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Final Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008; Technical Amendment to External Review for Multi-State Plan Program

AGENCY: 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: Final rules.

SUMMARY: This document contains 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 group and individual health insurance coverage. This document also contains a technical amendment relating to external review with respect to the multi-state plan program administered by the Office of Personnel Management.

DATES: *Effective date.* These final regulations are effective on January 13, 2014, except that the technical amendments to 29 CFR 2590.715–2719 and 45 CFR 147.136 are effective on December 13, 2013.

Applicability date. The mental health parity provisions of these final regulations apply to group health plans and health insurance issuers for plan years (or, in the individual market, policy years) beginning on or after July 1, 2014. Until the final rules become applicable, plans and issuers must continue to comply with the mental health parity provisions of the interim final regulations.

FOR FURTHER INFORMATION CONTACT: Amy Turner or Amber Rivers, Employee Benefits Security Administration, Department of Labor, at (202) 693–8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 622–6080 or (202) 317–5500; Jacob Ackerman, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at (410) 786–1565.

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 Web site (*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) Web site (*www.cms.gov/cciio*) and information on health reform can be found at *www.HealthCare.gov*. In addition, information about mental health is available at *www.mentalhealth.gov*.

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 Pub. L. 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/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, and applied to employment-related group health plans and health insurance coverage offered in connection with a group health plan. The changes made by MHPAEA were codified in these same sections and consist of new requirements, including parity for substance use disorder benefits, 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.

The Patient Protection and Affordable Care Act, Public Law 111–148, was enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010, Public Law 111–152, was enacted on March 30, 2010 (collectively, the "Affordable Care Act"). The Affordable Care Act reorganizes, amends, and adds to the provisions of part A of title XXVII of the PHS Act relating to group health plans and health insurance issuers in the group and individual markets. The Affordable Care Act adds section 715(a)(1) to ERISA and section 9815(a)(1) to the Code to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The PHS Act sections incorporated by these references are sections 2701 through 2728.

The Affordable Care Act extended MHPAEA to apply to the individual health insurance market and redesignated MHPAEA in the PHS Act as section 2726.[2] Additionally, section 1311(j) of the Affordable Care Act applies section 2726 of the PHS Act to qualified health plans (QHPs) in the same manner and to the same extent as such section applies to health insurance issuers and group health plans. Furthermore, the Department of Health and Human Services (HHS) final regulation regarding essential health benefits (EHB) requires health insurance issuers offering non-grandfathered health insurance coverage in the individual and small group markets, through an Affordable Insurance Exchange (Exchange, also called a Health Insurance Marketplace or Marketplace) or outside of an Exchange, to comply with the requirements of the

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

[2] These final regulations apply to both grandfathered and non-grandfathered health plans. *See* section 1251 of the Affordable Care Act and its implementing regulations at 26 CFR 54.9815–1251T, 29 CFR 2590.715–1251, and 45 CFR 147.140. Under section 1251 of the Affordable Care Act, grandfathered health plans are exempted only from certain Affordable Care Act requirements enacted in Subtitles A and C of Title I of the Affordable Care Act. The provisions extending MHPAEA requirements to the individual market and requiring that qualified health plans comply with MHPAEA were not part of these sections.

MHPAEA regulations in order to satisfy the requirement to cover EHB.[3]

On April 28, 2009, the Departments of the Treasury, Labor, and HHS published in the **Federal Register** (74 FR 19155) a request for information (RFI) soliciting comments on the requirements of MHPAEA. (Subsequent references to the "Departments" include all three Departments, unless the headings or context indicate otherwise.) On February 2, 2010, after consideration of the comments received in response to the RFI, the Departments published in the **Federal Register** (75 FR 5410) comprehensive interim final regulations implementing MHPAEA (interim final regulations). The interim final regulations generally became applicable to group health plans and group health insurance issuers for plan years beginning on or after July 1, 2010.

The interim final regulations established six classifications of benefits[4] and provided that the parity requirements be applied on a classification-by-classification basis. The general parity requirement set forth in paragraph (c)(2) of the interim final regulations prohibited plans and issuers from imposing a financial requirement or quantitative treatment limitation on mental health and substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification. For this purpose, the interim final regulations incorporated the two-thirds "substantially all" numerical standard from the regulations implementing MHPA 1996, and quantified "predominant" to mean that more than one-half of medical/surgical benefits in the classification are subject to the financial requirement or quantitative treatment limitation in the relevant classification. Using these numerical standards, the Departments established a mathematical test by which plans and issuers could determine what level of a financial requirement or quantitative treatment limitation, if any, is the most restrictive level that could be imposed on mental health or substance use disorder benefits within a classification. (This mathematical test is referred to in this preamble as the quantitative parity analysis.)

The interim final regulations also prohibited plans and issuers from applying cumulative financial requirements (such as deductibles or out-of-pocket maximums) or cumulative quantitative treatment limitations (such as annual or lifetime day or visit limits) 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.

Additionally, the interim final regulations set forth parity protections with respect to nonquantitative treatment limitations (NQTLs), which are limits on the scope or duration of treatment that are not expressed numerically (such as medical management techniques like prior authorization). The interim final regulations stated that a plan or issuer may not impose an NQTL 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 NQTL 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 same classification, except to the extent that recognized clinically appropriate standards of care may permit a difference. The Departments also set forth a special rule for evaluating parity of multi-tiered prescription drug benefits. The interim final regulations included several examples to illustrate each of these parity standards.

The interim final regulations also implemented MHPAEA's disclosure provisions requiring that the criteria for medical necessity determinations and the reason for any denial of reimbursement or payment under a group health plan (or health insurance coverage) with respect to mental health or substance use disorder benefits be made available upon request in certain circumstances.

The interim final regulations also specifically requested comments in several areas, including whether additional examples would be helpful to illustrate the application of the NQTL rule to other features of medical management or general plan design; 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; what additional clarifications might be helpful to facilitate compliance with the disclosure requirement for medical necessity criteria or denials of mental health or substance use disorder benefits; and 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.

In light of the comments and other feedback received in response to the interim final regulations, the Departments issued clarifications in several rounds of Frequently Asked Questions (FAQs). In the first FAQ about MHPAEA, the Departments set forth an enforcement safe harbor under which the Departments would not take enforcement action against plans and issuers that divide benefits furnished on an outpatient basis into two sub-classifications—(1) office visits, and (2) all other outpatient items and services—for purposes of applying the financial requirement and treatment limitation rules under MHPAEA.[5]

The Departments issued additional FAQs providing further clarifications.[6] The FAQs issued in December 2010 addressed the changes made to the definition of "small employer" after the enactment of the Affordable Care Act, made clear how the disclosure requirements under MHPAEA interact with other ERISA disclosure requirements (and that health care providers are entitled to request such information on behalf of participants), and provided temporary information on how to claim the increased cost exemption.[7] Additional FAQs issued in November 2011 addressed specific NQTLs, such as prior authorization and concurrent review.[8] The Departments

[3] *See* 45 CFR 147.150 and 156.115 (78 FR 12834, February 25, 2013).

[4] The six classifications of benefits are inpatient, in-network; inpatient, out-of-network; outpatient, in-network; outpatient, out-of-network; emergency care; and prescription drugs.

[5] *See* FAQ About Mental Health Parity and Addiction Equity Act, available at *http://www.dol.gov/ebsa/faqs/faq-mhpaea.html.*

[6] *See* FAQs about Affordable Care Act Implementation (Part V) and Mental Health Parity Implementation, available at *http://www.dol.gov/ebsa/faqs/faq-aca5.html* and *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html,* and FAQs about Affordable Care Act Implementation (Part VII) and Mental Health Parity Implementation, available at *http://www.dol.gov/ebsa/faqs/faq-aca7.html* and *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs7.html#Mental* Health Parity and Addiction Equity Act of 2008.

[7] *See* FAQs about Affordable Care Act Implementation (Part V) and Mental Health Parity Implementation, questions 8–11, available at *http://www.dol.gov/ebsa/faqs/faq-aca5.html* and *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html.*

[8] *See* FAQs about Affordable Care Act Implementation (Part VII) and Mental Health Parity Implementation, questions 2–6, available at *http://*

Continued

also clarified that plans and issuers may charge the specialist copayment for mental health and substance use disorder benefits only if it is determined that this level of copayment is the predominant level that applies to substantially all medical/surgical benefits within a classification.[9]

After consideration of the comments and other feedback received from stakeholders, the Departments are publishing these final regulations.

II. Overview of the Regulations

In general, these final regulations incorporate clarifications issued by the Departments through FAQs since the issuance of the interim final regulations, and provide new clarifications on issues such as NQTLs and the increased cost exemption. The HHS final regulation also implements the provisions of MHPAEA for the individual health insurance market.

A. Meaning of Terms

Under MHPAEA and the interim final regulations, the term "medical/surgical benefits" means benefits for medical or surgical services, as defined under the terms of the plan or health insurance coverage. This term does not include mental health or substance use disorder benefits. The terms "mental health benefits" and "substance use disorder benefits" mean benefits with respect to services for mental health conditions or substance use disorders, respectively, as defined under the terms of the plan and in accordance with applicable Federal and State law. The interim final regulations further provided that the plan terms defining whether the benefits are medical/surgical benefits or mental health or substance use disorder benefits must be consistent with generally recognized 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 International Classification of Diseases (ICD), or State guidelines).

These final regulations make minor, technical changes to the meaning of these terms for consistency and clarity. Specifically, the final regulations clarify that the definitions of "medical/surgical benefits," "mental health benefits," and "substance use disorder benefits" include benefits for items as well as services. The final regulations also clarify that medical conditions and surgical procedures, and mental health conditions and substance use disorders, are defined under the terms of the plan or coverage and in accordance with applicable Federal and State law.

One commenter suggested that the definitions of mental health benefits and substance use disorder benefits should be revised to refer only to the terms of the plan and applicable State law. The Departments decline to adopt this suggestion. The statutory definitions provided in MHPAEA specifically refer to applicable Federal law. Moreover, the reference to Federal law is appropriate because State law does not apply to all group health plans, and Federal law also identifies EHB categories, including the category of mental health and substance use disorder services, that non-grandfathered health plans in the individual and small group markets are required to cover beginning in 2014.

B. Clarifications—Parity Requirements

1. Classification of Benefits

As described earlier in this preamble, the interim final regulations set forth that the parity analysis be conducted on a classification-by-classification basis in six specific classifications of benefits. Subsequent to the issuance of the interim final regulations, several plans and issuers brought to the Departments' attention that, with respect to outpatient benefits, many plans and issuers require a copayment for office visits (such as physician or psychologist visits) and coinsurance for all other outpatient services (such as outpatient surgery). In response to this information, the Departments published an FAQ establishing an enforcement safe harbor under which the Departments would not take enforcement action against plans and issuers that divide benefits furnished on an outpatient basis into two sub-classifications ((1) office visits and (2) all other outpatient items and services) for purposes of applying the financial requirement and treatment limitation rules under MHPAEA.[10]

The Departments have incorporated the terms of the FAQ in paragraph (c)(3)(iii)(C) of these final regulations, permitting sub-classifications for office visits, separate from other outpatient services. Other sub-classifications not specifically permitted in these final regulations, such as separate sub-classifications for generalists and specialists, must not be used for purposes of determining parity. After the sub-classifications are established, a plan or issuer may not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in any sub-classification (*i.e.*, office visits or non-office visits) that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (c)(3)(i) of these final regulations. Example 6 under paragraph (c)(3)(iv) of these final regulations illustrates the approach that plans and issuers may employ when dividing outpatient benefits into sub-classifications in accordance with these final regulations.

Additionally, commenters requested that the final regulations permit plans and issuers to create sub-classifications to address plan designs that have two or more network tiers of providers. Commenters asserted that utilizing tiered networks helps plans manage the costs and quality of care and requested that the final regulations allow plans to conduct the parity analysis separately with respect to these various network tiers.

The Departments have considered these comments and recognize that tiered networks have become an important tool for health plan efforts to manage care and control costs. Therefore, for purposes of applying the financial requirement and treatment limitation rules under MHPAEA, these final regulations provide that if a plan (or health insurance coverage) provides in-network benefits through multiple tiers of in-network providers (such as an in-network tier of preferred providers with more generous cost sharing to participants than a separate in-network tier of participating providers), the plan may divide its benefits furnished on an in-network basis into sub-classifications that reflect those network tiers, if the tiering is based on reasonable factors and without regard to whether a provider is a mental health or substance use disorder provider or a medical/surgical provider.[11] After the sub-

www.dol.gov/ebsa/faqs/faq-aca7.html and *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs7.html#Mental* Health Parity and Addiction Equity Act of 2008.

[9] *See* FAQs about Affordable Care Act Implementation (Part VII) and Mental Health Parity Implementation, question 7, available at *http://www.dol.gov/ebsa/faqs/faq-aca7.html* and *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs7.html#Mental* Health Parity and Addiction Equity Act of 2008.

[10] *See* FAQ About Mental Health Parity and Addiction Equity Act, available at *http://www.dol.gov/ebsa/faqs/faq-mhpaea.html.*

[11] Under PHS Act section 2719A (incorporated into ERISA and the Code) and its implementing regulations, non-grandfathered group health plans and non-grandfathered group or individual health insurance coverage are prohibited from imposing any cost-sharing requirement expressed as a copayment amount or coinsurance rate with respect to a participant or beneficiary for out-of-network emergency services that exceeds the cost-sharing requirement imposed with respect to a participant or beneficiary if the services were provided in-

classifications are established, the plan or issuer may not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (c)(3)(i) of these final regulations.

The Departments are aware that some plans may have an uneven number of tiers between medical/surgical providers and mental health or substance use disorder providers (*e.g.*, 3 tiers for medical/surgical providers and 2 tiers for mental health or substance use disorder providers). The Departments may provide additional guidance if questions persist with respect to plans with an uneven number of tiers or if the Departments become aware of tier structures that may be inconsistent with the parity analysis required under these final regulations. Until the issuance of further guidance, the Departments will consider a plan or issuer to comply with the financial requirement and quantitative treatment limitation rules under MHPAEA if a plan or issuer treats the least restrictive level of the financial requirement or quantitative treatment limitation that applies to at least two-thirds of medical/surgical benefits across all provider tiers in a classification as the predominant level that it may apply to mental health or substance use disorder benefits in the same classification.

Some commenters requested clarification that all medical/surgical benefits and mental health or substance use disorder benefits offered by a plan or coverage must be contained within the six classifications of benefits and that plans and issuers could not classify certain benefits outside of the six classifications in order to avoid the parity requirements. Other commenters suggested that specific mental health or substance use disorder benefits be cross-walked or paired with specific medical/surgical benefits (*e.g.*, physical rehabilitation with substance use disorder rehabilitation) for purposes of the parity analysis.

The final regulations retain the six classifications enumerated in the interim final regulations, specify the permissible sub-classifications, and provide that the parity analysis be performed within each classification and sub-classification. The classifications and sub-classifications are intended to be comprehensive and cover the complete range of medical/surgical benefits and mental health or substance use disorder benefits offered by health plans and issuers. Medical/surgical benefits and mental health or substance use disorder benefits cannot be categorized as being offered outside of these classifications and therefore not subject to the parity analysis.

Cross-walking or pairing specific mental health or substance use disorder benefits with specific medical/surgical benefits is a static approach that the Departments do not believe is feasible, given the difficulty in determining "equivalency" between specific medical/surgical benefits and specific mental health and substance use disorder benefits and because of the differences in the types of benefits that may be offered by any particular plan.

2. Measuring Plan Benefits

Some commenters supported the "substantially all" and "predominant" tests as formulated in the interim final regulations, while other commenters were concerned that they were too restrictive and may create an administrative burden on plans. A few commenters requested clarification that the parity analysis would not need to be performed annually absent changes in plan design or indications that assumptions or data were inaccurate.

The interim final regulations incorporated the two-thirds "substantially all" numerical standard from the regulations implementing MHPA 1996, and quantified "predominant" to mean more than one-half of medical/surgical benefits in the classification are subject to the financial requirement or quantitative treatment limitation. The Departments believe group health plans and issuers have developed the familiarity and expertise to implement these parity requirements and therefore retain the numerical standards as set forth in the interim final regulations. The Departments clarify that a plan or issuer is not required to perform the parity analysis each plan year unless there is a change in plan benefit design, cost-sharing structure, or utilization that would affect a financial requirement or treatment limitation within a classification (or sub-classification).

These final regulations, like the interim final regulations, provide that 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. 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. One commenter asked whether plan benefits are measured based on allowed plan costs, for purposes of the "substantially all" and "predominant" tests. The dollar amount of plan payments is based on the amount the plan allows (before enrollee cost sharing) rather than the amount the plan pays (after enrollee cost sharing) because payment based on the allowed amount covers the full scope of the benefits being provided.

3. Cumulative Financial Requirements and Cumulative Quantitative Treatment Limitations

The interim final regulations provide that a plan or issuer may not apply cumulative financial requirements (such as deductibles and out-of-pocket maximums) or cumulative quantitative treatment limitations (such as annual or lifetime day or visit limits) for mental health or substance use disorder benefits in a classification that accumulate separately from any cumulative requirement or limitation established for medical/surgical benefits in the same classification. These final regulations retain this standard and continue to provide that cumulative requirements and limitations must also satisfy the quantitative parity analysis. Accordingly, these final regulations continue to prohibit plans and issuers from applying separate cumulative financial requirements and cumulative quantitative treatment limitations to medical/surgical and mental health and substance use disorder benefits in a classification, and continue to provide that such cumulative requirements or limitations are only permitted to be applied for mental health and substance use disorder benefits in a classification to the extent that such unified cumulative requirements or limitations also apply to substantially all medical/surgical benefits in the classification.

Several commenters argued that the requirement in the interim final regulations to use a single, combined deductible in a classification was burdensome and would require significant resources to implement, especially for Managed Behavioral Health Organizations (MBHOs) that often work with multiple plans. One commenter asserted that this

network. 26 CFR 54.9815–2719AT(b); 29 CFR 2590.715–2719A(b); 45 CFR 147.138(b).

requirement could impact the willingness of plan sponsors to offer mental health or substance use disorder benefits. A study sponsored by HHS, however, found that nearly all plans had eliminated the use of separate deductibles for mental health and substance use disorder benefits by 2011.[12] According to this study, even in 2010, only a very small percentage of plans were using separate deductibles. This study and other research [13] have shown that the overwhelming majority of plans have retained mental health and substance use disorder coverage after issuance of the interim final regulations and, for the very small percent of plans that have dropped mental health or substance use disorder coverage, there is no clear evidence they did so because of MHPAEA. Accordingly, these final regulations retain the requirement that plans and issuers use a single, combined deductible in a classification.

4. Interaction With PHS Act Section 2711 (No Lifetime or Annual Limits)

MHPA 1996 and paragraph (b) of the interim final regulations set forth the parity requirements with respect to aggregate lifetime and annual dollar limits on mental health benefits or substance use disorder benefits where a group health plan or health insurance coverage provides both medical/surgical benefits and mental health benefits or substance use disorder benefits.

