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary in a form and manner consistent with the rules in § 2560.503-1 of this Part for group health plans.

(e) Applicability – (1) Group health plans. The requirements of this section apply to a group health plan offering medical/surgical benefits and mental health or substance use disorder benefits. If, under an arrangement or arrangements to provide medical care benefits by an employer or employee organization (including for this purpose a joint board of trustees of a multiemployer trust affiliated with one or more multiemployer plans), any participant (or beneficiary) can simultaneously receive coverage for medical/surgical benefits and coverage for mental health or substance use disorder benefits, then the requirements of this section (including the exemption provisions in paragraph (g) of this section) apply separately with respect to each combination of medical/surgical benefits and of mental health or substance use disorder benefits that any participant (or beneficiary) can simultaneously receive from that employer's or employee organization's arrangement or arrangements to provide medical care benefits, and all such combinations are considered for purposes of this section to be a single group health plan.

(2) Health insurance issuers. The requirements of this section apply to a health insurance issuer offering health insurance coverage for mental health or substance use disorder benefits in connection with a group health plan subject to paragraph (e)(1) of this section.

(3) Scope. This section does not –

(i) Require a group health plan (or health insurance issuer offering coverage in connection with a group health plan) to provide any mental health benefits or substance use disorder benefits, and the provision of benefits by a plan (or health insurance coverage) for one or more mental health conditions or substance use disorders does not require the plan or health insurance coverage under this section to provide benefits for any other mental health condition or substance use disorder; or

(ii) Affect the terms and conditions relating to the amount, duration, or scope of mental health or substance use disorder benefits under the plan (or health insurance coverage) except as specifically provided in paragraphs (b) and (c) of this section.

(f) Small employer exemption—(1) In general. The requirements of this section do not apply to a group health plan (or health insurance issuer offering coverage in connection with a group health plan) for a plan year of a small employer. For purposes of this paragraph (f), the term small employer means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least two (or one in the case of an employer residing in a state that permits small groups to include a single individual) but not more than 50 employees on business days during the preceding calendar year. See section 732(a) of ERISA and § 2590.732(b) of this Part, which provide that this section (and certain other sections) does not apply to any group health plan (and health insurance issuer offering coverage in connection with a group health plan) for any plan year if, on the first day of the plan year, the plan has fewer than two participants who are current employees.

(2) Rules in determining employer size. For purposes of paragraph (f)(1) of this section—

(i) All persons treated as a single employer under subsections (b), (c), (m), and (o) of section 414 of the Code are treated as one employer;

(ii) If an employer was not in existence throughout the preceding calendar year, whether it is a small employer is determined based on the average number of employees the employer reasonably expects to employ on business days during the current calendar year; and

(iii) Any reference to an employer for purposes of the small employer exemption includes a reference to a predecessor of the employer.

(g) Increased cost exemption—[Reserved]

(h) Sale of nonparity health insurance coverage. A health insurance issuer may not sell a policy, certificate, or contract of insurance that fails to comply with paragraph (b) or (c) of this section, except to a plan for a year for which the plan is exempt from the requirements of this section because the plan meets the requirements of paragraph (f) or (g) of this section.

(i) Applicability dates—(1) In general. Except as provided in paragraph (i)(2) of this section, the requirements of this section are applicable for plan years beginning on or after July 1, 2010.

(2) Special effective date for certain collectively-bargained plans. For a group health plan maintained pursuant to one or more collective bargaining agreements ratified before October 3, 2008, the requirements of this section do not apply to the plan (or health insurance coverage offered in connection with the plan) for plan years beginning before the later of either –

(i) The date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension agreed to after October 3, 2008); or

(ii) July 1, 2010.

Signed at Washington, D.C. this __26_____ day of ____January_____, 2010.

Phyllis C. Borzi,
Assistant Secretary,
Employee Benefits Security Administration,
U.S. Department of Labor.

Department of Health and Human Services

45 CFR Subtitle A

■ For the reasons set forth in the preamble, the Department of Health and Human Services is amending 45 CFR Subtitle A, Subchapter B, Part 146, Subpart C as follows:

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

■ 1. The authority citation for Part 146 continues to read as follows:

Authority: Secs. 2702 through 2705, 2711through 2723, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg–1 through 300gg–5, 300gg–11 through 300gg–23, 300gg–91, and 300gg–92).

■ 2. Section 146.136 is revised to read as follows:

§ 146.136 Parity in mental health and substance use disorder benefits.

(a) Meaning of terms. For purposes of this section, except where the context clearly indicates otherwise, the following terms have the meanings indicated:

Aggregate lifetime dollar limit means a dollar limitation on the total amount of specified benefits that may be paid under a group health plan (or health insurance coverage offered in connection with such a plan) for any coverage unit.

Annual dollar limit means a dollar limitation on the total amount of specified benefits that may be paid in a 12-month period under a group health plan (or health insurance coverage offered in connection with such a plan) for any coverage unit.

Coverage unit means coverage unit as described in paragraph (c)(1)(iv) of this section.