PHS Act section 2711, as added by the Affordable Care Act, prohibits lifetime and annual limits on the dollar amount of EHB, as defined in section 1302(b) of the Affordable Care Act. The definition of EHB includes "mental health and substance use disorder services, including behavioral health treatment." [14] Thus, notwithstanding the provisions of MHPAEA that permit aggregate lifetime and annual dollar limits with respect to mental health or substance use disorder benefits as long as those limits are in accordance with the parity requirements for such limits, such dollar limits are prohibited with respect to mental health or substance use disorder benefits that are covered as EHB. While these final regulations generally retain the provisions of the interim final regulations regarding the application of the parity requirements to aggregate lifetime and annual dollar limits on mental health or substance use disorder benefits, language has been added specifying that these final regulations do not address the requirements of PHS Act section 2711. That is, the parity requirements regarding annual and lifetime limits described in these final regulations only apply to the provision of mental health and substance use disorder benefits that are not EHB. Because this greatly reduces the instances in which annual or lifetime limits will be permissible, the examples from the interim final regulations that expressly demonstrated how a plan could apply lifetime or annual dollar limits have been deleted.[15]

5. Interaction With PHS Act Section 2713 (Coverage of Preventive Health Services)

The interim final regulations provide that if a plan or issuer provides mental health or substance use disorder benefits in any classification, mental health or substance use disorder benefits must be provided in every classification in which medical/surgical benefits are provided. Under PHS Act section 2713, as added by the Affordable Care Act, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group and individual coverage are required to provide coverage for certain preventive services without cost sharing.[16] These preventive services presently include, among other things, alcohol misuse screening and counseling, depression counseling, and tobacco use screening as provided for in the guidelines issued by the United States Preventive Services Task Force.

The Departments received several comments asking whether or to what extent a non-grandfathered plan that provides mental health or substance use disorder benefits pursuant to PHS Act section 2713 is subject to the requirements of MHPAEA. Many commenters urged the Departments to clarify that the provision of mental health and substance use disorder benefits in this circumstance does not trigger a broader requirement to comply with MHPAEA for non-grandfathered plans that do not otherwise offer mental health or substance use disorder benefits.

The Departments agree that compliance with PHS Act section 2713 should not, for that reason alone, require that the full range of benefits for a mental health condition or substance user disorder be provided under MHPAEA. Accordingly, paragraph (e)(3)(ii) of these final regulations provides that nothing in these regulations requires a group health plan (or health insurance issuer offering coverage in connection with a group health plan) that provides mental health or substance use disorder benefits only to the extent required under PHS Act section 2713 to provide additional mental health or substance use disorder benefits in any classification.

C. Nonquantitative Treatment Limitations

1. Exceptions for Clinically Appropriate Standards of Care

The final regulations generally retain the provision in the interim final regulations setting forth the parity requirements with respect to NQTLs. Under both the interim final regulations and these final regulations, a plan or issuer may not impose an NQTL 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 NQTL 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

[12] Final Report: Consistency of Large Employer and Group Health Plan Benefits with Requirements of the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008. NORC at the University of Chicago for the Office of the Assistant Secretary for Planning and Evaluation. This study analyzed information on large group health plan benefit designs from 2009 through 2011 in several databases maintained by benefits consulting firms that advise plans on compliance with MHPAEA as well as other requirements.

[13] The 2010 Kaiser Family Foundation/HRET and the 2010 Mercer survey found that fewer than 2% of firms with over 50 employees dropped coverage of mental health or substance use disorder benefits. Final Report: Consistency of Large Employer and Group Health Plan Benefits with Requirements of the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008. NORC at the University of Chicago for the Office of the Assistant Secretary for Planning and Evaluation, pp. 43–44.

[14] *See* section 1302(b)(1)(E) of the Affordable Care Act.

[15] For self-insured group health plans, large group market health plans, and grandfathered health plans, to determine which benefits are EHB for purposes of complying with PHS Act section 2711, the Departments have stated that they will consider the plan to have used a permissible definition of EHB under section 1302(b) of the Affordable Care Act if the definition is one that is authorized by the Secretary of HHS (including any available benchmark option, supplemented as needed to ensure coverage of all ten statutory categories). Furthermore, the Departments intend to use their enforcement discretion and work with those plans that make a good faith effort to apply an authorized definition of EHB to ensure there are no annual or lifetime dollar limits on EHB. *See* FAQ–10 of Frequently Asked Questions on Essential Health Benefits Bulletin (published February 17, 2012), available at: *http://www.cms.gov/CCIIO/Resources/Files/Downloads/ehb-faq-508.pdf.*

[16] *See* 26 CFR 54.9815–2713T; 29 CFR 2590.715–2713; 45 CFR 147.130.

medical/surgical benefits in the same classification.

The interim final regulations also contained an exception to the NQTL requirements allowing for variation "to the extent that recognized clinically appropriate standards of care may permit a difference." A few commenters expressed support for the exception, emphasizing inherent differences in treatment for medical/surgical conditions and mental health conditions and substance use disorders. Many other commenters raised concerns that this exception could be subject to abuse and recommended the Departments set clear standards for what constitutes a "recognized clinically appropriate standard of care." For example, commenters suggested a recognized clinically appropriate standard of care must reflect input from multiple stakeholders and experts; be accepted by multiple nationally recognized provider, consumer, or accrediting organizations; be based on independent scientific evidence; and not be developed solely by a plan or issuer. Additionally, since publication of the interim final regulations, some plans and issuers may have attempted to invoke the exception to justify applying an NQTL to all mental health or substance use disorder benefits in a classification, while only applying the NQTL to a limited number of medical/surgical benefits in the same classification. These plans and issuers generally argue that fundamental differences in treatment of mental health and substance use disorders and medical/surgical conditions, justify applying stricter NQTLs to mental health or substance use disorder benefits than to medical/surgical benefits under the exception in the interim final regulations.

In consideration of these comments, the Departments are removing the specific exception for "recognized clinically appropriate standards of care." [17] Plans and issuers will continue to have the flexibility contained in the NQTL requirements to take into account clinically appropriate standards of care when determining whether and to what extent medical management techniques and other NQTLs apply to medical/surgical benefits and mental health and substance use disorder benefits, as long as the processes, strategies, evidentiary standards, and other factors used in applying an NQTL to mental health and substance use disorder benefits are comparable to, and applied no more stringently than, those with respect to medical/surgical benefits. In particular, the regulations do not require plans and issuers to use the same NQTLs for both mental health and substance use disorder benefits and medical/surgical benefits, but rather that the processes, strategies, evidentiary standards, and other factors used by the plan or issuer to determine whether and to what extent a benefit is subject to an NQTL are comparable to and applied no more stringently for mental health or substance use disorder benefits than for medical/surgical benefits. Disparate results alone do not mean that the NQTLs in use do not comply with these requirements. The final regulations provide examples of how health plans and issuers can comply with the NQTL requirements absent the exception for a recognized clinically appropriate standard of care.

However, MHPAEA specifically prohibits separate treatment limitations that are applicable only with respect to mental health or substance use disorder benefits. Moreover, as reflected in FAQs [18] released in November 2011, it is unlikely that a reasonable application of the NQTL requirement would result in all mental health or substance use disorder benefits being subject to an NQTL in the same classification in which less than all medical/surgical benefits are subject to the NQTL.

2. Parity Standards for NQTLs Versus Quantitative Treatment Limitations

As mentioned earlier in this preamble, MHPAEA and the interim final regulations prohibit plans and issuers from imposing a financial requirement or quantitative treatment limitation on mental health and substance use disorder benefits that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification. The interim final regulations incorporated the two-thirds "substantially all" numerical standard from the rules implementing the requirements of MHPA 1996, and quantified "predominant" to mean more than one-half. Using these numerical standards, the Departments established a mathematical test by which plans and issuers could determine what level of a financial requirement or quantitative treatment limitation, if any, is the most restrictive level that could be imposed on mental health or substance use disorder benefits within a classification.

The Departments recognized that plans and issuers impose a variety of NQTLs affecting the scope or duration of benefits that are not expressed numerically. Some commenters recommended that the Departments adopt the same quantitative parity analysis for NQTLs. While NQTLs are subject to the parity requirements, the Departments understood that such limitations cannot be evaluated mathematically. These final regulations continue to provide different parity standards with respect to quantitative treatment limitations and NQTLs, because although both kinds of limitations operate to limit the scope or duration of mental health and substance use disorder benefits, they apply to such benefits differently.[19]

3. Clarification Regarding the Application of Certain NQTLs

Under the interim final regulations, the Departments set forth the parity requirement with respect to NQTLs and provided an illustrative list of NQTLs that plans and issuers commonly use. These NQTLs included: medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative; formulary design for prescription drugs; standards for provider admission to participate in a network, including reimbursement rates; plan methods for determining usual, customary, and reasonable charges; 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 exclusions based on failure to complete a course of treatment. The interim final regulations also included examples illustrating the operation of the requirements for NQTLs.

After the interim final regulations were issued, some stakeholders asked questions regarding the application of

[17] HHS convened a technical expert panel on March 3, 2011 to provide input on the use of NQTLs for mental health and substance use disorder benefits. The panel was comprised of individuals with clinical expertise in mental health and substance use disorder treatment as well as general medical treatment. These experts were unable to identify situations for which the clinically appropriate standard of care exception was warranted—in part because of the flexibility inherent in the NQTL standard itself.

[18] *See* FAQs About Affordable Care Act Implementation (Part VII) and Mental Health Parity Implementation, question 5, available at: *http://www.dol.gov/ebsa/faqs/faq-aca7.html* and *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs7.html.*

[19] The Departments reiterated the different parity standards with respect to quantitative treatment limitations and nonquantitative treatment limitations in an FAQ. *See* FAQs on Understanding Implementation of the Mental Health Parity and Addiction Equity Act of 2008, question 6, available at *http://www.dol.gov/ebsa/faqs/faq-mhpaeaimplementation.html.*

the NQTL rule to other features of medical management or general plan design not specifically addressed in the interim final regulations. Many commenters requested that the Departments address additional NQTLs, such as prior authorization and concurrent review, service coding, provider network criteria, policy coverage conditions, and both in- and out-of-network limitations.

These final regulations make clear that, while an illustrative list is included in these final regulations, all NQTLs imposed on mental health and substance use disorder benefits by plans and issuers subject to MHPAEA are required to be applied in accordance with these requirements. To the extent that a plan standard operates to limit the scope or duration of treatment with respect to mental health or substance use disorder benefits, the processes, strategies, evidentiary standards, or other factors used to apply the standard must be comparable to, and applied no more stringently than, those imposed with respect to medical/surgical benefits. By being comparable, the processes, strategies, evidentiary standards and other factors cannot be specifically designed to restrict access to mental health or substance use disorder benefits. Specifically, plan standards, such as in- and out-of-network geographic limitations, limitations on inpatient services for situations where the participant is a threat to self or others, exclusions for court-ordered and involuntary holds, experimental treatment limitations, service coding, exclusions for services provided by clinical social workers, and network adequacy, while not specifically enumerated in the illustrative list of NQTLs, must be applied in a manner that complies with these final regulations. In response to the comments received, in paragraph (c)(4)(ii) of these final regulations, the Departments added two additional examples of NQTLs to the illustrative list: network tier design and restrictions based on geographic location, facility type, provider specialty and other criteria that limit the scope or duration of benefits for services provided under the plan or coverage. Furthermore, the Departments included additional and revised examples on how NQTLs, enumerated in these final regulations or otherwise, may be applied in accordance with the requirements of these final regulations.

The Departments are aware that some commenters have asked how the NQTL requirements apply to provider reimbursement rates. Plans and issuers may consider a wide array of factors in determining provider reimbursement rates for both medical/surgical services and mental health and substance use disorder services, such as service type; geographic market; demand for services; supply of providers; provider practice size; Medicare reimbursement rates; and training, experience and licensure of providers. The NQTL provisions require that these or other factors be applied comparably to and no more stringently than those applied with respect to medical/surgical services. Again, disparate results alone do not mean that the NQTLs in use fail to comply with these requirements. The Departments may provide additional guidance if questions persist with respect to provider reimbursement rates.

Some commenters requested that the Departments require plans and issuers to comply with certain guidelines, independent national or international standards, or State government guidelines. While plans and issuers are not required under these final regulations to comply with any such guidelines or standards with respect to the development of their NQTLs, these standards, such as the behavioral health accreditation standards set forth by the National Committee for Quality Assurance or the standards for implementing parity in managed care set forth by URAC, may be used as references and best practices in implementing NQTLs, if they are applied in a manner that complies with these final regulations.

D. Scope of Services

In response to the RFI and interim final regulations, the Departments received many comments addressing an issue characterized as "scope of services" or "continuum of care." Scope of services generally refers to the types of treatment and treatment settings that are covered by a group health plan or health insurance coverage. Some commenters requested that, with respect to a mental health condition or substance use disorder that is otherwise covered, the regulations clarify that a plan or issuer 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 require plans and issuers to provide benefits for the full scope of medically appropriate services to treat a mental health condition or substance use disorder if the plan or issuer 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 or coverage. Other commenters requested that MHPAEA be interpreted to require that group health plans and issuers provide benefits for any evidence-based treatment.

The interim final regulations established six broad classifications that in part define the scope of services under MHPAEA. The interim final regulations require that, if a plan or issuer provides coverage for mental health or substance use disorder benefits in any classification, mental health or substance use disorder benefits must be provided in every classification in which medical/surgical benefits are provided. The interim final regulations did not, however, address the scope of services that must be covered within those classifications. The Departments invited comments on whether and to what extent the final regulations should address the scope of services or continuum of care provided by a group health plan or health insurance coverage.

Many commenters requested that the Departments clarify how MHPAEA affects the scope of coverage for intermediate services (such as residential treatment, partial hospitalization, and intensive outpatient treatment) and how these services fit within the six classifications set forth by the interim final regulations. Some commenters suggested that the final regulations establish what intermediate mental health and substance use disorder services would be analogous to various intermediate medical/surgical services for purposes of the MHPAEA parity analysis. Other commenters suggested that the Departments not address scope of services in the final regulations.

The Departments did not intend that plans and issuers could exclude intermediate levels of care covered under the plan from MHPAEA's parity requirements. At the same time, the Departments did not intend to impose a benefit mandate through the parity requirement that could require greater benefits for mental health conditions and substance use disorders than for medical/surgical conditions. In addition, the Departments' approach defers to States to define the package of insurance benefits that must be provided in a State through EHB.[20]

Although the interim final regulations did not define the scope of the six classifications of benefits, they directed that plans and issuers assign mental

[20] *See* 45 CFR 147.150 and 156.115 (78 FR 12834, February 25, 2013).

health and substance use disorder benefits and medical/surgical benefits to these classifications in a consistent manner. This general rule also applies to intermediate services provided under the plan or coverage. Plans and issuers must assign covered intermediate mental health and substance use disorder benefits to the existing six benefit classifications in the same way that they assign comparable intermediate medical/surgical benefits to these classifications. For example, if a plan or issuer classifies care in skilled nursing facilities or rehabilitation hospitals as inpatient benefits, then the plan or issuer must likewise treat any covered care in residential treatment facilities for mental health or substance user disorders as an inpatient benefit. In addition, if a plan or issuer treats home health care as an outpatient benefit, then any covered intensive outpatient mental health or substance use disorder services and partial hospitalization must be considered outpatient benefits as well.

These final regulations also include additional examples illustrating the application of the NQTL rules to plan exclusions affecting the scope of services provided under the plan. The new examples clarify that plan or coverage restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services must comply with the NQTL parity standard under these final regulations.

E. Disclosure of Underlying Processes and Standards

MHPAEA requires that the criteria for plan medical necessity determinations 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) 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 in accordance with regulations. MHPAEA also requires that the reason for any denial under the plan (or 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 on request or as otherwise required by the plan administrator (or health insurance issuer) to the participant or beneficiary in accordance with regulations.

Several commenters expressed concern about the lack of health plan transparency, or made recommendations to improve transparency, including a request that plans and issuers be required to provide sufficient information to determine whether a plan is applying medical necessity criteria and other factors comparably to medical/surgical benefits and mental health and substance use disorder benefits. In addition, since the issuance of the interim final regulations, stakeholders have expressed concern that it is difficult to understand whether a plan complies with the NQTL provisions without information showing that the processes, strategies, evidentiary standards, and other factors used in applying an NQTL to mental health or substance use disorder benefits and medical/surgical benefits are comparable, impairing plan participants' means of ensuring compliance with MHPAEA.

In response to these concerns, the Departments published several FAQs clarifying the breadth of disclosure requirements applicable to group health plans and health insurance issuers under both MHPAEA and other applicable law, including ERISA and the Affordable Care Act.[21] The substance of these FAQs is included in new paragraph (d)(3) of the final regulations, which reminds plans, issuers, and individuals that compliance with MHPAEA's disclosure requirements is not determinative of compliance with any other provision of applicable Federal or State law. In particular, in addition to MHPAEA's disclosure requirements, provisions of other applicable law require disclosure of information relevant to medical/surgical, mental health, and substance use disorder benefits. For example, ERISA section 104 and the Department of Labor's implementing regulations[22] provide that, for plans subject to ERISA, instruments under which the plan is established or operated must generally be furnished by the plan administrator to plan participants[23] within 30 days of request. Instruments under which the plan is established or operated include documents with information on medical necessity criteria for both medical/surgical benefits and mental health and substance use disorder benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply an NQTL with respect to medical/surgical benefits and mental health or substance use disorder benefits under the plan.

In addition, the Department of Labor's claims procedure regulations (applicable to ERISA plans), as well as the Departments' claims and appeals regulations under the Affordable Care Act (applicable to all non-grandfathered group health plans and health insurance issuers in the group and individual markets),[24] set forth rules regarding claims and appeals, including the right of claimants (or their authorized representative) upon appeal of an adverse benefit determination (or a final internal adverse benefit determination) to be provided by the plan or issuer, upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the claimant's claim for benefits.[25] In addition, the plan or issuer must provide the claimant with any new or additional evidence considered, relied upon, or generated by the plan or issuer (or at the direction of the plan or issuer) in connection with a claim. If the plan or issuer is issuing an adverse benefit determination on review based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale. Such evidence or rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of adverse benefit determination on

[21] *See* FAQs for Employees about the Mental Health Parity and Addiction Equity Act, available at *http://www.dol.gov/ebsa/faqs/faq-mhpaea2.html;* FAQs about Affordable Care Act Implementation (Part V) and Mental Health Parity Implementation, available at *http://www.dol.gov/ebsa/faqs/faq-aca5.html and http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html.*

[22] 29 CFR 2520.104b 1.

[23] ERISA section 3(7) defines the term "participant" to include any employee or former employee who is or may become eligible to receive a benefit of any type from an employee benefit plan or whose beneficiaries may become eligible to receive any such benefit. Accordingly, employees who are not enrolled but are, for example, in a waiting period for coverage, or who are otherwise shopping amongst benefit package options at open season, generally are considered plan participants for this purpose.

[24] 29 CFR 2560.503–1. *See also* 26 CFR 54.9815–2719T(b)(2)(i), 29 CFR 2590.715–2719(b)(2)(i), and 45 CFR 147.136(b)(2)(i), requiring non-grandfathered plans and issuers to incorporate the internal claims and appeals processes set forth in 29 CFR 2560.503–1.

[25] *See* 29 CFR 2560.503–1. The Department of Labor's claim procedure regulation stipulates specific timeframes in which a plan administrator must notify a claimant of the plan's benefit determination, which includes, in the case of an adverse benefit determination, the reason for the denial. Accordingly, a plan administrator must notify a claimant of the plan's benefit determination with respect to a pre-service claim within a reasonable time period appropriate to the medical circumstances, but not later than 15 days after the receipt of the claim. With respect to post-service claims, a plan administrator must notify the claimant within a reasonable time period, but not later than 30 days after the receipt of the claim. In the case of an urgent care claim, a plan administrator must notify the claimant of the plan's benefit determination, as soon as possible, taking into account the medical exigencies, but not later than 72 hours after the receipt of the claimant's request.

review is required to be provided to give the claimant a reasonable opportunity to respond prior to that date.[26] The information required to be provided under these provisions includes documents of a comparable nature with information on medical necessity criteria for both medical/surgical benefits and mental health and substance use disorder benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply an NQTL with respect to medical/surgical benefits and mental health or substance use disorder benefits under the plan.