Cumulative financial requirements are financial requirements that determine whether or to what extent benefits are provided based on accumulated amounts and include deductibles and out-of-pocket maximums. (However, cumulative financial requirements do not include aggregate

lifetime or annual dollar limits because these two terms are excluded from the meaning of financial requirements.)

Cumulative quantitative treatment limitations are treatment limitations that determine whether or to what extent benefits are provided based on accumulated amounts, such as annual or lifetime day or visit limits.

Financial requirements include deductibles, copayments, coinsurance, or out-of-pocket maximums. Financial requirements do not include aggregate lifetime or annual dollar limits.

Medical/surgical benefits means benefits for medical or surgical services, as defined under the terms of the plan or health insurance coverage, but does not include mental health or substance use disorder benefits. Any condition defined by the plan as being or as not being a medical/surgical condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the International Classification of Diseases (ICD) or State guidelines).

Mental health benefits means benefits with respect to services for mental health conditions, as defined under the terms of the plan and in accordance with applicable Federal and State law. Any condition defined by the plan as being or as not being a mental health condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), the most current version of the ICD, or State guidelines).

Substance use disorder benefits means benefits with respect to services for substance use disorders, as defined under the terms of the plan and in accordance with applicable Federal and State law. Any disorder defined by the plan as being or as not being a substance use disorder must be defined to be consistent with generally recognized independent standards of current

medical practice (for example, the most current version of the DSM, the most current version of the ICD, or State guidelines).

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under a plan. (See paragraph (c)(4)(ii) of this section for an illustrative list of nonquantitative treatment limitations.) A permanent exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation.

(b) Parity requirements with respect to aggregate lifetime and annual dollar limits—(1)—General—(i) General parity requirement. A group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that provides both medical/surgical benefits and mental health or substance use disorder benefits must comply with paragraph (b)(2), (b)(3), or (b)(6) of this section.

(ii) Exception. The rule in paragraph (b)(1)(i) of this section does not apply if a plan (or health insurance coverage) satisfies the requirements of paragraph (f) or (g) of this section (relating to exemptions for small employers and for increased cost).

(2) Plan with no limit or limits on less than one-third of all medical/surgical benefits. If a plan (or health insurance coverage) does not include an aggregate lifetime or annual dollar limit on any medical/surgical benefits or includes an aggregate lifetime or annual dollar limit that applies to less than one-third of all medical/surgical benefits, it may not impose an aggregate lifetime or annual dollar limit, respectively, on mental health or substance use disorder benefits.

(3) Plan with a limit on at least two-thirds of all medical/surgical benefits. If a plan (or health insurance coverage) includes an aggregate lifetime or annual dollar limit on at least two-thirds of all medical/surgical benefits, it must either—

(i) Apply the aggregate lifetime or annual dollar limit both to the medical/surgical benefits to which the limit would otherwise apply and to mental health or substance use disorder benefits in a manner that does not distinguish between the medical/surgical benefits and mental health or substance use disorder benefits; or

(ii) Not include an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is less than the aggregate lifetime or annual dollar limit, respectively, on medical/surgical benefits. (For cumulative limits other than aggregate lifetime or annual dollar limits, see paragraph (c)(3)(v) of this section prohibiting separately accumulating cumulative financial requirements or cumulative quantitative treatment limitations.)

(4) Examples. The rules of paragraphs (b)(2) and (b)(3) of this section are illustrated by the following examples:

Example 1. (i) Facts. A group health plan has no annual limit on medical/surgical benefits and a $10,000 annual limit on mental health and substance use disorder benefits. To comply with the requirements of this paragraph (b), the plan sponsor is considering each of the following options –

(A) Eliminating the plan's annual dollar limit on mental health and substance use disorder benefits;

(B) Replacing the plan's annual dollar limit on mental health and substance use disorder benefits with a $500,000 annual limit on all benefits (including medical/surgical and mental health and substance use disorder benefits); and

(C) Replacing the plan's annual dollar limit on mental health and substance use disorder benefits with a $250,000 annual limit on medical/surgical benefits and a $250,000 annual limit on mental health and substance use disorder benefits.

(ii) Conclusion. In this Example 1, each of the three options being considered by the plan sponsor would comply with the requirements of this paragraph (b).

Example 2. (i) Facts. A plan has a $100,000 annual limit on medical/surgical inpatient benefits and a $50,000 annual limit on medical/surgical outpatient benefits. To comply with the parity requirements of this paragraph (b), the plan sponsor is considering each of the following options –

(A) Imposing a $150,000 annual limit on mental health and substance use disorder benefits; and

(B) Imposing a $100,000 annual limit on mental health and substance use disorder inpatient benefits and a $50,000 annual limit on mental health and substance use disorder outpatient benefits.

(ii) Conclusion. In this Example 2, each option under consideration by the plan sponsor would comply with the requirements of this section.