Even with these important disclosure requirements under existing law,[27] the Departments remain focused on transparency and whether individuals have the necessary information to compare NQTLs of medical/surgical benefits and mental health or substance use disorder benefits under the plan to effectively ensure compliance with MHPAEA. Accordingly, contemporaneous with the publication of these final regulations, the Departments of Labor and HHS are also publishing another set of MHPAEA FAQs, which, among other things, solicit comments on whether and how to ensure greater transparency and compliance. [28]

F. Small Employer Exemption

Paragraph (f) of these final regulations implements 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. Prior to the Affordable Care Act, MHPAEA defined a small employer, 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.

Section 2791 of the PHS Act was amended by the Affordable Care Act to define a small employer as one that has 100 or fewer employees, while also providing States the option to use 50 employees rather than 100 for 2014 and 2015.[29] This definition is incorporated by reference in the MHPAEA provisions contained in section 2726 of the PHS Act. However, the MHPAEA provisions codified in ERISA section 712 and Code section 9812, together with section 732(a) of ERISA and section 8931(a) of the Code, continue to define an exempt small employer as one that has 50 or fewer employees. The Departments issued an FAQ[30] in December 2010 stating that, "for group health plans and health insurance issuers subject to ERISA and the Code, the Departments will continue to treat group health plans of employers with 50 or fewer employees as exempt from the MHPAEA requirements under the small employer exemption, regardless of any State insurance law definition of small employer." The FAQ also acknowledged that, for non-Federal governmental plans, which are not subject to ERISA or the Code, the PHS Act was amended to define a small employer as one that has 100 or fewer employees. Consistent with the FAQs, the Department of Labor and the Department of the Treasury final regulations continue to exempt group health plans and group health insurance coverage of employers with 50 or fewer employees from MHPAEA. The HHS final regulations, which generally apply to non-Federal governmental plans, exempt group health plans and group health insurance coverage of employers with 100 or fewer employees (subject to State law flexibility for 2014 and 2015). Despite this difference, and certain other differences, in the applicability of the provisions of the Code, ERISA, and the PHS Act, the Departments do not find there to be a conflict in that no entity will be put in a position in which compliance with all of the provisions applicable to that entity is impossible.

At the same time, plans and issuers providing coverage in connection with group health plans sponsored by small employers should be aware that, on February 25, 2013, HHS published a final regulation on EHB [31] that requires issuers of non-grandfathered plans in the individual and small group markets to ensure that such plans provide all EHB, including mental health and substance use disorder benefits. The extent of the coverage of EHB is determined based on benchmark plans that are selected by the States. Furthermore, the EHB final regulation at 45 CFR 156.115(a)(3) requires issuers providing EHB to provide mental health and substance use disorder benefits in compliance with the requirements of the MHPAEA regulations, even where those requirements would not otherwise apply directly. Thus, all insured, non-grandfathered, small group plans must cover EHB in compliance with the MHPAEA regulations, regardless of MHPAEA's small employer exemption. (Also, as discussed in section H.1. below, MHPAEA was amended to include individual health insurance coverage. Accordingly, both grandfathered and non-grandfathered coverage in the individual market must comply with MHPAEA.)

G. Increased Cost Exemption

MHPAEA contains an increased cost exemption that is available for plans and health insurance issuers that make changes to comply with the law and incur an increased cost of at least two percent in the first year that MHPAEA applies to the plan or coverage or at least one percent in any subsequent plan or policy year. Under MHPAEA, plans or coverage 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 or policy year, and the exemption lasts for one plan or policy year. Thus, the increased cost exemption may only be claimed for alternating plan or policy years.[32]

The interim final regulations reserved paragraph (g) regarding the increased cost exemption and solicited comments. The Departments issued guidance establishing an interim enforcement safe harbor under which a plan that has incurred an increased cost of two percent during its first year of compliance can obtain an exemption for the second plan year by following the exemption procedures described in the Departments' 1997 regulations implementing MHPA 1996,[33] except that, as required under MHPAEA, for

[26] *See* 26 CFR 54.9815–2719T(b)(2)(ii)(C), 29 CFR 2590.715–2719(b)(2)(ii)(C), and 45 CFR 147.136(b)(2)(ii)(C).

[27] For other disclosure requirements that may be applicable to plans and issuers under existing Federal law, including disclosure requirements regarding prescription drug formulary coverage, *see* the summary plan description requirements for ERISA plans under 29 CFR 2520.102–3(j)(2) and (j)(3) and the preamble discussion at 65 FR 70226, 70237 (Nov. 11, 2000), as well as Department of Labor Advisory Opinion 96–14A (available at *http://www.dol.gov/ebsa/programs/ori/advisory96/96-14a.htm).* See also the summary of benefits and coverage requirements under 26 CFR 54.9815–2715(a)(2)(i)(K), 29 CFR 2590.715–2715(a)(2)i)(K), and 45 CFR 147.200(a)(2)(i)(K).

[28] Available at *http://www.dol.gov/ebsa/healthreform/* and *http://www.cms.gov/cciio/Resources/Fact-Sheets-and-FAQs/index.html.*

[29] *See* section 1304(b)(3) of the Affordable Care Act.

[30] *See* FAQs about Affordable Care Act Implementation (Part V) and Mental Health Parity Implementation, question 8, available at *http://www.dol.gov/ebsa/faqs/faq-aca5.html* and *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html.*

[31] 78 FR 12834.

[32] An employer or issuer may elect to continue to provide mental health and substance use disorder benefits in compliance with this section with respect to the plan or coverage involved regardless of any increase in total costs. That is, mere eligibility for the exemption does not require an employer or issuer to use it. An exempt plan or coverage can continue to provide mental health and substance use disorder benefits during the exemption period in compliance with some, all, or none of the parity provisions.

[33] 62 FR 66932, December 22, 1997.

the first year of compliance the applicable percentage of increased cost is two percent and the exemption lasts only one year.[34]

The Departments received several comments on the interim final regulations that requested guidance on attribution of cost increases to MHPAEA. Some commenters emphasized that the cost exemption must be based on actual total plan costs measured at the end of the plan year. Other commenters stated that plans should be permitted to estimate claims that have not yet been reported for purposes of calculating incurred expenditures. Additionally, some commenters stated that a plan's costs for purposes of the increased cost exemption should include not only claims costs, but also administrative expenses associated with complying with the parity requirements.

Paragraph (g) of these final regulations generally applies standards and procedures for claiming an increased cost exemption under MHPAEA consistent with MHPAEA's statutory standards and procedures as well as prior procedures set forth in the Departments' regulations implementing MHPA 1996. The test for an exemption must be based on the estimated increase in actual costs incurred by the plan or issuer that is directly attributable to expansion of coverage due to the requirements of this section and not otherwise due to occurring trends in utilization and prices, a random change in claims experience that is unlikely to persist, or seasonal variation commonly experienced in claims submission and payment patterns.

Under the final regulations, the increase in actual total costs attributable to MHPAEA is described by the formula $[(E_1 - E_0)/T_0] - D > k$, where E represents the level of health plan spending with respect to mental health and substance use disorder benefits over the measurement period, T is a measure of total actual costs incurred by a plan or coverage on all benefits (medical/surgical benefits and mental health and substance use disorder benefits under the plan), D is the average change in spending over the prior five years, and k is the applicable percentage of increased cost for qualifying for the cost exemption (i.e., one percent or two percent depending on the year). k will be expressed as a fraction for the purposes of this formula. The subscripts 1 and 0 refer to a base period and the most recent benefit period preceding the base period, respectively. Costs incurred under E include paid claims by the plan or coverage for services to treat mental health conditions and substance use disorders, and administrative costs associated with providing mental health or substance use disorder benefits (amortized over time).

In estimating the costs attributable to MHPAEA, a plan or issuer must rely on actual claims or encounter data incurred in the benefit period reported within 90 days of the end of the benefit period. Although MHPAEA specifies that determinations with regard to the cost exemption shall be made after a plan has complied with the law for six months of the plan year involved, the provision does not require that the benefit period used to make this calculation be limited to six months. Data from a six month period will not typically reflect seasonal variation in claims experience. To estimate $E_1 - E_0$, a plan or coverage must first calculate secular trends over five years in the volume of services and the prices paid for services for the major classifications of services by applying the formula $(E_1 - E_0)/T_0$ to mental health and substance use disorder spending to each of the five prior years and then calculating the average change in spending. The components of spending are estimated because secular trends can occur in prices and volume. After the average change in spending across the five years is calculated for each service type, the change in mental health and substance use disorder benefits spending attributable to MHPAEA is calculated net of the average annual spending growth that is due to a secular trend. This change in calculation is the main difference from the previous methodology used under prior guidance. It is recognized that for some smaller employers covered by MHPAEA, year to year spending may be somewhat unstable. In this case, an employer or issuer may propose an alternative estimation method. It is important to note that the language of the statute indicates that the base period against which the impact of MHPAEA is assessed moves up each year to the year prior to the current benefit year.

Administrative costs attributable to the implementation of MHPAEA must be reasonable and supported with detailed documentation from accounting records. Software and computing expenses associated with implementation of the prohibition on separate cumulative financial requirements or other provisions of the regulation should be based on a straight-line depreciation over the estimated useful life of the asset (computer hardware five years; software three years, according to the American Hospital Association's Estimated Useful Life of depreciable Hospital Assets). Any other fixed administrative costs should also be amortized.

Some commenters suggested additional clarifications regarding the statutory provision that determinations as to increases in actual costs must be made and certified by a qualified and licensed actuary who is a member in good standing of the American Academy of Actuaries. Some commenters suggested that the actuary must be qualified to perform such work based on meeting the Qualification Standards for Actuaries Issuing Statements of Actuarial Opinion in the United States. Other commenters suggested that the actuary must be independent and not employed by the group health plan or health insurance issuer claiming the exemption. The Departments believe the statutory language is sufficient to ensure reliable cost increase determinations. Moreover, this approach is consistent with the approach applicable to EHB in that the only qualification required for actuaries is that they be a member in good standing of the American Academy of Actuaries.[35] Accordingly, the Departments decline to adopt these suggestions. Determinations as to increases in actual costs attributable to implementation of the requirements of MHPAEA must be made and certified by a qualified and licensed actuary who is a member in good standing of the American Academy of Actuaries. All such determinations must be based on the formula specified in these final regulations in a written report prepared by the actuary. Additionally, the written report, along with all supporting documentation relied upon by the actuary, must be maintained by the group health plan or health insurance issuer for a period of six years.

Several commenters expressed concern regarding the administrative burden that would result from qualifying for the increased cost exemption for one year and then having to comply with the law the following year. MHPAEA's statutory language specifies that plans and issuers may qualify for the increased cost exemption for only one year at a time, stating that if the application of MHPAEA "results in an increase for the plan year involved of the actual total costs of coverage . . . by an amount that exceeds the applicable percentage . . . the

[34] *See* FAQs about Affordable Care Act Implementation (Part V) and Mental Health Parity Implementation, question 11, available at: *http://www.dol.gov/ebsa/faqs/faq-aca5.html* and *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html.*

[35] *See* 45 CFR 156.135(b).

provisions of this section shall not apply to such plan (or coverage) during the following plan year, and such exemption shall apply to the plan (or coverage) for 1 plan year." [36]

Before a group health plan or health insurance issuer may claim the increased cost exemption, it must furnish a notice of the plan's exemption from the parity requirements to participants and beneficiaries covered under the plan, the Departments (as described below), and appropriate State agencies. The notification requirements for the increased cost exemption under these final regulations are consistent with the requirements under the Departments' 1997 regulations implementing MHPA 1996.

With respect to participants and beneficiaries, a group health plan subject to ERISA may satisfy this requirement by providing a summary of material reductions in covered services or benefits under 29 CFR 2520.104b–3(d), if it includes all the information required by these final regulations.

With respect to notification to the Departments, a plan or issuer must furnish a notice that satisfies the requirements of these final regulations. A group health plan that is a church plan (as defined in section 414(e) of the Code) must notify the Department of the Treasury. A group health plan subject to Part 7 of Subtitle B of Title I of ERISA must notify the Department of Labor. A group health plan that is a non-Federal governmental plan or a health insurance issuer must notify HHS. In all cases, the exemption is not effective until 30 days after notice has been sent to both participants and beneficiaries and to the appropriate Federal agency. The Departments will designate addresses for delivery of these notices in future guidance.

Finally, a plan or issuer must make available to participants and beneficiaries (or their representatives), on request and at no charge, a summary of the information on which the exemption was based. For purposes of this paragraph (g), an individual who is not a participant or beneficiary and who presents a notice described in paragraph (g)(6) of the final regulations is considered to be a representative. Such a representative may request the summary of information by providing the plan a copy of the notice provided to the participant or beneficiary with any personally identifiable information redacted. The summary of information must include the incurred expenditures, the base period, the dollar amount of claims incurred during the base period that would have been denied under the terms of the plan absent amendments required to comply with parity, and the administrative expenses attributable to complying with the parity requirements. In no event should a summary of information include individually identifiable information.

The increased cost exemption provision in paragraph (g) of these final regulations is effective for plan or policy years beginning on or after July 1, 2014 (see paragraph (i) of these final regulations), which for calendar year plans means the provisions apply on January 1, 2015. Accordingly, plans and issuers must use the formula specified in paragraph (g) of these final regulations to determine whether they qualify for the increased cost exemption in plan or policy years beginning on or after July 1, 2014. For claiming the increased cost exemption in plan or policy years beginning before July 1, 2014, plans and issuers should follow the interim enforcement safe harbor outlined in previously issued FAQs.[37]

H. General Applicability Provisions and Application to Certain Types of Plans and Coverage

The interim final regulations combined in paragraph (e)(1) what had been separate rules under MHPA 1996 for (1) determining if a plan provides both medical/surgical and mental health or substance use disorder benefits; (2) applying the parity requirements on a benefit-package-by-benefit-package basis; and (3) counting the number of plans that an employer or employee organization maintains. The combined rule 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. Some comments expressed concern that the new combined rule would disrupt benefit programs that employers have maintained as separate plans for important reasons having nothing to do with a desire to escape the parity requirements and that the rule should be rescinded or issued only in proposed form. Other comments welcomed the rule as an important protection to prevent evasion of the parity requirements. The final regulations do not change the combined rule from the interim final regulations. In the Departments' view, the combined rule is necessary to prevent 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).

The preamble to the interim final regulations illustrated how the parity requirements would apply to various benefit package configurations, including multiple medical/surgical benefit packages combined with a single mental health and substance use disorder benefit package. One commenter asked for clarification in the case of a plan with an HMO option and a PPO option in which mental health and substance use disorder benefits are an integral part of each option. In such a case, the parity requirements apply separately to the HMO option and the PPO option.

The Departments are aware that employers and health insurance issuers sometimes contract with MBHOs or similar entities to provide or administer mental health or substance use disorder benefits in group health plans or in health insurance coverage. The fact that an employer or issuer contracts with one or more entities to provide or administer mental health or substance use disorder benefits does not, however, relieve the employer, issuer, or both of their obligations under MHPAEA. The coverage as a whole must still comply with the applicable provisions of MHPAEA, and the responsibility for compliance rests on the group health plan and/or the health insurance issuer, depending on whether the coverage is insured or self-insured. This means that the plan or issuer will need to provide sufficient information in terms of plan structure and benefits to the MBHO to ensure that the mental health and substance use disorder benefits are coordinated with the medical/surgical benefits for purposes of compliance with the requirements of MHPAEA. Liability for any violation of MHPAEA rests with the group health plan and/or health insurance issuer.

Several commenters requested clarification about whether a plan or issuer may exclude coverage for specific

[36] Code section 9812(c)(2), ERISA 712(c)(2), PHS Act section 2726(c)(2).

[37] *See* FAQs about Affordable Care Act Implementation (Part V) and Mental Health Parity Implementation, question 11, available at: *http://www.dol.gov/ebsa/faqs/faq-aca5.html* and *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html.*

diagnoses or conditions under MHPAEA. These final regulations continue to provide that nothing in these regulations requires a plan or issuer to provide any mental health benefits 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. Other Federal and State laws may prohibit the exclusion of particular disorders from coverage where applicable, such as the Americans with Disabilities Act. Other Federal and State laws may also require coverage of mental health or substance use disorder benefits, including the EHB requirements under section 2707 of the PHS Act and section 1302(a) of the Affordable Care Act.

1. Individual Health Insurance Market

Section 1563(c)(4) of the Affordable Care Act[38] amended section 2726 of the PHS Act to apply MHPAEA to health insurance issuers in the individual health insurance market. These changes are effective for policy years beginning on or after January 1, 2014. The HHS final regulation implements these requirements in new section 147.160 of title 45 of the Code of Federal Regulations. Under these provisions, unless otherwise specified, the parity requirements outlined in 45 CFR 146.136 of these final regulations apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner and to the same extent as such provisions apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the large group market. These provisions apply to both grandfathered and non-grandfathered individual health insurance coverage for policy years beginning on or after the applicability dates set forth in paragraph (i) of these final regulations.

2. Non-Federal Governmental Plans

Prior to enactment of the Affordable Care Act, sponsors of self-funded, non-Federal governmental plans were permitted to elect to exempt those plans from ("opt out of") certain provisions of title XXVII of the PHS Act. This election was authorized under section 2721(b)(2) of the PHS Act (renumbered as section 2722(a)(2) by the Affordable Care Act). The Affordable Care Act made a number of changes, with the result that sponsors of self-funded, non-Federal governmental plans can no longer opt out of as many requirements of title XXVII of the PHS Act. However, under the PHS Act, sponsors of self-funded, non-Federal governmental plans may continue to opt out of the requirements of MHPAEA.[39] If the sponsor of a self-funded, non-Federal governmental plan wishes to exempt its plan from the requirements of MHPAEA, it must follow the procedures and requirements outlined in section 2722 and corresponding Centers for Medicare & Medicaid Services (CMS) guidance, which includes notifying CMS to that effect in writing.[40]

3. Retiree-Only Plans

Some commenters requested clarification regarding the applicability of these final regulations to retiree-only plans. ERISA section 732(a) generally provides that part 7 of ERISA—and Code section 9831(a) generally provides that chapter 100 of the Code—does not apply to group health plans with less than two participants who are current employees (including retiree-only plans that, by definition, cover less than two participants who are current employees).[41] The Departments previously clarified in FAQs that the exceptions of ERISA section 732 and Code section 9831, including the exception for retiree-only health plans, remain in effect.[42] Since the provisions of MHPAEA contained in ERISA section 712 and Code section 9812 are contained in part 7 of ERISA and chapter 100 of the Code, respectively, group health plans that do not cover at least two employees who are current employees (such as plans in which only retirees participate) are exempt from the requirements of MHPAEA and these final regulations.[43]

4. Employee Assistance Programs

Several comments also requested clarification regarding the applicability of the parity requirements to employee assistance programs (EAPs). An example in the interim final regulations clarified that a plan or issuer that limits eligibility for mental health and substance use disorder benefits until after benefits under an EAP are exhausted has established an NQTL subject to the parity requirements, and stated that if no comparable requirement applies to medical/surgical benefits, such a requirement could not be applied to mental health or substance use disorder benefits.[44] The final regulations retain this example and approach.[45]

The Departments have also received questions regarding whether benefits under an EAP are considered to be excepted benefits. The Departments recently published guidance announcing their intentions to amend the excepted benefits regulations[46] to provide that benefits under an EAP are considered to be excepted benefits, but only if the program does not provide significant benefits in the nature of medical care or treatment.[47] Under this approach, EAPs that qualify as excepted benefits will not be subject to MHPAEA or these final regulations.

The guidance provides that until rulemaking regarding EAPs is finalized, through at least 2014, the Departments will consider an EAP to constitute excepted benefits only if the EAP does not provide significant benefits in the nature of medical care or treatment. For

[38] There are two sections numbered 1563 in the Affordable Care Act. The section 1563 that is the basis for this rulemaking is the section titled "Conforming amendments."

[39] *See* Memo on Amendments to the HIPAA Opt-Out Provision Made by the Affordable Care Act (September 21, 2010). Available at: *http://www.cms.gov/CCIIO/Resources/Files/Downloads/opt_out_memo.pdf.*

[40] *See* Self-Funded Non-Federal Governmental Plans: Procedures and Requirements for HIPAA Exemption Election. Available at: *http://www.cms.gov/CCIIO/Resources/Files/hipaa_exemption_election_instructions_04072011.html.*

[41] Prior to the enactment of the Affordable Care Act, the PHS Act had a parallel provision at section 2721(a); however, after the Affordable Care Act amended, reorganized, and renumbered title XXVII of the PHS Act, that exception no longer exists. *See* 75 FR 34538–34539.

[42] *See* FAQs About the Affordable Care Act Implementation Part III, question 1, available at *http://www.dol.gov/ebsa/faqs/faq-aca3.html* and *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs3.html*, which states that "statutory provisions in effect since 1997 exempting group health plans with 'less than two participants who are current employees' from HIPAA also exempt such plans from the group market reform requirements of the Affordable Care Act."

[43] Additionally, as provided in the interim final regulations regarding grandfathered health plans, HHS does not intend to use its resources to enforce the requirements of title XXVII of the PHS Act, including the requirements of MHPAEA and these final regulations, with respect to non-Federal governmental retiree-only plans and encourages States not to apply those provisions to issuers of retiree-only plans. HHS will not cite a State for failing to substantially enforce the provisions of part A of title XXVII of the PHS Act in these situations. *See* 75 FR at 34538, 34540 (June 17, 2010).

[44] See Example 5 in paragraph (c)(4)(iii) of the interim final regulations.

[45] See Example 6 in paragraph (c)(4)(iii) of the final regulations.

[46] 26 CFR 54.9831–1(c), 29 CFR 2590.732(c), 45 CFR 146.145(c).

[47] See IRS Notice 2013–54 (available at *http://www.irs.gov/pub/irs-drop/n-13-54.pdf*) and DOL Technical Release 2013–03 (available at *http://www.dol.gov/ebsa/newsroom/tr13-03.html*), Q&A 9. *See also* CMS Insurance Standards Bulletin—Application of Affordable Care Act Provisions to Certain Healthcare Arrangements (available at *http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/cms-hra-notice-9-16-2013.pdf*).

this purpose, employers may use a reasonable, good faith interpretation of whether an EAP provides significant benefits in the nature of medical care or treatment.

5. Medicaid and CHIP Managed Care Plans

These final regulations apply to group health plans and health insurance issuers. These final regulations do not apply to Medicaid managed care organizations (MCOs), alternative benefit plans (ABPs), or the Children's Health Insurance Program (CHIP). However, MHPAEA requirements are incorporated by reference into statutory provisions that do apply to those entities. On January 16, 2013, CMS released a State Health Official Letter regarding the application of the MHPAEA requirements to Medicaid MCOs, ABPs, and CHIP.[48] In this guidance, CMS adopted the basic framework of MHPAEA and applied the statutory principles as appropriate across these Medicaid and CHIP authorities. The letter also stated that CMS intends to issue additional guidance that will assist States in their efforts to implement the MHPAEA requirements in their Medicaid programs.

I. Interaction With State Insurance Laws

Several commenters requested that the final regulations clearly describe how MHPAEA interacts with State insurance laws. Commenters sought clarification as to how MHPAEA may or may not preempt State laws that require parity for mental health or substance use disorder benefits, mandate coverage of mental health or substance use disorder benefits, or require a minimum level of coverage (such as a minimum dollar, day, or visit level) for mental health conditions or substance use disorders. These commenters expressed a desire that the final regulations articulate that existing State laws on mental health or substance use disorder benefits would remain in effect to the extent they did not prevent the application of MHPAEA.

The preemption provisions of section 731 of ERISA and section 2724 of the PHS Act (added by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and implemented in 29 CFR 2590.731 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 and other applicable provisions.[49] The HIPAA conference report indicates that this is intended to be the "narrowest" preemption of State laws.[50]

For example, a State law may mandate that an issuer offer coverage for a particular condition or require that an issuer offer a minimum dollar amount of mental health or substance use disorder benefits. (While MHPAEA does not require plans or issuers to offer any mental health benefits, once benefits are offered, for whatever reason (except as previously described related to PHS Act section 2713), MHPAEA applies to the benefits.) These State law provisions do not prevent the application of MHPAEA, and therefore would not be preempted. To the extent the State law mandates that an issuer provide some coverage for any mental health condition or substance use disorder, benefits for that condition or disorder must be provided in parity with medical/surgical benefits under MHPAEA. This means that 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.

J. Enforcement

Comments received in response to the interim final regulations suggested some confusion and concern regarding the Departments' authority to impose penalties and ensure compliance with the requirements under MHPAEA. The enforcement responsibilities of the Federal government and the States with respect to health insurance issuers are set forth in the PHS Act. Pursuant to PHS Act section 2723(a), States have primary enforcement authority over health insurance issuers regarding the provisions of part A of title XXVII of the PHS Act, including MHPAEA. HHS (through CMS) has enforcement authority over the issuers in a State if the State notifies CMS that it has not enacted legislation to enforce or is otherwise not enforcing, or if CMS determines that the State is not substantially enforcing, a provision (or provisions) of part A of title XXVII of the PHS Act. Currently, CMS believes that most States have the authority to enforce MHPAEA and are acting in the areas of their responsibility. In States that lack the authority to enforce MHPAEA, CMS is either directly enforcing MHPAEA or collaborating with State departments of insurance to ensure enforcement.

The Departments of Labor and the Treasury generally have primary enforcement authority over private sector employment-based group health plans, while HHS has primary enforcement authority over non-Federal governmental plans, such as those sponsored by State and local government employers.

Some commenters suggested that States need a stronger understanding of MHPAEA and its implementing regulations to better inform the public about the protections of the law and to ensure proper compliance by issuers. These commenters believed that States would benefit from additional and continued guidance from CMS regarding the requirements of MHPAEA and its impact upon State law. The Departments encourage State regulators to familiarize themselves with the MHPAEA requirements, in particular the rules governing NQTLs, and any guidance issued by the Departments, so that the States can instruct issuers in their jurisdictions on the correct implementation of the statute and regulations, and appropriately enforce the provisions. The Departments will continue to provide technical assistance to State regulators either individually or through the National Association of Insurance Commissioners to ensure that the States have the tools they need to implement and enforce MHPAEA.

K. Applicability Dates

MHPAEA's statutory provisions were self-implementing and generally became effective for plan years beginning after October 3, 2009.[51] The requirements of the interim final regulations generally became effective on the first day of the first plan year beginning on or after July

[48] Application of the Mental Health Parity and Addiction Equity Act to Medicaid MCOs, CHIP, and Alternative Benefit (Benchmark) Plans, available at: *http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SHO-13-001.pdf.*

[49] The preemption provision of PHS Act section 2724 also applies to individual health insurance coverage.

[50] *See* House Conf. Rep. No. 104–736, at 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2008.

[51] There is a special effective date for group health plans maintained pursuant to one or more collective bargaining agreements ratified before October 3, 2008, which states that the requirements of the interim final 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 also provides that any plan amendment made pursuant to a collective bargaining agreement solely to conform to the requirements of MHPAEA will not be treated as a termination of the agreement.

1, 2010. These final regulations apply to group health plans and health insurance issuers offering group health insurance coverage on the first day of the first plan year beginning on or after July 1, 2014. Examples, cross-references, and other clarifications have been added in some places to facilitate compliance and address common questions, much of which has already been published by the Departments.[52] Each plan or issuer subject to the interim final regulations must continue to comply with the applicable provisions of the interim final regulations until the corresponding provisions of these final regulations become applicable to that plan or issuer.

L. Technical Amendment Relating to OPM Multi-State Plan Program and External Review

This document also contains a technical amendment relating to external review with respect to the Multi-State Plan Program (MSPP) administered by the Office of Personnel Management (OPM). Section 2719 of the PHS Act and its implementing regulations provide that group health plans and health insurance issuers must comply with either a State external review process or the Federal external review process. Generally, if a State has an external review process that meets, at a minimum, the consumer protections set forth in the interim final regulations on internal claims and appeals and external review,[53] then an issuer (or a plan) subject to the State process must comply with the State process.[54] For plans and issuers not subject to an existing State external review process (including self-insured plans), a Federal external review process applies.[55] The statute requires the Departments to establish standards, "through guidance," governing a Federal external review process. Through guidance issued by the Departments, HHS has established a Federal external review process for self-insured non-Federal governmental health plans, as well as for plans and issuers in States that do not have an external review process that meets the minimum consumer protections in the regulations.

In proposed regulations published on March 21, 2013 (78 FR 17313), the Departments proposed to amend the interim final regulations implementing PHS Act section 2719 to specify that MSPs will be subject to the Federal external review process under PHS Act section 2719(b)(2) and paragraph (d) of the internal claims and appeals and external review regulations. This proposal reflects the Departments' interpretation of section 2719(b)(2) as applicable to all plans not subject to a State's external review process. OPM has interpreted section 1334(a)(4) of the Affordable Care Act to require OPM to maintain authority over external review because Congress directed that OPM implement the MSPP in a manner similar to the manner in which it implements the contracting provisions of the FEHBP, and in the FEHBP, OPM resolves all external appeals on a nationwide basis as a part of its contract administration responsibilities.[56] This assures consistency in benefit administration for those OPM plans that are offered on a nationwide basis. Accordingly, under OPM's interpretation, it would be inconsistent with section 1334(a)(4) of the Affordable Care Act for MSPs and MSPP issuers to follow State-specific external review processes under section 2719(b)(1) of the PHS Act. OPM's final rule on the establishment of the multi-State plan program nonetheless does require the MSPP external review process to meet the requirements of PHS Act section 2719 and its implementing regulations.[57]

The Departments also proposed to amend the interim final regulations implementing PHS Act section 2719 to specify that the scope of the Federal external review process, as described in paragraph (d)(1)(ii), is the minimum required scope of claims eligible for external review for plans using a Federal external review process, and that Federal external review processes developed in accordance with paragraph (d) may have a scope that exceeds the minimum requirements.

The Departments did not receive any comments relating to these proposed amendments and therefore retain the amendments in this final rule without change, except for one minor correction.[58] The Departments made a typographical error in the March 21, 2013 proposed rule, inadvertently omitting the word "internal" from paragraph (d)(1)(i). That provision should have stated that the Federal external review process "applies, at a minimum, to any adverse benefit determination or final *internal* adverse benefit determination. . . ." (emphasis added). The Departments did not intend to remove the word "internal" from the interim final rule through the proposed amendment, and we are correcting the final amendment to include the word.

III. Economic Impact and Paperwork Burden

Executive Orders 12866 (Regulatory Planning and Review, September 30, 1993) and 13563 (Improving Regulation and Regulatory Review, February 2, 2011) direct agencies to propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs, to assess the costs and benefits of regulatory alternatives, and to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity).

Agencies must determine whether a regulatory action is "significant" which is defined in Executive Order 12866 as an action that is likely to result in a rule (1) having an annual effect on the

[52] For additional examples and other clarifications published by the Departments to facilitate compliance under the interim final rules, *see also http://www.dol.gov/ebsa/faqs/faq-mhpaea.html;* FAQs about Affordable Care Act Implementation (Part V) and Mental Health Parity Implementation, available at *http://www.dol.gov/ebsa/faqs/faq-aca5.html* and *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html;* FAQs about Affordable Care Act Implementation (Part VII) and Mental Health Parity Implementation, available at *http://www.dol.gov/ebsa/faqs/faq-aca7.html* and *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs7.html;* FAQs on Understanding Implementation of the Mental Health Parity and Addiction Equity Act of 2008, available at *http://www.dol.gov/ebsa/faqs/faq-mhpaeaimplementation.html;* and FAQs for Employees about the Mental Health Parity and Addiction Equity Act, available at *http://www.dol.gov/ebsa/faqs/faq-mhpaea2.html.*

[53] The interim final regulations relating to internal claims and appeals and external review processes are codified at 26 CFR 54.9815–2719T, 29 CFR 2590.715–2719, and 45 CFR 147.136. These requirements do not apply to grandfathered health plans. The interim final regulations relating to status as a grandfathered health plan are codified at 26 CFR 54.9815–1251T, 29 CFR 2590.715–1251, and 45 CFR 147.140.

[54] More information on the regulatory requirements for State external review processes, including the regulations, Uniform Health Carrier External Review Model Act promulgated by the National Association of Insurance Commissioners, technical releases, and other guidance, is available at *http://www.dol.gov/ebsa* and *http://cciio.cms.gov.*

[55] More information on the regulatory requirements for the Federal external review process, including the regulations, technical releases, and other guidance, is available at *http://www.dol.gov/ebsa* and *http://cciio.cms.gov.*

[56] See the OPM proposed rule on establishment of the MSPP, 77 FR 72582, 72585 (Dec. 5, 2012); see also the final rule, 78 FR 15559, 15574 (Mar. 11, 2013) ("we believe our approach to external review is required by section 1334 of the Affordable Care Act[.]".

[57] See 45 CFR 800.115(k) and 45 CFR part 800; see also 78 FR at 15574 ("the level playing field provisions of section 1324 of the Affordable Care Act would not be triggered because MSPs and MSPP issuers would comply with the external review requirements in section 2719(b) of the PHS Act, just as other health insurance issuers in the group and individual markets are required to do.").

[58] Treasury is not adopting amendments to the external review regulations in 26 CFR at this time. Any changes to the Treasury external review regulations will be made when the entire section of those regulations is adopted as final regulations.

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.

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

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 at least one year. Accordingly, the Departments provide the following assessment of the potential costs and benefits of these final regulations. As elaborated below, the Departments believe that the benefits of the rule justify its costs.

As described earlier in this preamble, these final regulations expand on the protections and parity requirements set forth in the interim final regulations, incorporate clarifications issued by the Departments through sub-regulatory guidance since the issuance of the interim final regulations, and provide clarifications related to NQTLs and disclosure requirements. These final regulations also include additional clarifications and examples illustrating the parity requirements and their applicability, as well as provisions to implement the increased cost exemption with respect to financial requirements and treatment limitations. The HHS final regulation also implements the parity requirements for individual health insurance coverage.

A recent study on plan responses to MHPAEA indicates that by 2011, most plans had removed most financial requirements and treatment limitations that did not meet the requirements of MHPAEA and the interim final regulations.[59] The use of higher copays and coinsurance for inpatient mental health and substance use disorder services declined rapidly in large employer plans following implementation of MHPAEA.[60] In addition, nearly all plans had eliminated the use of separate deductibles for mental health or substance use disorder out-of-pocket costs by 2011.[61] (Even by 2010, only 3.2 percent of plans had used separate deductibles.) The HHS study also found that the number of plans that applied unequal inpatient day limits, outpatient visit limits or other quantitative treatment limitations for mental health or substance use disorder benefits had dropped significantly by 2011.

Since this study found that the implementation of the requirements of MHPAEA has progressed consistent with the interim final rules, this impact analysis includes estimates of any additional costs and benefits resulting from changes made to the provisions in the interim final regulations by these final regulations. As background, in section III.D of this preamble, the Departments summarize the cost estimates included in the interim final regulations.

B. Need for Regulatory Action

Congress directed the Departments to issue regulations implementing the MHPAEA provisions. In response to this Congressional directive, these final regulations clarify and interpret the MHPAEA provisions under section 712 of ERISA, section 2726 of the PHS Act, and section 9812 of the Code. Historically, plans have offered coverage for mental health conditions and substance use disorders at lower levels than coverage for other conditions. Plans limited coverage through restrictive benefit designs that discouraged enrollment by individuals perceived to be high-cost due to their behavioral health conditions and by imposing special limits on mental health and substance use disorder benefits out of concern that otherwise utilization and costs would be unsustainable. Parity advocates argued that these approaches were unfair and limited access to needed treatment for vulnerable populations. In addition, research demonstrated that restrictive benefit designs were not the only way to address costs.[62] Initially, MHPA 1996 was designed to eliminate more restrictive annual and lifetime dollar limits on mental health benefits. However, as illustrated in a General Accountability Office report on implementation of MHPA 1996, the statute had an unintended consequence: most plans coming into compliance instead turned to more restrictive financial requirements and treatment limitations.[63]

These final regulations provide the specificity and clarity needed to effectively implement the provisions of MHPAEA and prevent the use of prohibited limits on coverage, including nonquantitative treatment limitations that disproportionately limit coverage of treatment for mental health conditions or substance use disorders. The requirements in these final regulations are needed to address questions and concerns that have been raised regarding the implications of the interim final regulations with regard to intermediate level services, NQTLs, and the increasing use of multi-tiered provider networks. The Departments' assessment of the expected economic effects of these regulations is discussed in detail below.

C. Response to Comments on the Economic Impact Analysis for the Interim Final Regulations—Department of Labor and Department of Health and Human Services

The Departments received the following public comments regarding the economic impact analysis in the interim final regulations.

One commenter urged that the discussion on cost implications for increased utilization of mental health and substance use disorder services must take into account the cost savings that will result from the elimination of the costs associated with "unique and discriminatory medical management controls" (or NQTLs). Although the Departments concur that the nature and rigor of utilization management affects

[59] Final Report: Consistency of Large Employer and Group Health Plan Benefits with Requirements of the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008. NORC at the University of Chicago for the Office of the Assistant Secretary for Planning and Evaluation. This study analyzed information on large group health plan benefit designs from 2009 through 2011 in several databases maintained by benefits consulting firms that advise plans on compliance with MHPAEA as well as other requirements.

[60] Ibid.

[61] Ibid.

[62] See discussion in the preamble to the interim final rule on the effect of managed care in controlling health plan spending on mental health and substance use disorder treatment under state parity laws and in the Federal Employee Health Benefit Program, Interim Final Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, 75 Fed. Reg. 5410, 5424–5425 (see e.g., footnote 46) (February 2, 2010).

[63] General Accountability Office, *Mental Health Parity Act: Despite New Federal Standards, Mental Health Benefits Remain Limited*, May 2000, (GAO/HEHS–00–95), p. 5. In this 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.

the cost of care and the administrative expenses associated with care management, there is scant evidence at this time on the way that utilization management will evolve under MHPAEA. Existing evidence suggests that plans and issuers can apply a range of tools to manage care and that even when management of care is consistent with the principles of parity, care management continues. (See the discussion of Oregon state parity law later in this preamble).

Several commenters asserted that the Departments had underestimated the cost and burden of complying with the interim final regulations. However, a study sponsored by HHS found that by 2011 most plans had removed most financial requirements that did not meet the requirements of MHPAEA and the interim final regulations.[64] In addition, the number of plans that applied unequal inpatient day limits, outpatient visit limits, or other quantitative treatment limitations for mental health or substance use disorder benefits had dropped significantly by 2011. Yet, there is no evidence that plans' costs and burdens have been significantly impacted by the requirements of the statute and its implementing interim final regulations. Research has shown that only a very small percentage of plans have dropped mental health or substance use disorder benefits after implementation of MHPAEA and even for those plans that did so, there is no clear evidence that they dropped mental health or substance use disorder benefits because of MHPAEA. Moreover, no plans have applied for the increased cost exemption under MHPAEA. Finally, in spending reports that have been reported in the aggregate, there is no evidence that spending growth for behavioral health saw a significant upturn in 2011, the first full year in which the interim final regulations generally were in effect.