(5) Determining one-third and two-thirds of all medical/surgical benefits. For purposes of this paragraph (b), the determination of whether the portion of medical/surgical benefits subject to an aggregate lifetime or annual dollar limit represents one-third or two-thirds of all medical/surgical benefits is based on the dollar amount of all plan payments for medical/surgical benefits expected to be paid under the plan for the plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the aggregate lifetime or annual dollar limits). Any reasonable method may be used to determine whether the dollar amount expected to be paid under the plan will constitute one-third or two-thirds of the dollar amount of all plan payments for medical/surgical benefits.

(6) Plan not described in paragraph (b)(2) or (b)(3) of this section—(i) In general. A group health plan (or health insurance coverage) that is not described in paragraph (b)(2) or (b)(3) of this section with respect to aggregate lifetime or annual dollar limits on medical/surgical benefits, must either—

(A) Impose no aggregate lifetime or annual dollar limit, as appropriate, on mental health or substance use disorder benefits; or

(B) Impose an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is no less than an average limit calculated for medical/surgical benefits in the following manner. The average limit is calculated by taking into account the weighted average of the aggregate lifetime or annual dollar limits, as appropriate, that are applicable to the categories of medical/surgical benefits. Limits based on delivery systems, such as inpatient/outpatient treatment or normal treatment of common, low-cost conditions (such as treatment of normal births), do not constitute categories for purposes of this paragraph (b)(6)(i)(B). In addition, for purposes of determining weighted averages, any benefits that are not within a category that is subject to a separately-designated dollar limit under the plan are taken into account as a single separate category by using an estimate of the upper limit on the dollar amount that a plan may reasonably be expected to incur with respect to such benefits, taking into account any other applicable restrictions under the plan.

(ii) Weighting. For purposes of this paragraph (b)(6), the weighting applicable to any category of medical/surgical benefits is determined in the manner set forth in paragraph (b)(5) of this section for determining one-third or two-thirds of all medical/surgical benefits.

(iii) Example. The rules of this paragraph (b)(6) are illustrated by the following example:

Example. (i) Facts. A group health plan that is subject to the requirements of this section includes a $100,000 annual limit on medical/surgical benefits related to cardio-pulmonary diseases. The plan does not include an annual dollar limit on any other category of medical/surgical benefits. The plan determines that 40% of the dollar amount of plan payments for medical/surgical benefits are related to cardio-pulmonary diseases. The plan determines that $1,000,000 is a reasonable estimate of the upper limit on the dollar amount that the plan may incur with respect to the other 60% of payments for medical/surgical benefits.

(ii) Conclusion. In this Example, the plan is not described in paragraph (b)(3) of this section because there is not one annual dollar limit that applies to at least two-thirds of all medical/surgical benefits. Further, the plan is not described in paragraph (b)(2) of this section because more than one-third of all medical/surgical benefits are subject to an annual dollar limit. Under this paragraph (b)(6), the plan sponsor can choose either to include no annual dollar limit on mental health or substance use disorder benefits, or to include an annual dollar limit on mental health or substance use disorder benefits that is not less than the weighted average of the annual dollar limits applicable to each category of medical/surgical benefits. In this example, the minimum weighted average annual dollar limit that can be applied to mental health or substance use disorder benefits is $640,000 (40% x $100,000 + 60% x $1,000,000 = $640,000).

(c) Parity requirements with respect to financial requirements and treatment limitations -- (1) Clarification of terms -- (i) Classification of benefits. When reference is made in this paragraph (c) to a classification of benefits, the term "classification" means a classification as described in paragraph (c)(2)(ii) of this section.

(ii) Type of financial requirement or treatment limitation. When reference is made in this paragraph (c) to a type of financial requirement or treatment limitation, the reference to type means its nature. Different types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations include annual, episode, and lifetime day and visit limits. See paragraph (c)(4)(ii) of this section for an illustrative list of nonquantitative treatment limitations.

(iii) Level of a type of financial requirement or treatment limitation. When reference is made in this paragraph (c) to a level of a type of financial requirement or treatment limitation, level refers to the magnitude of the type of financial requirement or treatment limitation. For example, different levels of coinsurance include 20 percent and 30 percent; different levels of a copayment include $15 and $20; different levels of a deductible include $250 and $500; and different levels of an episode limit include 21 inpatient days per episode and 30 inpatient days per episode.

(iv) Coverage unit. When reference is made in this paragraph (c) to a coverage unit, coverage unit refers to the way in which a plan (or health insurance coverage) groups individuals for purposes of determining benefits, or premiums or contributions. For example, different coverage units include self-only, family, and employee-plus-spouse.

(2) General parity requirement – (i) General rule. A group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that provides both medical/surgical benefits and mental health or substance use disorder benefits may not apply any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification. Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial requirement or treatment limitation. The application of the rules of this paragraph (c)(2) to financial requirements and quantitative treatment limitations is addressed in paragraph (c)(3) of this section; the application of the rules of this paragraph (c)(2) to nonquantitative treatment limitations is addressed in paragraph (c)(4) of this section.