One commenter asserted that plans are not set up to conduct a parity analysis within the six classifications and as a result the interim final regulations impose a substantial burden, especially on employers that offer multiple plans. In response, the Departments note that the alternative to using the six classifications would require conducting a parity analysis across all types of benefits grouped together that would have resulted in incongruous and unintended consequences with, for example, day limits for inpatient care being the standard for outpatient benefits. Moreover, there is no evidence that plans or issuers have found these requirements to be overly burdensome.

One commenter stated that the Federal Employees' Health Benefits Program (FEHBP) parity requirements and State parity laws are not comparable to the standards in the interim final regulations and therefore are not predictive of the possible cost impacts of the interim final regulations, especially regarding NQTLs. In response, the Departments note that, like MHPAEA, the parity requirements for FEHBP apply to financial requirements and treatment limitations for both mental health conditions and substance use disorders. Furthermore, the FEHBP requirements are more expansive in that "plans must cover all categories of mental health or substance use disorders to the extent that the services are included in authorized treatment plans . . . developed in accordance with evidence-based clinical guidelines, and meet[ing] medical necessity criteria." [65] Under the MHPAEA statute, plans and issuers have discretion as to which diagnoses and conditions are covered under the plan.

Several State parity laws are very similar to MHPAEA. For example, Vermont's parity law applies to both mental health and substance use disorder benefits.[66] The Vermont parity law also requires that management of care for these conditions be in accordance with rules adopted by the State Department of Insurance to assure that timely and appropriate access to care is available; that the quantity, location and specialty distribution of health care providers is adequate and that administrative or clinical protocols do not serve to reduce access to medically necessary treatment.[67] These requirements are very similar to the NQTL requirements under MHPAEA which likewise seek to ensure plans and issuers do not inequitably limit access to mental health or substance use disorder treatment. In addition, the NQTLs requirements likewise require comparable approaches to utilization management through protocols and other strategies in determining coverage of mental health and substance use disorder treatment compared to medical/surgical treatment. A study of this State parity law also did not find significant increases in cost.[68]

The Oregon State parity law is also very similar to MHPAEA in that it applies to mental health and substance use disorder financial requirements and treatment limitations and also applies to NQTLs. According to the Oregon Insurance Division, utilization management tools such as "selectively contracted panels of providers, health policy benefit differential designs, preadmission screening, prior authorization, case management, utilization review, or other mechanisms designed to limit eligible expenses to treatment that is medically necessary" may not be used for management of mental health or substance use disorder benefits unless they were used in the same manner that such methods were used for other medical conditions.[69] A study of the Oregon parity law found that plans removed coverage limits as required and used management techniques to the same degree or less under this law and the impact on mental health and substance use disorder spending was minimal.[70] Together, the similarities between the FEHBP, Vermont, and Oregon parity requirements lead the Departments to conclude that any differences in terms of the impacts on cost would be small.

Several commenters argued that the requirement in the interim final regulations to use a single or shared deductible in a classification is overly burdensome and would require significant resources to implement, particularly by MBHOs since they often work with multiple plans. One commenter asserted that this requirement could impact the willingness of sponsors to offer mental health or substance use disorder benefits. In response, the Departments note that a study sponsored by HHS found that nearly all plans had eliminated the use of separate deductibles for mental health and substance use disorder benefits by

[64] Final Report: Consistency of Large Employer and Group Health Plan Benefits with Requirements of the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008. NORC at the University of Chicago for the Office of the Assistant Secretary for Planning and Evaluation. This study analyzed information on large group health plan benefit designs from 2009 through 2011 in several databases maintained by benefits consulting firms that advise plans on compliance with MHPAEA as well as other requirements.

[65] FEHB Program Carrier Letter, No. 2009–08, April 20, 2009.

[66] Vt. Stat. Ann tit. 8, § 4089b (1998).

[67] Ibid.

[68] Rosenbach M, Lake T, Young C, et al. Effects of the Vermont Mental Health and Substance Abuse Parity Law. DHHS Pub. No. SMA 03–3822, Rockville, MD: Substance Abuse and Mental Health Services Administration, 2003.

[69] Q&A Oregon Mental Health Parity Law for Providers. Oregon Insurance Division Web site. *http://www.cbs.state.or.us/ins/FAQs/mental-health-parity_provider-faqs.pdf.*

[70] McConnell JK, Gast SH, Ridgely SM. Behavioral health insurance parity: Does Oregon's experience presage the national experience with the Mental Health Parity and Addiction Equity Act? *American Journal of Psychiatry* 2012; 169(1): 31–38.

2011.[71] According to this study, even in 2010, only a very small percentage of plans were using separate deductibles. This study and other research have shown that only a very small percent of plans have dropped mental health or substance use disorder benefits after implementation of MHPAEA and there is no clear evidence they did so because of MHPAEA.

One commenter urged that the regulations be revised to be less burdensome for plans that are part of a more comprehensive network of benefits within Medicaid healthcare delivery systems. These final regulations apply to group health plans and health insurance issuers but do not, by their own terms, apply to Medicaid. In response, the Departments note that CMS oversees implementation of federal requirements for the Medicaid program. CMS issued a state health official letter on the application of MHPAEA to Medicaid managed care organizations, the Children's Health Insurance Program, and Alternative Benefit (Benchmark) plans on January 16, 2013.[72]

Two commenters raised concerns about the burden imposed on plans by the requirement that provider reimbursement rates be based on comparable criteria particularly for MBHOs that may as a result have to use multiple rate schedules. The Departments believe that the process of establishing rate schedules is already complex, that MBHOs that contract with other multiple plans are likely to already have multiple rate schedules, and that adding a parity requirement to ensure that rates for behavioral health providers are based on comparable criteria to those used for medical/surgical providers does not add much to this complexity.

One commenter argued that the costs for outpatient mental health and substance use disorder benefits will be higher than estimated because the NQTL parity standard would hamper plans' ability to manage care and control costs. In response, the Departments note that, as discussed above, the Oregon State parity law also applies to NQTLs and a study of this law found that plans in that State removed coverage limits as required and used management techniques to the same degree or less under the Oregon law and the impact on mental health and substance use disorder spending was minimal.[73]

D. Summary of the Regulatory Impact Analysis for the Interim Final Regulations—Department of Labor and Department of Health and Human Services

In the regulatory impact analysis for the interim final regulations, the Departments quantified the costs associated with three aspects of that rulemaking: The cost of implementing a unified deductible, compliance review costs, and costs associated with information disclosure requirements in MHPAEA. The Departments estimated the cost of developing the interface necessary to implement a single deductible as $35,000 per affected interface between a managed behavioral health company and a group health plan with a total estimated cost at $39.2 million (amounting to $0.60 per health plan enrollee) in the first year. The interim final regulations' impact analysis estimated the cost to health plans and insurance issuers of reviewing coverage for compliance with MHPAEA and the interim final regulations at $27.8 million total. This estimate was based on findings that there were about 460 issuers and at least 120 MBHOs and assumed that per-plan compliance costs would be low because third party administrators for self-insured plans would spread the cost across multiple client plans.

Regarding the requirement to disclose medical necessity criteria, the Departments assumed that each plan would receive one such request on average, that it would take a trained staff person about five minutes to respond, and with an average hourly rate of $27, the total annual cost would be about $1 million. The Departments assumed only 38 percent of requests would be delivered electronically with de minimis cost and that the materials, printing and postage costs of responding to about 290,000 requests by paper would be an additional $192,000 for a total of about $1.2 million per year. These costs totaled $114.6 million undiscounted over ten years (2010–2019). The Departments did not include a cost for the requirement in MHPAEA to disclose the reasons for any claims denials because the Department of Labor's claims procedure regulation (at 29 CFR 2560.503–1) already required such disclosures and the same third-party administrators and insurers are hired by ERISA and non-ERISA covered plans so both types of plans were likely to already be in compliance with these rules.

In terms of transfers, in the interim final regulations impact analysis, the Departments estimated premiums would rise 0.4 percent due to MHPAEA, reflecting a transfer from individuals not using mental health and substance use disorder benefits to those that do. This estimated increase in premiums amounted to a transfer of $2.36 billion in 2010 gradually increasing each year over a ten year period to $2.81 billion in 2019. This estimate was based on findings in the literature. For a more complete discussion, see section III.I later in this preamble.

E. Summary of the Impacts of the Final Rule—Department of Labor and Department of Health and Human Services

Table 1, below, summarizes the costs associated with the final regulations above the costs estimated for the interim final regulations. Over a five-year period of 2014 to 2018, the total undiscounted cost of the rule is estimated to be $1.16 billion in 2012 dollars. Columns D and E display the costs discounted at 3 percent and 7 percent, respectively. Column F shows a transfer of $3.5 billion over the five-year period. All other numbers included in the text are not discounted, except where noted.

[71] Final Report: Consistency of Large Employer and Group Health Plan Benefits with Requirements of the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008. NORC at the University of Chicago for the Office of the Assistant Secretary for Planning and Evaluation.

[72] Application of the Mental Health Parity and Addiction Equity Act to Medicaid MCOs, CHIP, and Alternative Benefit (Benchmark) Plans, available at: *http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SHO-13-001.pdf.*

[73] McConnell JK, Gast SH, Ridgely SM. Behavioral health insurance parity: does Oregon's experience presage the national experience with the Mental Health Parity and Addiction Equity Act? *American Journal of Psychiatry* 2012; 169(1): 31–38.

TABLE 1—TOTAL COSTS OF FINAL REGULATIONS

[In millions of 2012 dollars]

Year	Incremental change in individual market plan spending (A)	Disclosure requirements (B)	Total undiscounted costs A+B	Total 3% discounted costs (D)	Total 7% discounted costs (E)	Transfers (undiscounted) (F)
2014	$189.9	$4.3	$194.2	$194.2	$194.2	$699.2
2015	208.4	4.3	212.7	206.5	198.8	732.0
2016	226.8	4.3	231.1	217.9	201.9	764.8
2017	245.3	4.3	249.6	228.4	203.7	797.6
2018	263.8	4.3	268.1	238.2	204.5	830.4
Total	1,134.2	21.5	1,155.6	1085.1	1,003.1	3,824.0

1. Estimated Number of Affected Entities

MHPAEA has already brought about coverage changes for approximately 103 million participants in 420,700 ERISA-covered employment-based group health plans with more than 50 participants, and an estimated 29.5 million participants in the approximately 23,000 public, non-Federal employer group health plans with more than 50 participants sponsored by State and local governments. Plans with 50 or fewer participants were previously exempt from MHPAEA.[74] In addition, approximately 510 health insurance issuers providing mental health or substance use disorder benefits in the group and individual health insurance markets and at least 120 MBHOs providing mental health or substance use disorder benefits to group health plans are also affected by these final regulations.[75]

As discussed earlier, the Affordable Care Act extended MHPAEA to apply to a health insurance issuer offering individual health insurance coverage and the HHS final regulation regarding EHB requires QHPs and non-grandfathered health insurance plans in the individual and small group markets to provide covered mental health and substance use disorder services in a manner that complies with the parity requirements of the MHPAEA implementing regulations in order to satisfy the requirement to cover EHB. According to the 2012 Medical Loss Ratio filings, about 11 million people are covered in the individual market; another 7 million are expected to gain coverage in 2014 under the Affordable Care Act.[76] There are an estimated 12.3 million participants in about 837,000 non-grandfathered ERISA-covered employment-based group plans with 50 or fewer participants, and an estimated 800,000 participants in approximately 59,000 non-grandfathered public, non-Federal employer group health plans with 50 or fewer participants sponsored by State and local governments which were previously exempt from MHPAEA.

About one-third of those who are currently covered in the individual market have no coverage for substance use disorder services and nearly 20 percent have no coverage for mental health services, including outpatient therapy visits and inpatient crisis intervention and stabilization.[77] In addition, even when individual market plans provide these benefits, the federal parity law previously did not apply to these plans to ensure that coverage for mental health and substance use disorder services is generally comparable to coverage for medical and surgical care.

In the small group market, coverage of mental health and substance use disorder treatment is more common than in the individual market. We estimate that about 95 percent of those with small group market coverage have substance abuse and mental health benefits.[78] Again, the federal parity law previously did not apply to small group plans. In many States, State parity laws offer those covered in this market some parity protection, but most State parity laws are narrower than the federal parity requirement.

2. Anticipated Benefits

a. Benefits Attributable to the Statute or Interim Final Regulations

In enacting MHPAEA, one of Congress' primary objectives was to improve access to mental health and substance use disorder benefits by eliminating more restrictive visit limits and inpatient days covered as well as higher cost-sharing for mental health and substance use disorder benefits that were prevalent in private insurance plans after implementation of MHPA 1996.[79]

A recent study funded by HHS found that large group health plans and insurance issuers have made significant changes to financial requirements and treatment limitations for mental health and substance use disorder benefits in the first few years following enactment of MHPAEA.[80] The statute went into effect for plan years beginning after October 3, 2009 (calendar year 2010 for

[74] The Departments' estimates of the numbers of affected participants are based on DOL estimates using the 2012 CPS. ERISA plan counts are based on DOL estimates using the 2011 MEP–IC and Census Bureau statistics. The number of State and local government employer-sponsored plans was estimated using 2012 Census data and DOL 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.

[75] The Departments' estimate of the number of insurers is based on medical loss ratio reports submitted by issuers for 2012 reporting year and industry trade association membership. Please note that these estimates could undercount small State-regulated insurers.

[76] "Effects on Health Insurance and the Federal Budget for the Insurance Coverage Provisions in the Affordable Care Act—May 2013 Baseline," Congressional Budget Office, May 14, 2013.

[77] ASPE Issue Brief, "Essential Health Benefits: Individual Market Coverage," ed. U.S. Department of Health & Human Services (2011).

[78] ASPE Issue Brief, "Essential Health Benefits: Comparing Benefits in Small Group Products and State and Federal Employee Plans," ed. U.S. Department of Health & Human Services (2011).

[79] See the interim final regulations for a fuller discussion of the legislative history.

[80] Final Report: Consistency of Large Employer and Group Health Plan Benefits with Requirements of the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 at pages vii–ix. NORC at the University of Chicago for the Office of the Assistant Secretary for Planning and Evaluation. This study analyzed information on large group health plan benefit designs from 2009 through 2011 in several databases maintained by benefits consulting firms that advise plans on compliance with MHPAEA as well as other requirements.

many plans) and the interim final regulations went into effect for plans years beginning on or after July 10, 2010 (calendar year 2011 for many plans). This HHS study found that by 2011, most plans had removed most financial requirements and treatment limitations that did not meet the requirements of MHPAEA and its implementing interim final regulations.

According to this HHS study, in 2010, ten percent of a nationally representative sample of large employers' behavioral health benefits had *inpatient* financial requirements (*e.g.,* deductibles, co-pays, or co-insurance) that needed modification to comply with MHPAEA. Analysis of a separate set of large employer-based plans for 2011 found virtually all 230 large employer-based plans included had inpatient benefits that conformed to MHPAEA standards. A third database of plan designs from 2009 through 2011 confirmed that the use of higher copayments and coinsurance for inpatient mental health and substance use disorder services declined rapidly in large employer plans following implementation of MHPAEA.[81]

Among the representative sample of plans for 2010 included in this study, more than 30 percent had copayments or coinsurance rates for *outpatient* mental health and substance use disorder benefits that were inconsistent with MHPAEA. In a separate sample of large employer-based plans for 2011, the use of higher coinsurance for mental health and substance use disorder benefits dropped dramatically. However, the study found that about 20 percent of the 140 plans tested continued to utilize outpatient in-network co-pays that failed to meet MHPAEA standards. A third database of plan designs for 2009 through 2011 confirmed a dramatic decline in the use of more restrictive cost-sharing for outpatient mental health and substance use disorder benefits although a minority continued to use high copays.

Nearly all plans had eliminated the use of separate deductibles for mental health or substance use disorder out-of-pocket costs by 2011. (Even by 2010, only 3.2 percent of plans had used separate deductibles.)[82]

The HHS study also found that the number of plans that applied unequal inpatient day limits, outpatient visit limits or other quantitative treatment limitations for mental health or substance use disorder benefits had dropped significantly by 2011. In 2010, it found that most large employer-based plans used day limits on mental health *inpatient* benefits that generally conformed to MHPAEA standards. While almost 20 percent of these plans imposed more restrictive day limits on in-network, inpatient benefits for substance use disorders than applied to medical/surgical benefits, the separate sample of 2011 large employer-based plans indicated a significant decline with only eight percent of plans using stricter day limits for inpatient benefits for substance use disorders. These findings were corroborated by analysis of an additional database of plan designs from 2009 through 2011, which also indicated a dramatic decline in the proportion of plans using more restrictive inpatient day limits on mental health and substance use disorder benefits (from 50 percent in 2009 to ten percent in 2010).

In 2010, more than 50 percent of large employer-based plans in the study's representative sample used more restrictive visit limits for outpatient mental health and substance use disorder services that did not conform to MHPAEA standards. But, in the 2011 sample of large employer-based health plans, less than seven percent were using unequal visit limits. This trend was also evident in the plan design database comparing plans across 2009, 2010, and 2011. There too, substantial reductions in quantitative treatment limitations for mental health and substance use disorder benefits in large employer-based plans were seen after enactment of MHPAEA.

b. Potential Benefits of the Final Regulations

The Departments expect that MHPAEA and these final regulations will have their greatest impact on people needing the most intensive treatment and financial protection. The Departments cannot estimate how large this impact will be, but the numbers of beneficiaries who have a medical necessity for substantial amount of care are likely to be relatively small.

Improving coverage in the small group and individual markets will also expand financial protection for a significant segment of those covered and soon to be covered by private health insurance. One indicator of the consequences of unprotected financial risk is bankruptcies. The literature on bankruptcies identifies mental health care as a source of high spending that is less protected than other areas of health care.[83] One estimate is that about 17 percent of bankruptcies are due to health care bills.[84] Another estimate using the same data is that about ten percent of medical bankruptcies are attributable to high mental health care costs, and an additional two to three percent of bankruptcies are attributable to drug and alcohol abuse.[85] Improvements in coverage of mental health and substance use disorder services expected to result from implementation of MHPAEA can be expected to reduce some of the financial risk and also yield successful treatment for people with mental health or substance use disorder problems.

Earlier entry into treatment may have a salutary impact on entry into disability programs. Of the 8.6 million disabled workers receiving Social Security Disability Insurance benefits, 28 percent are identified as having a disability related to mental disorders, not including intellectual disability. Mental disorders are the second largest diagnostic category among awards to disabled workers, after conditions associated with the musculoskeletal system and connective tissue (29 percent) but ahead of those related to the circulatory system (8.5 percent).[86]

Improving coverage of mental health and substance use disorder treatment could also more generally improve productivity and improve earnings among those with these conditions. Studies have shown that the high prevalence of depression causes $31 billion to $51 billion annually in lost productivity in the United States.[87] 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.[88] A recent meta-analysis of randomized studies that

[81] Ibid at page xii.

[82] Ibid at page xi.

[83] Robertson CT, R Egelhof, M Hoke, Get Sick, Get Out: The Medical Causes of Home Mortgage Foreclosures, Health Matrix 18:65–105, 2008.

[84] Dranove D and ML Millenson, Medical Bankruptcy: Myth Versus Fact, Health Affairs 25, w74–w83 February 28, 2006.