(ii) Classifications of benefits used for applying rules – (A) In general. If a plan (or health insurance coverage) provides mental health or substance use disorder benefits in any classification of benefits described in this paragraph (c)(2)(ii), mental health or substance use disorder benefits must be provided in every classification in which medical/surgical benefits are provided. In determining the classification in which a particular benefit belongs, a plan (or health insurance issuer) must apply the same standards to medical/surgical benefits and to mental health

or substance use disorder benefits. To the extent that a plan (or health insurance coverage) provides benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment limitation) for benefits in the classification, the rules of this paragraph (c) apply separately with respect to that classification for all financial requirements or treatment limitations. The following classifications of benefits are the only classifications used in applying the rules of this paragraph (c):

(1) Inpatient, in-network. Benefits furnished on an inpatient basis and within a network of providers established or recognized under a plan or health insurance coverage.

(2) Inpatient, out-of-network. Benefits furnished on an inpatient basis and outside any network of providers established or recognized under a plan or health insurance coverage. This classification includes inpatient benefits under a plan (or health insurance coverage) that has no network of providers.

(3) Outpatient, in-network. Benefits furnished on an outpatient basis and within a network of providers established or recognized under a plan or health insurance coverage.

(4) Outpatient, out-of-network. Benefits furnished on an outpatient basis and outside any network of providers established or recognized under a plan or health insurance coverage. This classification includes outpatient benefits under a plan (or health insurance coverage) that has no network of providers.

(5) Emergency care. Benefits for emergency care.

(6) Prescription drugs. Benefits for prescription drugs. See special rules for multi-tiered prescription drug benefits in paragraph (c)(3)(iii) of this section.

(B) Application to out-of-network providers. See paragraph (c)(2)(ii)(A) of this section, under which a plan (or health insurance coverage) that provides mental health or substance use

disorder benefits in any classification of benefits must provide mental health or substance use disorder benefits in every classification in which medical/surgical benefits are provided, including out-of-network classifications.

(C) Examples. The rules of this paragraph (c)(2)(ii) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

Example 1. (i) Facts. A group health plan offers inpatient and outpatient benefits and does not contract with a network of providers. The plan imposes a $500 deductible on all benefits. For inpatient medical/surgical benefits, the plan imposes a coinsurance requirement. For outpatient medical/surgical benefits, the plan imposes copayments. The plan imposes no other financial requirements or treatment limitations.

(ii) Conclusion. In this Example 1, because the plan has no network of providers, all benefits provided are out-of-network. Because inpatient, out-of-network medical/surgical benefits are subject to separate financial requirements from outpatient, out-of-network medical/surgical benefits, the rules of this paragraph (c) apply separately with respect to any financial requirements and treatment limitations, including the deductible, in each classification.

Example 2. (i) Facts. A plan imposes a $500 deductible on all benefits. The plan has no network of providers. The plan generally imposes a 20 percent coinsurance requirement with respect to all benefits, without distinguishing among inpatient, outpatient, emergency, or prescription drug benefits. The plan imposes no other financial requirements or treatment limitations.

(ii) Conclusion. In this Example 2, because the plan does not impose separate financial requirements (or treatment limitations) based on classification, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance across all benefits.

Example 3. (i) Facts. Same facts as Example 2, except the plan exempts emergency care benefits from the 20 percent coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(ii) Conclusion. In this Example 3, because the plan imposes separate financial requirements based on classifications, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance separately for –

(A) Benefits in the emergency classification; and

(B) All other benefits.

Example 4. (i) Facts. Same facts as Example 2, except the plan also imposes a preauthorization requirement for all inpatient treatment in order for benefits to be paid. No such requirement applies to outpatient treatment.

(ii) Conclusion. In this Example 4, because the plan has no network of providers, all benefits provided are out-of-network. Because the plan imposes a separate treatment limitation based on classifications, the rules of this paragraph (c) apply with respect to the deductible and coinsurance separately for –

(A) Inpatient, out-of-network benefits; and

(B) All other benefits.

(3) Financial requirements and quantitative treatment limitations – (i) Determining "substantially all" and "predominant" – (A) Substantially all. For purposes of this paragraph (c), a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification of benefits if it applies to at least two-thirds of all medical/surgical benefits in that classification. (For this purpose, benefits expressed as subject to a zero level of a type of financial requirement are treated as benefits not subject to that type of financial requirement, and benefits expressed as subject to a quantitative treatment limitation that is unlimited are treated as benefits not subject to that type of quantitative treatment limitation.) If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that type cannot be applied to mental health or substance use disorder benefits in that classification.

(B) Predominant – (1) If a type of financial requirement or quantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits in a classification as determined under paragraph (c)(3)(i)(A) of this section, the level of the financial requirement or

quantitative treatment limitation that is considered the predominant level of that type in a classification of benefits is the level that applies to more than one-half of medical/surgical benefits in that classification subject to the financial requirement or quantitative treatment limitation.