[85] Dranove D and ML Millenson, Medical Bankruptcy: Myth Versus Fact, Health Affairs 25, w74–w83 February 28, 2006.

[86] Social Security Administration (SSA). (2012). Annual Statistical Report on the Social Security Disability Insurance Program, 2011. SSA Publication No. 13–11826.

[87] 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.

[88] 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.

examined the impact of treating depression on labor market outcomes showed that while the labor supply effects were smaller than the impact on clinical symptoms, there were consistently significant and positive effects of treatment on labor supply.[89] [90] Although the expected impact of MHPAEA on labor supply is likely modest for large employers, it is probably considerably larger for small group and individual plans where pre-MHPAEA coverage was more limited than in the large group market.

As stated earlier, these final regulations clarify that the general rule regarding consistency in classification of benefits applies to intermediate services provided under the plan or coverage. These final regulations are expected to maintain or perhaps slightly improve coverage for intermediate levels of care. These services that fall between inpatient care for acute conditions and regular outpatient care can be effective at improving outcomes for people with mental health conditions or substance use disorders.[91] [92] [93]

This final rule allows for policies such as multi-tiered provider networks. Multi-tiered networks are spreading rapidly among large group policies. There is some early evidence that such approaches can successfully attenuate costs and improve quality of care.

3. Anticipated Costs

a. Illustrative Results From Past Policy Interventions

Existing evidence on implementation of parity in States and FEHBP suggests there will not be significant increases in plan expenditures and premiums as a result of the increased access to mental health and substance use disorder services that are expected to result from these final regulations. Since the effective date of the interim final regulations, no employer has applied for a cost exemption. A recent research study funded by HHS shows that in general, large employer-sponsored plans eliminated higher financial requirements and more limited inpatient day limits, outpatient visit limits and other quantitative treatment limitations for mental health or substance use disorder benefits fairly quickly in the first few years following the enactment of MHPAEA. Differences in cost sharing for prescription medications and emergency care also declined, and by 2011 almost all large employer-based plans studied appeared to comply with MHPAEA for those benefits.[94] Over that same period, a very small percent of employers dropped mental health or substance use disorder coverage. Moreover, there is no clear evidence that the small number of plans that did drop mental health and substance use disorder coverage did so because of MHPAEA.

Furthermore, evidence suggests that plans did not exclude more mental health or substance use disorder diagnoses from coverage in response to MHPAEA and there is no evidence that plans or employers reduced medical/surgical benefits to comply with parity requirements.[95] All of these findings indicate that any increases in the costs of covering mental health and substance use disorder benefits following implementation of MHPAEA did not have a substantial impact on overall plan spending.

Other recent analyses of claims data from self-insured employer-sponsored group health plans have suggested that an overwhelming majority of privately insured individuals who used mental health or substance use disorder services prior to MHPAEA did so at a rate far below pre-parity limits on benefits.[96] Using econometric models to estimate the effect of MHPAEA on high-utilization beneficiaries who are most likely to use expanded coverage, researchers have estimated that MHPAEA may at most increase total health care costs by 0.6 percent.[97] Furthermore, a recent study of substance use disorder spending from 2001 to 2009 by large employer-sponsored health plans shows that substance use disorder spending remained a relatively constant share of all health spending, comprising about 0.4 percent of all health spending in 2009. This low share of overall spending means that even large increases in utilization of substance use disorder treatment are unlikely to have a significant impact on premiums.[98]

Although most State parity laws are more limited than MHPAEA, some are comparable, and studies on the impact of these more comparable laws provide a fair indication of the effect of MHPAEA. For example, Oregon's State parity law enacted in 2007 is quite comparable in that it applies to treatment limits (including NQTLs) and financial requirements for mental health and substance use disorder benefits. A study of the Oregon parity law found that plans removed coverage limits and used management techniques more consistently but did not significantly increase spending on mental health and substance use disorder care.[99] Vermont's parity law also applies to both mental health and substance use disorder services. A study of this State parity law also did not find significant increases in spending.[100]

b. Costs (and Transfers) Attributable to the Final Regulations

The Departments do not expect the clarification that plans should classify intermediate services consistently for mental health and substance use disorders and medical/surgical benefits will result in a significant increase in costs. Nor do the Departments expect the clarification that the NQTL rules apply to these types of services to cause a substantial increase in plan spending. Analyses of claims data for large group health plans conducted by two different contractors for HHS indicate that most plans cover intermediate behavioral health services, particularly partial hospitalization and intensive outpatient services, but intermediate services account for less than one percent of total health plan spending.[101] Internal

[89] Timbie JW, M Horvitz-Lennon, RG Frank and SLT Normand, A Meta-Analysis of Labor Supply Interventions for Major Depressive Disorder, Psychiatric Services 57(2) 212–219, 2006.

[90] Wang PS, GE Simon, J Avorn et al, Telephone Screening, Outreach, and Care Management for Depressed Workers and Impact on Clinical and Work Productivity Outcomes, JAMA 298(12) 1401–1411, 2007.

[91] Bateman A, Fonagy P: Treatment of borderline personality disorder with psychoanalytically oriented partial hospitalization: an 18-month follow-up. Am J Psychiatry 2001; 158:36–42.

[92] Horvitz-Lennon M, Normand SL, Gaccione P and Frank RG. "Partial vs. Full Hospitalization for Adults in Psychiatric Distress: A Systematic Review of the Published Literature." *American Journal of Psychiatry*, 158(5), 2001.

[93] Drake, Robert E., Erica L. O'Neal, and Michael A. Wallach. "A systematic review of psychosocial research on psychosocial interventions for people with co-occurring severe mental and substance use disorders." *Journal of substance abuse treatment* 34.1 (2008): 123–138.

[94] Final Report for ASPE: Consistency of Large Employer and Group Health Plan Benefits with Requirements of the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 at page x. NORC at the University of Chicago for the Office of the Assistant Secretary for Planning and Evaluation.

[95] Ibid at page xi.

[96] Mark, TL, Vandivort-Warren, R, Miller, K, Mental health spending by private insurance: Implications for the Mental Health Parity and Addiction Equity Act, Psych Services, 2012; 63(4): 313–318.

[97] Ibid.

[98] Ibid.

[99] Ibid.

[100] Mark, TL, Vandivort-Warren, R, Spending trends on substance abuse treatment under private employer-sponsored insurance, 2001–2009, Drug and Alcohol Dependence, 2012; 125:203–207.

[101] Short-Term Analysis to Support Mental Health and Substance Use Disorder Parity Implementation. RAND Corporation for the Office of the Assistant Secretary for Planning and Evaluation. February 8, 2012 (*http://aspe.hhs.gov/daltcp/reports/2012/mhsud.shtml*); internal analysis of claims data for large self-insured employers and health plans.

research and analysis by HHS indicates that the number of enrollees who use intermediate services for mental health and substance use disorders is very small. Furthermore, those who used intermediate services did so at modest rates. In addition, the number of enrollees who used intermediate services for medical/surgical benefits was similarly small. Available data suggest that intermediate behavioral health services account for between eight percent and eleven percent of total behavioral health spending in private insurance. This means that since behavioral health care accounts for about 5.5 percent of health plan spending, intermediate behavioral health spending amounts to between 0.4 and 0.6 percent of total health plan spending. In light of the small number of enrollees that utilize this intermediate level of care and the small percentage of total costs that intermediate mental health and substance use disorder services comprise, the Departments expect that any increase in coverage would be very unlikely to have any significant effect on total health plan spending.

Moreover, the Departments investigated the patterns of classification of intermediate services and found that they are generally covered in the six classifications set out in the interim final regulations. Behavioral health intermediate services are generally categorized in a similar fashion as analogous medical services; for example, residential treatment tends to be categorized in the same way as skilled nursing facility care in the inpatient classification. Thus, the Departments do not expect much change in how most plans consider intermediate behavioral health care in terms of the six existing benefit classifications.

Tiered provider networks are expanding in private health insurance. The interim final regulations made no allowance for such insurance innovations. The final regulations clarify how the parity requirements apply to multi-tiered provider networks. The evidence on the impact of these networks is beginning to emerge.[102] There is some evidence that points to small reductions in health spending associated with tiered provider networks. There are also studies showing little to no savings associated with these network designs. Some modest impact on quality has been observed in some cases and none in others.[103] The Departments are therefore assuming no cost impact of this provision.

There is limited data on spending for mental health and substance use disorder treatment under individual health insurance plans. The Departments therefore rely on some recent tabulations from the Medical Expenditure Panel Survey (MEPS) and a recent report on premiums and coverage in the individual health insurance market along with information from several other sources to make projections of the likely impact of applying MHPAEA to the individual market.[104] The Departments began by estimating baseline spending in the individual market. The Departments calculate the weighted average premium for the individual insurance market from the paper by Whitmore and colleagues that was reported in 2007 dollars and inflate it to 2012 dollars using the GDP deflator. Because premiums report more than just health care costs, the Departments convert the premium into plan payments for services by applying the medical loss ratio of 0.70 reported in the technical appendix to the Medical Loss Ratio interim final rule.[105] The resulting estimate is $2437 in 2012 dollars. That figure represents total health spending by plans per member per year. The Departments obtain an estimate of the behavioral health costs by assuming that about four percent of those expenditures are for behavioral health. That figure is obtained by recognizing that coverage for behavioral health in the individual market is more limited than in the employer sponsored insurance market where mental health and substance use disorder care accounts for about 5.5 percent of spending overall.[106] Applying the four percent figure to the plan spending estimates results in an estimate of $98 per member per year in plan spending for mental health and substance use disorder benefits. The Departments then calculate the share of spending paid out-of-pocket by using the MEPS data to obtain an estimate of outpatient mental health and substance use disorder out-of-pocket spending, because outpatient services generally carry higher cost sharing than inpatient care and because overall non-inpatient care accounts for about 65 to 70 percent of behavioral health care. The MEPS data indicate that out-of-pocket costs for mental health and substance use disorder care accounts for 47 percent of total spending. This contrasts with an estimate of 26 percent for medical/surgical care. The implication of this is a total (plan and out-of-pocket) spending estimate for mental health and substance use disorder benefits of $185 per member per year in 2012. It is important to recognize that roughly 40 percent of total behavioral health spending in private insurance is accounted for by spending on psychotropic drugs and drug benefits will remain relatively unchanged, to the extent prescription drug tiers are based on neutral factors independent of whether a particular drug is prescribed to treat a medical/surgical condition, or a mental health condition or substance use disorder. This is because psychotropic drugs are typically under the same benefit design and formulary rules as all other drugs in private health insurance. Thus the baseline spending that would be affected by MHPAEA is estimated to be $111 per member per year.

To obtain the impact of extending MHPAEA to the individual market, the Departments assume that a primary impact of MHPAEA is to equalize cost sharing arrangements between mental health and substance use disorder benefits and medical/surgical benefits. The Departments therefore assume that the out-of-pocket share for mental health and substance use disorder services covered in the individual insurance market will decline from 47 percent to 26 percent. The Departments apply an estimate of the price elasticity of demand to the total spending level for mental health and substance use disorder for people covered in the individual market. Two recent studies have shown that the price elasticity of demand for mental health and substance use disorder care has declined significantly in the era of managed care.[107] They show that the elasticity of

[102] Thomas JM, G Nalli AF Cockburn. What we know and don't know about tiered provider networks, Journal of Health Care Finance 33(4), 53–67, 2007; Sinaiko AD, Tiered provider Networks as a Strategy to Improve Health Care Quality and Efficiency, NICHM Foundation February 2012.

[103] Ibid.

[104] Whitmore H, JR Gabel, J Pickreign R McDevitt, The Individual Insurance Market Before Reform: Low Premiums and Low Benefits, Medical Care Research and Review 68(5): 594–606, 2011.

[105] Technical Appendix to the Regulatory Impact Analysis for the Interim Final Rule for Health Insurance Issuers Implementing the Medical Loss Ratio Requirements under the Patient Protection and Affordable Care Act, Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, November 22, 2010, available at *http://www.cms.gov/CCIIO/Resources/Files/Downloads/mlr_20101122_technical_appendix.pdf.*

[106] Substance Abuse and Mental Health Services Administration. National Expenditures for Mental Health Services and Substance Abuse Treatment, 1986–2009. HHS Publication No. SMA–13–4740. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

[107] Meyerhoefer CD and Zuvekas, S, "New Estimates of the Demand for Physical and Mental Health Treatment", *Health Economics* 19(3): 297–

demand for ambulatory care fell between -0.16 and -0.26. This is relevant because the Whitmore paper reports that roughly 95 percent of individual policies are either under managed care arrangements of some form or are part of a Health Savings Account policy (17.5 percent). The Departments therefore apply an elasticity of -0.21 to the 45 percent reduction in out-of-pocket costs for people using mental health and substance use disorder care. That yields a projected 9.5 percent increase in total spending for mental health and substance use disorder care for people in the individual market. Applying the 9.5 percent estimate to the $111 baseline subject to MHPAEA provisions results in an impact estimate of $10.55 per covered person in 2012 or a 5.7 percent increase in total mental health and substance use disorder spending and a 0.04 percent change in total plan spending. The Departments apply the per insured person cost of mental health and substance use disorder care in the individual market estimate to an estimate of the population that would be covered under individual coverage after January of 2014. Based on the Congressional Budget Office estimates of the impact of the Affordable Care Act, the Departments expect enrollment in the individual market to be approximately 18 million people as of 2014.[108] Applying the $10.55 estimate to the 18 million people[109] suggests a total spending increase of about $189.9 million in 2012 dollars. The Departments project that, by 2018, the 25 million-enrollee estimate shown in CBO's report will capture all individual plan coverage. Assuming a constant rate of growth in enrollment, the five year cost will be $1.13 billion. This estimate reflects increased spending on mental health and substance use disorder services resulting from coverage expansion that is attributable to MHPAEA above and beyond historical levels in the small group and individual markets and beyond the EHB coverage requirements for mental health and substance use disorder coverage.

MHPAEA can be expected to affect coverage in the small group market through the provisions governing EHBs. The Departments estimate that there are currently approximately 27 million people insured under small group benefits. The Congressional Budget Office (CBO) and HHS projections are in agreement that there will be little change in the size of this market in the coming years. Thus for the purposes of this analysis the Departments assume that the market will remain stable at 27.3 million insured (including 26.1 million in ERISA plans and 1.2 million in public plans).[110] In examining coverage in the small group market using data from 2012, the Departments find that plans used comparable levels of management to large group plans in that less than 1 percent of either small group or large group enrollees are covered by indemnity insurance arrangements. HMOs account for 15 percent of small group and 16 percent of large group enrollees. PPOs/POS plans account for 61 percent of small group and 67 percent of large group enrollees. High deductible plans make up 17 percent of small group and 24 percent of large group enrollees.[111] In addition, other recent analyses show that the actuarial value of health insurance benefits in large and small group plans are largely identical.[112] Data from recent studies of parity implementation in Oregon that focused in great part on small group coverage shows that parity had the effect of reducing out-of-pocket spending. Yet because it was done in the context of managed care arrangements (including regulations of management practices) there was no statistically significant impact on total spending on mental health and substance use disorder services attributable to parity.[113] For this reason, the Departments assume that virtually all the impact of MHPAEA on the small group market involves a shift of final responsibility for payment from households to insurers. The Oregon parity results (McConnell et al., 2012) are consistent with a shift of roughly 0.5 percent of spending. This shift in cost constitutes a transfer (see additional analysis in section III.D.4 below).

The final regulations retain the disclosure provisions for group health plans and health insurance coverage offered in connection with a group health plan. In addition, these disclosure provisions are extended to non-grandfathered insurance coverage in the small group market through the EHB requirements and to the individual market as a result of the amendments to the PHS Act under the Affordable Care Act as discussed in section II.F and II.H.1 of this preamble. The burden and cost related to these disclosure requirements are discussed in detail in the Paperwork Reduction Act section below and are estimated to be approximately $4.3 million per year.

4. Transfers

The application of MHPAEA to the individual market will also shift responsibility for some existing payments from individuals to health plans by reducing cost sharing from 47 percent to 26 percent, or $336 million in the first year increasing to $467 million by 2018 reflecting increases in the number of individual enrollees. The Departments estimate that this shift in cost-sharing to plans combined with the increase in spending due to increased utilization discussed above could be expected to lead to an increase of 0.8% in premiums in the individual market. The small group plan average premium in 2012 was $5588. Applying the 0.5 percent estimated shift in spending derived above in section III.E.3 to the average premium as a proxy for plan spending, the Departments obtain a figure of $27.94. Multiplying that figure by 13 million enrollees in small group plans yields an estimated transfer amount of $363 million per year. Likewise, premiums in the small group market may be expected to increase by 0.5%.

F. Regulatory Alternatives

In addition to the regulatory approach outlined in these final regulations, the Departments considered several alternatives when developing policy regarding NQTLs, disclosure requirements, multi-tier provider networks, and how parity applies to intermediate services.

Multiple stakeholders requested clarification regarding the application of the parity requirements to NQTLs. The Departments considered narrowing the clinically appropriate standard of care exception instead of eliminating it.

315 2010;. Lu C, Frank, RG and McGuire TG. "Demand Response of Mental Health Services to Cost Sharing Under Managed Care." *Journal of Mental Health Policy and Economics* 11(3):113–126 2008.

[108] "Effects on Health Insurance and the Federal Budget for the Insurance Coverage Provisions in the Affordable Care Act—May 2013 Baseline," Congressional Budget Office, May 14, 2013.

[109] The figure of 11 million enrollees based on the 2012 MLR filings data discussed earlier in this preamble is added to the CBO estimate of enrollees in the individual market in 2014.

[110] Congressional Budget Office, Letter to the Honorable Paul Ryan: Analysis of the Administration's Announced delay of certain Requirements Under the Affordable Care Act, July 30, 2013; and CBO's May 2013 Estimates of the Effects of the Affordable Care Act on Health Insurance Coverage, May 14, 2013.

[111] Kaiser Family Foundation and Health Research and Educational Trust, Employer Health Benefits—2012 Annual Survey.

[112] McDevitt R, J Gabel, R Lore et al, Group Insurance: A Better Deal for Most People than Individual Plans, Health Affairs 29(1): 156–164, 2010.

[113] McConnell KJ, SHN Gast, MS Ridgely et al. Behavioral Health Insurance Parity: Does Oregon's Experience Presage the National Experience with the Mental Health Parity and Addiction Equity Act?, American Journal of Psychiatry 2012; 169(1): 31–38.

However, this approach could result in even more confusion regarding how to apply the parity standard for NQTLs. Moreover, a technical expert panel comprised of individuals with clinical expertise in mental health and substance use disorder treatment as well as general medical treatment, and experience developing and using evidence-based practice guidelines, could not identify situations in which the exception allowing a clinically appropriate standard of care to justify a different use of NQTLs would be needed.[114] Thus, the Departments believe that clarification in paragraph (c)(4) of the regulations will not reduce the flexibility afforded to plans and issuers by the underlying rule.

As stated earlier, concerns have also been raised regarding disclosure and transparency. The Departments considered whether participants and beneficiaries have adequate access to information regarding the processes, strategies, evidentiary standards, or other factors used to apply the NQTL and also comparable information regarding medical/surgical benefits to ensure compliance with MHPAEA. These final regulations make clear that plans and issuers are required to make this information available in accordance with MHPAEA and other applicable law, such as ERISA and the Affordable Care Act, more generally. The Departments also are publishing contemporaneously with publication of these final regulations, another set of FAQs.[115] Among other things, these FAQs solicit comments on whether more should be done, and how, to ensure transparency and compliance.

The Departments are aware of the increasing use of multi-tier provider networks and commenters have asked how parity requirements should apply to those arrangements. The Departments considered as an alternative requiring plans to collapse their provider tiers in conducting an assessment of compliance with parity. However, this would have negated a primary reason to have provider tiers which is to offer incentives for providers to accept lower reimbursement in exchange for lower copays for their services and presumably greater patient volume. The Departments considered this alternative to be interfering unreasonably with legitimate plan cost-management techniques. The approach in the final regulations strikes a reasonable balance between allowing plans to use provider tiers to effectively manage costs and the policy principles of MHPAEA.

As described earlier in this preamble, many commenters to the interim final regulations requested that the Departments clarify how MHPAEA affects the scope of coverage for intermediate services (such as residential treatment for substance use disorders or mental health conditions, partial hospitalization, and intensive outpatient treatment) and how these services fit within the six classifications set forth by the interim final regulations. Some stakeholders recommended establishing a separate classification for this intermediate level of care. The Departments considered this approach but determined that whereas the existing classifications—inpatient, in-network; inpatient, out-of-network; outpatient, in-network; outpatient, out-of-network; emergency care, and prescription medications—are classifications commonly used by health plans and issuers, a separate classification for intermediate care is not commonly used by plans and issuers. The Departments believe that a clearer, more reasonable approach is to incorporate the principles of parity into existing benefit designs and care management strategies. Thus, the final regulations provide examples of intermediate services and clarify that plans and issuers must assign covered intermediate level mental health and substance use disorder benefits to the existing six benefit classifications in the same way that they assign comparable intermediate medical/surgical benefits to these classifications.

G. Regulatory Flexibility Act—Department of Labor and Department of Health and Human Services

The Regulatory Flexibility Act (RFA) requires agencies that issue a rule to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The RFA generally defines a "small entity" as—(1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a nonprofit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000 (States and individuals are not included in the definition of "small entity"). A change in revenues of more than 3 percent to 5 percent is often used by the Departments of Labor and HHS as the measure of significant economic impact on a substantial number of small entities.

As discussed in the Web Portal interim final rule with comment period published on May 5, 2010 (75 FR 24481), HHS examined the health insurance industry in depth in the Regulatory Impact Analysis for the proposed rule on establishment of the Medicare Advantage program (69 FR 46866, August 3, 2004). In that analysis it was determined that there were few, if any, insurance firms underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) that fell below the size thresholds for "small" business (currently $35.5 million in annual receipts for health insurance issuers).[116] HHS also used the data from Medical Loss Ratio annual report submissions for the 2012 reporting year to develop an estimate of the number of small entities that offer comprehensive major medical coverage. These estimates may overstate the actual number of small health insurance issuers that would be affected by these regulations, since they do not include receipts from these companies' other lines of business. It is estimated that there are 58 small entities with less than $35.5 million each in earned premiums that offer individual or group health insurance coverage and would therefore be subject to the requirements of these regulations. Forty-three percent of these small issuers belong to larger holding groups, and many, if not all, of these small issuers are likely to have other lines of business that would result in their revenues exceeding $35.5 million. For these reasons, the Departments expect that these final regulations will not significantly affect a substantial number of small issuers.

As noted previously, MHPAEA provisions are extended to non-grandfathered insurance coverage in the small group market through the EHB requirements. Group health plans and health insurance coverage offered by small employers will incur costs to comply with the provisions of these final regulations. There are an estimated 837,000 ERISA-covered non-grandfathered employer group health plans with 50 or fewer participants, and an estimated 59,000 non-grandfathered public, non-Federal employer group health plans with 50 or fewer participants sponsored by State and local governments which were

[114] Short-Term Analysis to Support Mental Health and Substance Use Disorder Parity Implementation. RAND Corporation for the Office of the Assistant Secretary for Planning and Evaluation. February 8, 2012 (*http://aspe.hhs.gov/daltcp/reports/2012/mhsud.shtml*).

[115] Available at: *http://www.dol.gov/ebsa/healthreform/and http://www.cms.gov/cciio/Resources/Fact-Sheets-and-FAQs/index.html.*

[116] "Table of Small Business Size Standards Matched To North American Industry Classification System Codes," effective July 23, 2013, U.S. Small Business Administration, available at *http://www.sba.gov.*

previously exempt from MHPAEA. Approximately 13 million participants of these plans will benefit from the provisions of these regulations. As explained earlier in this impact analysis, virtually all the impact of MHPAEA on the small group market will involve a shift of final responsibility for payment from households to insurers, resulting in an estimated increase of 0.5 percent in spending. The cost related to the disclosure requirements is estimated to be approximately $2.4 million for non-grandfathered small group plans that were previously exempt from MHPAEA. The Departments expect the rules to reduce the compliance burden imposed on plans and insurers by the statute and the implementing interim final regulations by clarifying definitions and terms contained in the statute and providing examples of acceptable methods to comply with specific provisions.

H. Special Analyses—Department of the Treasury

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, as supplemented by Executive Order 13563. 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. It is hereby certified that the collections of information contained in these final regulations will not have a significant impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required.

The final regulations generally apply to employers who provide health coverage through group health plans to employees that include benefits for mental health or substance use disorder conditions. The IRS expects the final regulations to reduce the compliance burden imposed on plans and issuers by clarifying definitions and terms contained in the statute and providing examples of acceptable methods to comply with specific provisions. MHPAEA and the regulations under it do not apply to employers with 50 or fewer employees (although, separately, the EHB regulations adopt MHPAEA). Moreover, small employers subject to the rule that have more than 50 employees will generally provide any health coverage through insurance or a third-party administrator. The issuers of insurance or other third-party administrators of the health plans, rather than the small employers, will as a practical matter, satisfy the requirements of the regulations in order to provide a marketable product. For this reason, the burden imposed by the reporting requirement of the statute and these final regulations on small entities is expected to be near zero. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding these final regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small businesses.

I. Paperwork Reduction Act

The table below summarizes the hour burden and costs related to the disclosure requirements in these regulations. For plans that use issuers or third party administrators, the costs are reported as cost burden while for plans that administer claims in-house, the burden is reported as hour burden.

Plan type	Number of respondents	Labor hours	Cost burden
ERISA-Covered Employer Group Health Plans	1,258,000	11,976	$2,989,000
Public, Non-Federal Employer Group Health Plans	82,324	2,517	1,375,312
Individual Market Health Plans	418	25,465	51,066

1. Departments of Labor and the Treasury

In accordance with the requirements of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)), the interim final regulations solicited comments on the information collections included therein. The Departments submitted an information collection request (ICR) to OMB in accordance with 44 U.S.C. 3507(d), contemporaneously with the publication of the interim final regulations for OMB's review. OMB approved the ICR on April 27, 2010, under OMB Control Numbers 1210–0138 (Department of Labor) and 1545–2165 (Department of the Treasury/IRS). The Departments also submitted an ICR to OMB in accordance with 44 U.S.C. 3507(d) for the ICR as revised by the final regulations. OMB approved the ICR under OMB control numbers 1210–0138 and 1545–2165, which will expire on November 30, 2016.

As discussed earlier in this preamble, the final regulations retain the disclosure provisions for group health plans and health insurance coverage offered in connection with a group health plan. (In addition, these disclosure provisions are extended to non-grandfathered insurance coverage in the small group market through the EHB requirements and to the individual market as a result of the amendments to the PHS Act under the Affordable Care Act, as discussed in section II.F and II.H.1 of this preamble.)

The MHPAEA disclosures are information collection requests (ICRs) subject to the PRA. The final regulations (29 CFR 2590.712(d)(2)) require a Claims Denial Disclosure to be made available upon request or as otherwise required by the plan administrator (or the health insurance issuer offering such coverage) to a participant or beneficiary that provides 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.

The Departments did not submit an IRC to OMB for the Claims Denial Disclosure, because the Department of Labor's ERISA claims procedure regulation (29 CFR 2560.503–1) and disclosure regulation (29 CFR 2520.104b–1) already require such disclosure. The same third-party administrators and insurers are hired by ERISA and non-ERISA covered plans, so both types of plans were likely to already be in compliance with the Department of Labor rules. Therefore, the hour and cost burden associated with the claims denial notice already is accounted in the ICR for the ERISA claims procedure regulation that was approved under OMB Control Number 1210–0053.

The final regulations (29 CFR 2590.712(d)(1)) also require 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 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 there are about 1,258,000 ERISA covered health plans affected by the regulations. The Departments estimate that approximately seven percent of large plans and all small plans administer claims using service providers; therefore, about 11 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 $26.85 [117] per hour. This results in an annual hour burden of nearly 12,000 hours and an associated equivalent cost of nearly $322,000 for the approximately 144,000 requests done in-house by plans. The remaining 1,114,000 medical necessity criteria disclosures will be provided through service providers resulting in a cost burden of approximately $2,493,000.

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 780,000 medical necessity criteria disclosures sent by paper will be approximately $496,000.[118] 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.[119] The Departments will provide notice of OMB approval via a **Federal Register** notice.

These paperwork burden estimates are summarized as follows:

Type of Review: Ongoing.

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

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

OMB Number: 1210–0138; 1545–2165.

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

Total Respondents: 1,258,000.

Total Responses: 1,258,000.

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours: 5,988 hours (Employee Benefits Security Administration); 5,988 hours (Internal Revenue Service).

Estimated Total Annual Burden Cost: $1,494,000 (Employee Benefits Security Administration); $1,494,000 (Internal Revenue Service).

2. Department of Health and Human Services

As discussed earlier in this preamble, the final regulations retain the disclosure provisions for group health plans and health insurance coverage offered in connection with a group health plan. (In addition, these disclosure provisions are extended to non-grandfathered insurance coverage in the small group market through the EHB requirements and to the individual market as a result of the amendments to the PHS Act under the Affordable Care Act, as discussed in section II.F and II.H.1 of this preamble.) The burden estimates below have been updated to reflect these changes.

In addition, as described earlier in this preamble, the final regulations reiterate that, in addition to MHPAEA's disclosure requirements, provisions of other applicable law require disclosure of information relevant to medical/surgical, mental health, and substance use disorder benefits. For example, the Departments' claims and appeals regulations under the Affordable Care Act (applicable to non-grandfathered group health plans (including non-ERISA plans) and non-grandfathered health insurance issuers in the group and individual markets),[120] set forth rules regarding claims and appeals, including the right of claimants (or their authorized representative) upon appeal of an adverse benefit determination (or a final internal adverse benefit determination) to be provided, upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the claimant's claim for benefits.[121] The burden associated with this disclosure is accounted for in the ICR approved under OMB control number 0938–1099.

Medical Necessity Disclosure

HHS estimates that there are about 30.2 million participants covered by approximately 82,0004 State and local public plans that are subject to the MHPAEA disclosure requirements.[122] HHS is unable to estimate with certainty the number of requests for medical necessity criteria disclosures that will be received by plan administrators; however, HHS has assumed that, on average, each plan affected by the rule will receive one request. HHS estimates that approximately 93 percent of large plans administer claims using third party administrators. 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 administrators, the costs are reported as cost burden while for plans that administer claims in-house, the burden is reported as hour burden. For purposes of this estimate, HHS 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 [123] per hour. This results in an annual hour burden of 350 hours and an associated equivalent cost of about $9,000 for the approximately 4,200 requests handled by plans. The remaining 78,000 claims (94.9 percent) are provided through a third-party administrator or an issuer and results in a cost burden of approximately $175,000.

In the individual market there will be an estimated 18 million enrollees [124] enrolled in plans offered by 418 issuers

[117] EBSA estimates based on the National Occupational Employment Survey (June 2012, Bureau of Labor Statistics) and the Employment Cost Index (September 2012, Bureau of Labor Statistics).

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

[119] 5 CFR 1320.1 through 1320.18.

[120] 29 CFR 2560.503–1. *See also* 26 CFR 54.9815–2719T(b)(2)(i), 29 CFR 2590.715–2719(b)(2)(i), and 45 CFR 147.136(b)(2)(i), requiring non-grandfathered plans and issuers to incorporate the internal claims and appeals processes set forth in 29 CFR 2560.503–1.

[121] As described earlier in this preamble, this includes documents with information on medical necessity criteria for both medical/surgical benefits and mental health and substance use disorder benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply a nonquantitative treatment limitation with respect to medical/surgical benefits and mental health or substance use disorder benefits under the plan.

[122] 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.

[123] EBSA estimates based on the National Occupational Employment Survey (June 2012, Bureau of Labor Statistics) and the Employment Cost Index (September 2012, Bureau of Labor Statistics).

[124] Estimate based on medical loss ratio reports submitted by issuers for 2012 reporting year and from the study "Effects on Health Insurance and the Federal Budget for the Insurance Coverage Provisions in the Affordable Care Act—May 2013 Baseline," by Congressional Budget Office, May 14, 2013.

offering coverage in multiple states. Assuming that, on average, each issuer will receive one request in each State that it offers coverage in, there will be a total of about 2,600 requests in each year. The annual burden to issuers for sending the medical necessity disclosures is estimated to be 220 hours with an associated equivalent cost of approximately $6,000.

Claims Denial Disclosure

As described earlier in this preamble, the Department of Labor's ERISA claims procedure regulation (29 CFR 2560.503–1) already requires such disclosures. Although non-ERISA covered plans, such as plans sponsored by State and local governments and individual plans that are subject to the PHS Act, are not required to comply with the ERISA claims procedure regulation, the 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, HHS estimates that for State and local public plans, there will be approximately 30.9 million claims for mental health or substance use disorder benefits with approximately 4.6 million denials that could result in a request for the reason for denial. HHS 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 (464,000 requests). HHS estimates that a medically trained clerical staff member may require five minutes to respond to each request at a labor rate of $26.85 per hour. This results in an annual burden of nearly 2,000 hours and an associated equivalent cost of nearly $53,000 for the approximately 24,000 requests completed by plans. The remaining 440,000 are provided through an issuer or a third-party administrator, which results in a cost burden of approximately $984,000. In the individual market, under similar assumptions, HHS estimates that there will be approximately 18.4 million claims for mental health or substance use disorder benefits with approximately 2.75 million denials that could result in a request for explanation of denial. Assuming ten percent of denials result in such a request, it is estimated that there will be about 275,000 requests for an explanation of reason for denial, which will be completed with a burden of 23,000 hours and equivalent cost of approximately $616,000.

In association with the explanation of denial, participants may request a copy of the medical necessity criteria. While HHS does not know how many notices of denial will result in a request for the criteria of medical necessity, HHS assumes that ten percent of those requesting an explanation of the reason for denial will also request the criteria of medical necessity, resulting in about 46,000 requests, 2,400 of which will be completed in-house with a burden of 200 hours and equivalent cost of approximately $5,000 and about 44,000 requests handled by issuers or third-party providers with a cost burden of approximately $98,000. In the individual market, under similar assumptions, HHS estimates that there will be about 27,500 requests for medical necessity criteria, which will be completed with a burden of 2,295 hours and equivalent cost of approximately $62,000.

HHS also calculated the cost to deliver the requested information. Many insurers or plans may already have the information prepared in electronic format, and HHS assumes that requests will be delivered electronically resulting in a de minimis cost.[125] HHS estimates that the cost burden associated with distributing the approximately 256,000 disclosures sent by paper will be approximately $169,000.[126]

The ICRs associated with the medical necessity and claims denial disclosures are currently approved under OMB control number 0938–1080. The Department will seek OMB approval for revised ICRs that will include the burden to small group health plans and individual market plans related to the disclosure requirements in the final regulations. A **Federal Register** notice will be published, providing the public with an opportunity to comment on the ICRs.

J. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act (UMRA) of 1995 requires that agencies assess anticipated costs and benefits before issuing any final rule that includes a Federal mandate that could result in expenditure in any one year by State, local or tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold level is approximately $141 million. These regulations are not subject to the UMRA because they were not preceded by a notice of proposed rulemaking. However, consistent with policy embodied in the UMRA, these regulations have been designed to be a low-burden alternative for State, local and tribal governments, and the private sector while achieving the objectives of MHPAEA.

K. Federalism Statement—Department of Labor and Department of Health and Human Services

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

In the Departments' view, these regulations have Federalism implications, because they have direct effects on the States, the relationship between the Federal 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 2724 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

[125] 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.

[126] This estimate is based on an average document size of four pages, $.05 cents per page material and printing costs, $0.46 cent postage costs.

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. For example, HHS has provided training on MHPAEA for state regulators though the National Association Insurance Commissioners (NAIC) and has been available to State regulators to address any issues that arise. HHS has also collaborated with regulators in a number of States on MHPAEA enforcement strategies with the goal of maintaining state regulator involvement in the implementation and enforcement of MHPAEA in their States. It is expected that the Departments will continue to 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.

L. Congressional Review Act

These final 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.), which specifies that before a rule can take effect, the Federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and have been transmitted to Congress and the Comptroller General for review.

IV. Statutory Authority

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

The Department of Labor 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 1–2011, 77 FR 1088 (January 9, 2012).

The Department of Health and Human Services 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 Parts 146 and 147

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

John Dalrymple,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Approved: November 6, 2013.

Mark J. Mazur,

Assistant Secretary of the Treasury (Tax Policy).

Signed this 6th day of November, 2013.

Phyllis C. Borzi,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Dated: October 25, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 5, 2013.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Chapter I

Accordingly, 26 CFR Part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ **Paragraph 1.** The authority citation for part 54 is amended by removing the entry for § 54.9812–1T and by adding an entry in numerical order to read as follows:

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

Section 54.9812–1 also issued under 26 U.S.C. 9833. * * *

■ **Par. 2.** Section 54.9812–1T is removed.

■ **Par. 3.** Section 54.9812–1 is added to read as follows:

§ 54.9812–1 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 with respect to items or services for medical conditions or surgical procedures, as defined under the terms of the plan or health insurance coverage and in accordance with applicable Federal and State law, but does not include mental health or substance use disorder benefits. Any condition defined by the plan or coverage 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 items or services for mental health conditions, as defined under the terms of the plan or health insurance coverage and in accordance with applicable Federal and State law. Any condition defined by the plan or coverage 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 items or services for substance use disorders, as defined under the terms of the plan or health insurance coverage 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 or coverage. (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 for purposes of this definition.

(b) *Parity requirements with respect to aggregate lifetime and annual dollar limits.* This paragraph (b) details the application of the parity requirements with respect to aggregate lifetime and annual dollar limits. This paragraph (b) does not address the provisions of PHS Act section 2711, as incorporated in ERISA section 715 and Code section 9815, which prohibit imposing lifetime and annual limits on the dollar value of essential health benefits.

(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)(5) 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) *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.

(5) *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)(5)(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)(5), the weighting applicable to any category of medical/surgical benefits is determined in the manner set forth in paragraph (b)(4) of this section for determining one-third or two-thirds of all medical/surgical benefits.

(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 (illustrated in examples in paragraph (c)(2)(ii)(C) of this section). 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. See special rules for plans with multiple network tiers in paragraph (c)(3)(iii) of this section.

(*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. See special rules for office visits and plans with multiple network tiers in paragraph (c)(3)(iii) of this section.

(*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. See special rules for office visits in paragraph (c)(3)(iii) of this section.

(*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 care, 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 care 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. (See also PHS Act section 2707(b) and Affordable Care Act section 1302(c), which establish limitations on annual deductibles for non-grandfathered health plans in the small group market and annual limitations on out-of-pocket maximums for all non-grandfathered health plans.)

(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 rules*—(A) *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.