(2) If, with respect to a type of financial requirement or quantitative treatment limitation that applies to at least two-thirds of all medical/surgical benefits in a classification, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to the financial requirement or quantitative treatment limitation, the plan (or health insurance issuer) may combine levels until the combination of levels applies to more than one-half of medical/surgical benefits subject to the financial requirement or quantitative treatment limitation in the classification. The least restrictive level within the combination is considered the predominant level of that type in the classification. (For this purpose, a plan may combine the most restrictive levels first, with each less restrictive level added to the combination until the combination applies to more than one-half of the benefits subject to the financial requirement or treatment limitation.)

(C) Portion based on plan payments. For purposes of this paragraph (c), the determination of the portion of medical/surgical benefits in a classification of benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation) is based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan for the plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the financial requirement or quantitative treatment limitation).

(D) Clarifications for certain threshold requirements. For any deductible, the dollar amount of plan payments includes all plan payments with respect to claims that would be subject to the deductible if it had not been satisfied. For any out-of-pocket maximum, the dollar amount of plan payments includes all plan payments associated with out-of-pocket payments that are taken into account towards the out-of-pocket maximum as well as all plan payments associated with out-of-pocket payments that would have been made towards the out-of-pocket maximum if it had not been satisfied. Similar rules apply for any other thresholds at which the rate of plan payment changes.

(E) Determining the dollar amount of plan payments. Subject to paragraph (c)(3)(i)(D) of this section, any reasonable method may be used to determine the dollar amount expected to be paid under a plan for medical/surgical benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation).

(ii) Application to different coverage units. If a plan (or health insurance coverage) applies different levels of a financial requirement or quantitative treatment limitation to different coverage units in a classification of medical/surgical benefits, the predominant level that applies to substantially all medical/surgical benefits in the classification is determined separately for each coverage unit.

(iii) Special rule for multi-tiered prescription drug benefits. If a plan (or health insurance coverage) applies different levels of financial requirements to different tiers of prescription drug benefits based on reasonable factors determined in accordance with the rules in paragraph (c)(4)(i) of this section (relating to requirements for nonquantitative treatment limitations) and without regard to whether a drug is generally prescribed with respect to medical/surgical benefits

or with respect to mental health or substance use disorder benefits, the plan (or health insurance coverage) satisfies the parity requirements of this paragraph (c) with respect to prescription drug benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up.

(iv) Examples. The rules of paragraphs (c)(3)(i), (c)(3)(ii), and (c)(3)(iii) of this section are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

Example 1. (i) Facts. For inpatient, out-of-network medical/surgical benefits, a group health plan imposes five levels of coinsurance. Using a reasonable method, the plan projects its payments for the upcoming year as follows:

Coinsurance rate	0 %	10%	15%	20%	30%	Total
Projected payments	$200x	$100x	$450x	$100x	$150x	$1,000x
Percent of total plan costs	20%	10%	45%	10%	15%	
Percent subject to coinsurance level	N/A	12.5% (100x/800x)	56.25% (450x/800x)	12.5% (100x/800x)	18.75% (150x/800x)	

The plan projects plan costs of $800x to be subject to coinsurance ($100x + $450x + $100x + $150x = $800x). Thus, 80 percent ($800x/$1,000x) of the benefits are projected to be subject to coinsurance, and 56.25 percent of the benefits subject to coinsurance are projected to be subject to the 15 percent coinsurance level.

(ii) Conclusion. In this Example 1, the two-thirds threshold of the substantially all standard is met for coinsurance because 80 percent of all inpatient, out-of-network medical/surgical benefits are subject to coinsurance. Moreover, the 15 percent coinsurance is the predominant level because it is applicable to more than one-half of inpatient, out-of-network medical/surgical benefits subject to the coinsurance requirement. The plan may not impose any level of coinsurance with respect to inpatient, out-of-network mental health or substance use disorder benefits that is more restrictive than the 15 percent level of coinsurance.

Example 2. (i) Facts. For outpatient, in-network medical/surgical benefits, a plan imposes five different copayment levels. Using a reasonable method, the plan projects payments for the upcoming year as follows:

Copayment amount	$0	$10	$15	$20	$50	Total

Projected payments	$200x	$200x	$200x	$300x	$100x	$1,000x
Percent of total plan costs	20%	20%	20%	30%	10%	
Percent subject to copayments	N/A	25% (200x/800x)	25% (200x/800x)	37.5% (300x/800x)	12.5% (100x/800x)	

The plan projects plan costs of $800x to be subject to copayments ($200x + $200x +$300x + $100x = $800x). Thus, 80 percent ($800x/$1,000x) of the benefits are projected to be subject to a copayment.

(ii) Conclusion. In this Example 2, the two-thirds threshold of the substantially all standard is met for copayments because 80 percent of all outpatient, in-network medical/surgical benefits are subject to a copayment. Moreover, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to a copayment (for the $10 copayment, 25%; for the $15 copayment, 25%; for the $20 copayment, 37.5%; and for the $50 copayment, 12.5%). The plan can combine any levels of copayment, including the highest levels, to determine the predominant level that can be applied to mental health or substance use disorder benefits. If the plan combines the highest levels of copayment, the combined projected payments for the two highest copayment levels, the $50 copayment and the $20 copayment, are not more than one-half of the outpatient, in-network medical/surgical benefits subject to a copayment because they are exactly one-half ($300x + $100x = $400x; $400x/$800x = 50%). The combined projected payments for the three highest copayment levels – the $50 copayment, the $20 copayment, and the $15 copayment – are more than one-half of the outpatient, in-network medical/surgical benefits subject to the copayments ($100x + $300x + $200x = $600x; $600x/$800x = 75%). Thus, the plan may not impose any copayment on outpatient, in-network mental health or substance use disorder benefits that is more restrictive than the least restrictive copayment in the combination, the $15 copayment.

Example 3. (i) Facts. A plan imposes a $250 deductible on all medical/surgical benefits for self-only coverage and a $500 deductible on all medical/surgical benefits for family coverage. The plan has no network of providers. For all medical/surgical benefits, the plan imposes a coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(ii) Conclusion. In this Example 3, because the plan has no network of providers, all benefits are provided out-of-network. Because self-only and family coverage are subject to different deductibles, whether the deductible applies to substantially all medical/surgical benefits is determined separately for self-only medical/surgical benefits and family medical/surgical benefits. Because the coinsurance is applied without regard to coverage units, the predominant coinsurance that applies to substantially all medical/surgical benefits is determined without regard to coverage units.

Example 4. (i) Facts. A plan applies the following financial requirements for prescription drug benefits. The requirements are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or

substance use disorder benefits. Moreover, the process for certifying a particular drug as "generic", "preferred brand name", "non-preferred brand name", or "specialty" complies with the rules of paragraph (c)(4)(i) of this section (relating to requirements for nonquantitative treatment limitations).

	Tier 1	Tier 2	Tier 3	Tier 4
Tier description	Generic drugs	Preferred brand name drugs	Non-preferred brand name drugs (which may have Tier 1 or Tier 2 alternatives)	Specialty drugs
Percent paid by plan	90%	80%	60%	50%

(ii) Conclusion. In this Example 4, the financial requirements that apply to prescription drug benefits are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits; the process for certifying drugs in different tiers complies with paragraph (c)(4) of this section; and the bases for establishing different levels or types of financial requirements are reasonable. The financial requirements applied to prescription drug benefits do not violate the parity requirements of this paragraph (c)(3).

(v) No separate cumulative financial requirements or cumulative quantitative treatment limitations – (A) A group health plan (or health insurance coverage offered in connection with a group health plan) may not apply any cumulative financial requirement or cumulative quantitative treatment limitation for mental health or substance use disorder benefits in a classification that accumulates separately from any established for medical/surgical benefits in the same classification.

(B) The rules of this paragraph (c)(3)(v) are illustrated by the following examples:

Example 1. (i) Facts. A group health plan imposes a combined annual $500 deductible on all medical/surgical, mental health, and substance use disorder benefits.

(ii) Conclusion. In this Example 1, the combined annual deductible complies with the requirements of this paragraph (c)(3)(v).

Example 2. (i) Facts. A plan imposes an annual $250 deductible on all medical/surgical benefits and a separate annual $250 deductible on all mental health and substance use disorder benefits.

(ii) Conclusion. In this Example 2, the separate annual deductible on mental health and substance use disorder benefits violates the requirements of this paragraph (c)(3)(v).

Example 3. (i) Facts. A plan imposes an annual $300 deductible on all medical/surgical benefits and a separate annual $100 deductible on all mental health or substance use disorder benefits.

(ii) Conclusion. In this Example 3, the separate annual deductible on mental health and substance use disorder benefits violates the requirements of this paragraph (c)(3)(v).

Example 4. (i) Facts. A plan generally imposes a combined annual $500 deductible on all benefits (both medical/surgical benefits and mental health and substance use disorder benefits) except prescription drugs. Certain benefits, such as preventive care, are provided without regard to the deductible. The imposition of other types of financial requirements or treatment limitations varies with each classification. Using reasonable methods, the plan projects its payments for medical/surgical benefits in each classification for the upcoming year as follows:

Classification	Benefits Subject to Deductible	Total Benefits	Percent Subject to Deductible
Inpatient, in-network	$1,800x	$2,000x	90%
Inpatient, out-of-network	$1,000x	$1,000x	100%
Outpatient, in-network	$1,400x	$2,000x	70%
Outpatient, out-of-network	$1,880x	$2,000x	94%
Emergency care	$300x	$500x	60%

(ii) Conclusion. In this Example 4, the two-thirds threshold of the substantially all standard is met with respect to each classification except emergency care because in each of those other classifications at least two-thirds of medical/surgical benefits are subject to the $500 deductible. Moreover, the $500 deductible is the predominant level in each of those other classifications because it is the only level. However, emergency care mental health and substance use disorder benefits cannot be subject to the $500 deductible because it does not apply to substantially all emergency care medical/surgical benefits.

(4) Nonquantitative treatment limitations – (i) General rule. A group health plan (or health insurance coverage) may not impose a nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan (or health insurance coverage) as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and

are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation with respect to medical surgical/benefits in the classification, except to the extent that recognized clinically appropriate standards of care may permit a difference.

(ii) Illustrative list of nonquantitative treatment limitations. Nonquantitative treatment limitations include –

(A) Medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;

(B) Formulary design for prescription drugs;

(C) Standards for provider admission to participate in a network, including reimbursement rates;

(D) Plan methods for determining usual, customary, and reasonable charges;

(E) Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols); and

(F) Exclusions based on failure to complete a course of treatment.

(iii) Examples. The rules of this paragraph (c)(4) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

Example 1. (i) Facts. A group health plan limits benefits to treatment that is medically necessary. The plan requires concurrent review for inpatient, in-network mental health and substance use disorder benefits but does not require it for any inpatient, in-network medical/surgical benefits. The plan conducts retrospective review for inpatient, in-network medical/surgical benefits.

(ii) Conclusion. In this Example 1, the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation – medical necessity – applies to both mental health and substance use disorder benefits and to medical/surgical benefits for inpatient, in-network services, the concurrent review process does not apply to medical/surgical benefits. The concurrent review process is not comparable to the retrospective review process. While such a difference might be permissible in certain individual cases based on recognized clinically appropriate standards of care, it is not permissible for distinguishing between all medical/surgical benefits and all mental health or substance use disorder benefits.

Example 2. (i) Facts. A plan requires prior approval that a course of treatment is medically necessary for outpatient, in-network medical/surgical, mental health, and substance use disorder benefits. For mental health and substance use disorder treatments that do not have prior approval, no benefits will be paid; for medical/surgical treatments that do not have prior approval, there will only be a 25 percent reduction in the benefits the plan would otherwise pay.

(ii) Conclusion. In this Example 2, the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation – medical necessity – is applied both to mental health and substance use disorder benefits and to medical/surgical benefits for outpatient, in-network services, the penalty for failure to obtain prior approval for mental health and substance use disorder benefits is not comparable to the penalty for failure to obtain prior approval for medical/surgical benefits.

Example 3. (i) Facts. A plan generally covers medically appropriate treatments. For both medical/surgical benefits and mental health and substance use disorder benefits, evidentiary standards used in determining whether a treatment is medically appropriate (such as the number of visits or days of coverage) are based on recommendations made by panels of experts with appropriate training and experience in the fields of medicine involved. The evidentiary standards are applied in a manner that may differ based on clinically appropriate standards of care for a condition.

(ii) Conclusion. In this Example 3, the plan complies with the rules of this paragraph (c)(4) because the nonquantitative treatment limitation – medical appropriateness – is the same for both medical/surgical benefits and mental health and substance use disorder benefits, and the processes for developing the evidentiary standards and the application of them to mental health and substance use disorder benefits are comparable to and are applied no more stringently than for medical/surgical benefits. This is the result even if, based on clinically appropriate standards of care, the application of the evidentiary standards does not result in similar numbers of visits, days of coverage, or other benefits utilized for mental health conditions or substance use disorders as it does for any particular medical/surgical condition.

Example 4. (i) Facts. A plan generally covers medically appropriate treatments. In determining whether prescription drugs are medically appropriate, the plan automatically excludes coverage for antidepressant drugs that are given a black box warning label by the Food and Drug Administration (indicating the drug carries a significant risk of serious adverse effects).

For other drugs with a black box warning (including those prescribed for other mental health conditions and substance use disorders, as well as for medical/surgical conditions), the plan will provide coverage if the prescribing physician obtains authorization from the plan that the drug is medically appropriate for the individual, based on clinically appropriate standards of care.

(ii) Conclusion. In this Example 4, the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation – medical appropriateness – is applied to both mental health and substance use disorder benefits and medical/surgical benefits, the plan's unconditional exclusion of antidepressant drugs given a black box warning is not comparable to the conditional exclusion for other drugs with a black box warning.

Example 5. (i) Facts. An employer maintains both a major medical program and an employee assistance program (EAP). The EAP provides, among other benefits, a limited number of mental health or substance use disorder counseling sessions. Participants are eligible for mental health or substance use disorder benefits under the major medical program only after exhausting the counseling sessions provided by the EAP. No similar exhaustion requirement applies with respect to medical/surgical benefits provided under the major medical program.

(ii) Conclusion. In this Example 5, limiting eligibility for mental health and substance use disorder benefits only after EAP benefits are exhausted is a nonquantitative treatment limitation subject to the parity requirements of this paragraph (c). Because no comparable requirement applies to medical/surgical benefits, the requirement may not be applied to mental health or substance use disorder benefits.

(5) Exemptions. The rules of this paragraph (c) do not apply if a group health plan (or health insurance coverage) satisfies the requirements of paragraph (f) or (g) of this section (relating to exemptions for small employers and for increased cost).

(d) Availability of plan information – (1) Criteria for medical necessity determinations. The criteria for medical necessity determinations made under a group health plan with respect to mental health or substance use disorder benefits (or health insurance coverage offered in connection with the plan with respect to such benefits) must be made available by the plan administrator (or the health insurance issuer offering such coverage) to any current or potential participant, beneficiary, or contracting provider upon request.

(2) Reason for denial. The reason for any denial under a non-Federal governmental plan (or health insurance coverage offered in connection with such plan) of reimbursement or

payment for services with respect to mental health or substance use disorder benefits in the case of any participant or beneficiary must be made available within a reasonable time and in a reasonable manner by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary upon request. For this purpose, a non-Federal governmental plan (or health insurance coverage offered in connection with such plan) that provides the reason for the claim denial in a form and manner consistent with the requirements of 29 CFR 2560.503-1 for group health plans complies with the requirements of this paragraph (d)(2).

(e) Applicability – (1) Group health plans. The requirements of this section apply to a group health plan offering medical/surgical benefits and mental health or substance use disorder benefits. If, under an arrangement or arrangements to provide medical care benefits by an employer or employee organization (including for this purpose a joint board of trustees of a multiemployer trust affiliated with one or more multiemployer plans), any participant (or beneficiary) can simultaneously receive coverage for medical/surgical benefits and coverage for mental health or substance use disorder benefits, then the requirements of this section (including the exemption provisions in paragraph (g) of this section) apply separately with respect to each combination of medical/surgical benefits and of mental health or substance use disorder benefits that any participant (or beneficiary) can simultaneously receive from that employer's or employee organization's arrangement or arrangements to provide medical care benefits, and all such combinations are considered for purposes of this section to be a single group health plan.

(2) Health insurance issuers. The requirements of this section apply to a health insurance issuer offering health insurance coverage for mental health or substance use disorder benefits in connection with a group health plan subject to paragraph (e)(1) of this section.

(3) Scope. This section does not –

(i) Require a group health plan (or health insurance issuer offering coverage in connection with a group health plan) to provide any mental health benefits or substance use disorder benefits, and the provision of benefits by a plan (or health insurance coverage) for one or more mental health conditions or substance use disorders does not require the plan (or health insurance coverage) under this section to provide benefits for any other mental health condition or substance use disorder; or

(ii) Affect the terms and conditions relating to the amount, duration, or scope of mental health or substance use disorder benefits under the plan (or health insurance coverage) except as specifically provided in paragraphs (b) and (c) of this section.

(f) Small employer exemption—(1) In general. The requirements of this section do not apply to a group health plan (or health insurance issuer offering coverage in connection with a group health plan) for a plan year of a small employer. For purposes of this paragraph (f), the term small employer means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least two but not more than 50 employees on business days during the preceding calendar year and who employs at least two employees on the first day of the plan year (except that for purposes of this paragraph, a small employer shall include an employer with one employee in the case of an employer residing in a State that permits small groups to include a single individual). See also section 2721(a) of the PHS Act and § 146.145(b) of this Part, which provide that this section (and certain other sections) does not apply to any group health plan (and health insurance issuer offering coverage in connection with a group health plan) for any plan year if, on the first day of the plan year, the plan has fewer than two participants who are current employees.

(2) Rules in determining employer size. For purposes of paragraph (f)(1) of this section—

(i) All persons treated as a single employer under subsections (b), (c), (m), and (o) of section 414 of the Internal Revenue Code of 1986 (26 U.S.C. 414) are treated as one employer;

(ii) If an employer was not in existence throughout the preceding calendar year, whether it is a small employer is determined based on the average number of employees the employer reasonably expects to employ on business days during the current calendar year; and

(iii) Any reference to an employer for purposes of the small employer exemption includes a reference to a predecessor of the employer.

(g) Increased cost exemption—[Reserved]

(h) Sale of nonparity health insurance coverage. A health insurance issuer may not sell a policy, certificate, or contract of insurance that fails to comply with paragraph (b) or (c) of this section, except to a plan for a year for which the plan is exempt from the requirements of this section because the plan meets the requirements of paragraph (f) or (g) of this section.

(i) Applicability dates—(1) In general. Except as provided in paragraph (i)(2) of this section, the requirements of this section are applicable for plan years beginning on or after July 1, 2010.

(2) Special effective date for certain collectively-bargained plans. For a group health plan maintained pursuant to one or more collective bargaining agreements ratified before October 3, 2008, the requirements of this section do not apply to the plan (or health insurance coverage offered in connection with the plan) for plan years beginning before the later of either –

(i) The date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension agreed to after October 3, 2008); or

(ii) July 1, 2010.

Approved: November 12, 2009

Charlene Frizzera,

Acting Administrator,

Centers for Medicare & Medicaid Services.

Approved: December 2, 2009

Kathleen Sebelius,

Secretary.

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