(B) *Multiple network tiers.* If a plan (or health insurance coverage) provides benefits through multiple tiers of in-network providers (such as an in-network tier of preferred providers with more generous cost-sharing to participants than a separate in-network tier of participating providers), the plan may divide its benefits furnished on an in-network basis into sub-classifications that reflect network tiers, if the tiering is based on reasonable factors determined in accordance with the rules in paragraph (c)(4)(i) of this section (such as quality, performance, and market standards) and without regard to whether a provider provides services with respect to medical/surgical benefits or mental health or substance use disorder benefits. After the sub-classifications are established, the plan or issuer may not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (c)(3)(i) of this section.

(C) *Sub-classifications permitted for office visits, separate from other outpatient services.* For purposes of applying the financial requirement and treatment limitation rules of this paragraph (c), a plan or issuer may divide its benefits furnished on an outpatient basis into the two sub-classifications described in this paragraph (c)(3)(iii)(C). After the sub-classifications are established, the plan or issuer may not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (c)(3)(i) of this section. Sub-classifications other than these special rules, such as separate sub-classifications for generalists and specialists, are not permitted. The two sub-classifications permitted under this paragraph (c)(3)(iii)(C) are:

(*1*) Office visits (such as physician visits), and

(*2*) All other outpatient items and services (such as outpatient surgery, facility charges for day treatment centers, laboratory charges, or other medical items).

(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).

Example 5. (i) *Facts.* A plan has two-tiers of network of providers: a preferred provider tier and a participating provider tier. Providers are placed in either the preferred tier or participating tier based on reasonable factors determined in accordance with the rules in paragraph (c)(4)(i) of this section, such as accreditation, quality and performance measures (including customer feedback), and relative reimbursement rates. Furthermore, provider tier placement is determined without regard to whether a provider specializes in the treatment of mental health conditions or substance use disorders, or medical/surgical conditions. The plan divides the in-network classifications into two sub-classifications (in-network/preferred and in-network/participating). The plan does not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(ii) *Conclusion.* In this *Example 5,* the division of in-network benefits into sub-classifications that reflect the preferred and participating provider tiers does not violate the parity requirements of this paragraph (c)(3).

Example 6. (i) *Facts.* With respect to outpatient, in-network benefits, a plan imposes a $25 copayment for office visits and a 20 percent coinsurance requirement for outpatient surgery. The plan divides the outpatient, in-network classification into two sub-classifications (in-network office visits and all other outpatient, in-network items and services). The plan or issuer does not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(ii) *Conclusion.* In this *Example 6,* the division of outpatient, in-network benefits into sub-classifications for office visits and all other outpatient, in-network items and services does not violate the parity requirements of this paragraph (c)(3).

Example 7. (i) *Facts.* Same facts as *Example 6,* but for purposes of determining parity, the plan divides the outpatient, in-network classification into outpatient, in-network generalists and outpatient, in-network specialists.

(ii) *Conclusion.* In this *Example 7,* the division of outpatient, in-network benefits into any sub-classifications other than office visits and all other outpatient items and services violates the requirements of paragraph (c)(3)(iii)(C) of this section.

(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.

(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) For plans with multiple network tiers (such as preferred providers and participating providers), network tier design;

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

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

(F) 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);

(G) Exclusions based on failure to complete a course of treatment; and

(H) Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the plan or coverage.

(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 plan requires prior authorization from the plan's utilization reviewer that a treatment is medically necessary for all inpatient medical/surgical benefits and for all inpatient mental health and substance use disorder benefits. In practice, inpatient benefits for medical/surgical conditions are routinely approved for seven days, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan. On the other hand, for inpatient mental health and substance use disorder benefits, routine approval is given only for one day, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan.

(ii) *Conclusion.* In this Example 1, the plan violates the rules of this paragraph (c)(4) because it is applying a stricter nonquantitative treatment limitation in practice to mental health and substance use disorder benefits than is applied to medical/surgical benefits.

Example 2. (i) *Facts.* A plan applies concurrent review to inpatient care where there are high levels of variation in length of stay (as measured by a coefficient of variation exceeding 0.8). In practice, the application of this standard affects 60 percent of mental health conditions and substance use disorders, but only 30 percent of medical/surgical conditions.

(ii) *Conclusion.* In this *Example 2,* the plan complies with the rules of this paragraph (c)(4) because the evidentiary standard used by the plan is applied no more stringently for mental health and substance use disorder benefits than for medical/surgical benefits, even though it results in an overall difference in the application of concurrent review for mental health conditions or substance use disorders than for medical/surgical conditions.

Example 3. (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 and uses comparable criteria in determining whether a course of treatment is medically necessary. 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 3,* 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, it is not applied in a comparable way. 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 4. (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 is based on clinically appropriate standards of care for a condition.

(ii) *Conclusion.* In this *Example 4,* the plan complies with the rules of this paragraph (c)(4) because the processes for developing the evidentiary standards used to determine medical appropriateness and the application of these standards 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 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 5. (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 5,* the plan violates the rules of this paragraph (c)(4). Although the standard for applying a nonquantitative treatment limitation is the same for both mental health and substance use disorder benefits and medical/surgical benefits—whether a drug has a black box warning—it is not applied in a comparable manner. 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 6. (i) *Facts.* An employer maintains both a major medical plan 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 plan 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 plan.

(ii) *Conclusion.* In this *Example 6,* 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.

Example 7. (i) *Facts.* Training and State licensing requirements often vary among types of providers. A plan applies a general standard that any provider must meet the highest licensing requirement related to supervised clinical experience under applicable State law in order to participate in the plan's provider network. Therefore, the plan requires master's-level mental health therapists to have post-degree, supervised clinical experience but does not impose this requirement on master's-level general medical providers because the scope of their licensure under applicable State law does require clinical experience. In addition, the plan does not require post-degree, supervised clinical experience for psychiatrists or Ph.D. level psychologists since their licensing already requires supervised training.

(ii) *Conclusion.* In this *Example 7,* the plan complies with the rules of this paragraph (c)(4). The requirement that master's-level mental health therapists must have supervised clinical experience to join the network is permissible, as long as the plan consistently applies the same standard to all providers even though it may have a disparate impact on certain mental health providers.

Example 8. (i) *Facts.* A plan considers a wide array of factors in designing medical management techniques for both mental health and substance use disorder benefits and medical/surgical benefits, such as cost of treatment; high cost growth; variability in cost and quality; elasticity of demand; provider discretion in determining diagnosis, or type or length of treatment; clinical efficacy of any proposed treatment or service; licensing and accreditation of providers; and claim types with a high percentage of fraud. Based on application of these factors in a comparable fashion, prior authorization is required for some (but not all) mental health and substance use disorder benefits, as well as for some medical/surgical benefits, but not for others. For example, the plan requires prior authorization for: outpatient surgery; speech, occupational, physical, cognitive and behavioral therapy extending for more than six months; durable medical equipment; diagnostic imaging; skilled nursing visits; home infusion therapy; coordinated home care; pain management; high-risk prenatal care; delivery by cesarean section; mastectomy; prostate cancer treatment; narcotics prescribed for more than seven days; and all inpatient services beyond 30 days. The evidence considered in developing its medical management techniques includes consideration of a wide array of recognized medical literature and professional standards and protocols (including comparative effectiveness studies and clinical trials). This evidence and how it was used to develop these medical management techniques is also well documented by the plan.

(ii) *Conclusion.* In this *Example 8,* the plan complies with the rules of this paragraph (c)(4). Under the terms of the plan as written and in operation, the processes, strategies, evidentiary standards, and other factors considered by the plan in implementing its prior authorization requirement with respect to mental health and substance use disorder benefits are comparable to, and applied no more stringently than, those applied with respect to medical/surgical benefits.

Example 9. (i) *Facts.* A plan generally covers medically appropriate treatments. The plan automatically excludes coverage for inpatient substance use disorder treatment in any setting outside of a hospital (such as a freestanding or residential treatment center). For inpatient treatment outside of a hospital for other conditions (including freestanding or residential treatment centers prescribed for mental health conditions, as well as for medical/surgical conditions), the plan will provide coverage if the prescribing physician obtains authorization from the plan that the inpatient treatment is medically appropriate for the individual, based on clinically appropriate standards of care.

(ii) *Conclusion.* In this *Example 9,* 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 substance use disorder treatment in any setting outside of a hospital is not comparable to the conditional exclusion of inpatient treatment outside of a hospital for other conditions.

Example 10. (i) *Facts.* A plan generally provides coverage for medically appropriate medical/surgical benefits as well as mental health and substance use disorder benefits. The plan excludes coverage for inpatient, out-of-network treatment of chemical dependency when obtained outside of the State where the policy is written. There is no similar exclusion for medical/surgical benefits within the same classification.

(ii) *Conclusion.* In this Example 10, the plan violates the rules of this paragraph (c)(4). The plan is imposing a nonquantitative treatment limitation that restricts benefits based on geographic location. Because there is no comparable exclusion that applies to medical/surgical benefits, this exclusion may not be applied to mental health or substance use disorder benefits.

Example 11. (i) *Facts.* A plan requires prior authorization for all outpatient mental health and substance use disorder services after the ninth visit and will only approve up to five additional visits per authorization. With respect to outpatient medical/surgical benefits, the plan allows an initial visit without prior authorization. After the initial visit, the plan pre-approves benefits based on the individual treatment plan recommended by the attending provider based on that individual's specific medical condition. There is no explicit, predetermined cap on the amount of additional visits approved per authorization.

(ii) *Conclusion.* In this *Example 11,* the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation—prior authorization to determine medical appropriateness—is applied to both mental health and substance use disorder benefits and medical/surgical benefits for outpatient services, it is not applied in a comparable way. While the plan is more generous with respect to the number of visits initially provided without pre-authorization for mental health benefits, treating all mental health conditions and substance use disorders in the same manner, while providing for individualized treatment of medical conditions, is not a comparable application of this nonquantitative treatment limitation.

(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 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 by the plan administrator (or the health insurance issuer offering such coverage) 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).

(3) *Provisions of other law.* Compliance with the disclosure requirements in paragraphs (d)(1) and (d)(2) of this section is not determinative of compliance with any other provision of applicable Federal or State law. In particular, in addition to those disclosure requirements, provisions of other applicable law require disclosure of information relevant to medical/surgical, mental health, and substance use disorder benefits. For example, ERISA section 104 and 29 CFR 2520.104b–1 provide that, for plans subject to ERISA, instruments under which the plan is established or operated must generally be furnished to plan participants within 30 days of request. Instruments under which the plan is established or operated include documents with information on medical necessity criteria for both medical/surgical benefits and mental health and substance use disorder benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply a nonquantitative treatment limitation with respect to medical/surgical benefits and mental health or substance use disorder benefits under the plan. In addition, 29 CFR 2560.503–1 and 29 CFR 2590.715–2719 set forth rules regarding claims and appeals, including the right of claimants (or their authorized representative) upon appeal of an adverse benefit determination (or a final internal adverse benefit determination) to be provided upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the claimant's claim for benefits. This includes documents with information on medical necessity criteria for both medical/surgical benefits and mental health and substance use disorder benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply a nonquantitative treatment limitation with respect to medical/surgical benefits and mental health or substance use disorder benefits under the plan.

(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;

(ii) Require a group health plan (or health insurance issuer offering coverage in connection with a group health plan) that provides coverage for mental health or substance use disorder benefits only to the extent required under PHS Act section 2713 to provide additional mental health or substance use disorder benefits in any classification in accordance with this section; or

(iii) 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.

(4) *Coordination with EHB requirements.* Nothing in paragraph (f) or (g) of this section changes the requirements of 45 CFR 147.150 and 45 CFR 156.115, providing that a health insurance issuer offering non-grandfathered health insurance coverage in the individual or small group market providing mental health and substance use disorder services, including behavioral health treatment services, as part of essential health benefits required under 45 CFR 156.110(a)(5) and 156.115(a), must comply with the provisions of 45 CFR 146.136 to satisfy the requirement to provide essential health benefits.

(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 9831(a) 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*—(1) *In general.* If the application of this section to a group health plan (or health insurance coverage offered in connection with such plans) results in an increase for the plan year involved of the actual total cost of coverage with respect to medical/surgical benefits and mental health and substance use disorder benefits as determined and certified under paragraph (g)(3) of this section by an amount that exceeds the applicable percentage described in paragraph (g)(2) of this section of the actual total plan costs, the provisions of this section shall not apply to such plan (or coverage) during the following plan year, and such exemption shall apply to the plan (or coverage) for one plan year. An employer or issuer may elect to continue to provide mental health and substance use disorder benefits in compliance with this section with respect to the plan or coverage involved regardless of any increase in total costs.

(2) *Applicable percentage.* With respect to a plan or coverage, the applicable percentage described in this paragraph (g) is—

(i) 2 percent in the case of the first plan year in which this section is applied to the plan or coverage; and

(ii) 1 percent in the case of each subsequent plan year.

(3) *Determinations by actuaries*—(i) Determinations as to increases in actual costs under a plan or coverage that are attributable to implementation of the requirements of this section shall be made and certified by a qualified and licensed actuary who is a member in good standing of the American Academy of Actuaries. All such determinations must be based on the formula specified in paragraph (g)(4) of this section and shall be in a written report prepared by the actuary.

(ii) The written report described in paragraph (g)(3)(i) of this section shall be maintained by the group health plan or health insurance issuer, along with all supporting documentation relied upon by the actuary, for a period of six years following the notification made under paragraph (g)(6) of this section.

(4) *Formula.* The formula to be used to make the determination under paragraph (g)(3)(i) of this section is expressed mathematically as follows:

$[(E_1 - E_0)/T_0] - D > k$

(i) E_1 is the actual total cost of coverage with respect to mental health and substance use disorder benefits for the base period, including claims paid by the plan or issuer with respect to mental health and substance use disorder benefits and administrative costs (amortized over time) attributable to providing these benefits consistent with the requirements of this section.

(ii) E_0 is the actual total cost of coverage with respect to mental health and substance use disorder benefits for the length of time immediately before the base period (and that is equal in length to the base period), including claims paid by the plan or issuer with respect to mental health and substance use disorder benefits and administrative costs (amortized over time) attributable to providing these benefits.

(iii) T_0 is the actual total cost of coverage with respect to all benefits during the base period.

(iv) k is the applicable percentage of increased cost specified in paragraph (g)(2) of this section that will be expressed as a fraction for purposes of this formula.

(v) D is the average change in spending that is calculated by applying the formula $(E_1 - E_0)/T_0$ to mental health and substance use disorder spending in each of the five prior years and then calculating the average change in spending.

(5) *Six month determination.* If a group health plan or health insurance issuer seeks an exemption under this paragraph (g), determinations under paragraph (g)(3) of this section shall be made after such plan or coverage has complied with this section for at least the first 6 months of the plan year involved.

(6) *Notification.* A group health plan or health insurance issuer that, based on the certification described under paragraph (g)(3) of this section, qualifies for an exemption under this paragraph (g), and elects to implement the exemption, must notify participants and beneficiaries covered under the plan, the Secretary, and the appropriate State agencies of such election.

(i) *Participants and beneficiaries*—(A) *Content of notice.* The notice to participants and beneficiaries must include the following information:

(*1*) A statement that the plan or issuer is exempt from the requirements of this section and a description of the basis for the exemption.

(*2*) The name and telephone number of the individual to contact for further information.

(*3*) The plan or issuer name and plan number (PN).

(*4*) The plan administrator's name, address, and telephone number.

(*5*) For single-employer plans, the plan sponsor's name, address, and telephone number (if different from paragraph (g)(6)(i)(A)(*3*) of this section) and the plan sponsor's employer identification number (EIN).

(*6*) The effective date of such exemption.

(*7*) A statement regarding the ability of participants and beneficiaries to contact the plan administrator or health insurance issuer to see how benefits may be affected as a result of the plan's or issuer's election of the exemption.

(*8*) A statement regarding the availability, upon request and free of charge, of a summary of the information on which the exemption is based (as required under paragraph (g)(6)(i)(D) of this section).

(B) *Use of summary of material reductions in covered services or benefits.* A plan or issuer may satisfy the requirements of paragraph (g)(6)(i)(A) of this section by providing participants and beneficiaries (in accordance with paragraph (g)(6)(i)(C) of this section) with a summary of material reductions in covered services or benefits consistent with 29 CFR 2520.104b–3(d) that also includes the information specified in paragraph (g)(6)(i)(A) of this section. However, in all cases, the exemption is not effective until 30 days after notice has been sent.

(C) *Delivery.* The notice described in this paragraph (g)(6)(i) is required to be provided to all participants and beneficiaries. The notice may be furnished by any method of delivery that satisfies the requirements of section 104(b)(1) of ERISA (29 U.S.C. 1024(b)(1)) and its implementing regulations (for example, first-class mail). If the notice is provided to the participant and any beneficiaries at the participant's last known address, then the requirements of this paragraph (g)(6)(i) are satisfied with respect to the participant and all beneficiaries residing at that address. If a beneficiary's last known address is different from the participant's last known address, a separate notice is required to be provided to the beneficiary at the beneficiary's last known address.

(D) *Availability of documentation.* The plan or issuer must make available to participants and beneficiaries (or their representatives), on request and at no charge, a summary of the information on which the exemption was based. (For purposes of this paragraph (g), an individual who is not a participant or beneficiary and who presents a notice described in paragraph (g)(6)(i) of this section is considered to be a representative. A representative may request the summary of information by

providing the plan a copy of the notice provided to the participant under paragraph (g)(6)(i) of this section with any personally identifiable information redacted.) The summary of information must include the incurred expenditures, the base period, the dollar amount of claims incurred during the base period that would have been denied under the terms of the plan or coverage absent amendments required to comply with paragraphs (b) and (c) of this section, the administrative costs related to those claims, and other administrative costs attributable to complying with the requirements of this section. In no event should the summary of information include any personally identifiable information.

(ii) *Federal agencies*—(A) *Content of notice.* The notice to the Secretary must include the following information:

(*1*) A description of the number of covered lives under the plan (or coverage) involved at the time of the notification, and as applicable, at the time of any prior election of the cost exemption under this paragraph (g) by such plan (or coverage);

(*2*) For both the plan year upon which a cost exemption is sought and the year prior, a description of the actual total costs of coverage with respect to medical/surgical benefits and mental health and substance use disorder benefits; and

(*3*) For both the plan year upon which a cost exemption is sought and the year prior, the actual total costs of coverage with respect to mental health and substance use disorder benefits under the plan.

(B) *Reporting with respect to church plans.* A church plan (as defined in section 414(e)) claiming the exemption of this paragraph (g) for any benefit package, must provide notice to the Department of the Treasury. This requirement is satisfied if the plan sends a copy, to the address designated by the Secretary in generally applicable guidance, of the notice described in paragraph (g)(6)(ii)(A) of this section identifying the benefit package to which the exemption applies.

(C) *Reporting with respect to ERISA plans.* See 29 CFR 2590.712(g)(6)(ii) for delivery with respect to ERISA plans.

(iii) *Confidentiality.* A notification to the Secretary under this paragraph (g)(6) shall be confidential. The Secretary shall make available, upon request and not more than on an annual basis, an anonymous itemization of each notification that includes—

(A) A breakdown of States by the size and type of employers submitting such notification; and

(B) A summary of the data received under paragraph (g)(6)(ii) of this section.

(iv) *Audits.* The Secretary may audit the books and records of a group health plan or a health insurance issuer relating to an exemption, including any actuarial reports, during the 6 year period following notification of such exemption under paragraph (g)(6) of this section. A State agency receiving a notification under paragraph (g)(6) of this section may also conduct such an audit with respect to an exemption covered by such notification.

(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, this section applies to group health plans and health insurance issuers offering group health insurance coverage on the first day of the first plan year beginning on or after July 1, 2014.

(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 date on which the last of the collective bargaining agreements terminates (determined without regard to any extension agreed to after October 3, 2008).

Employee Benefits Security Administration

29 CFR Chapter XXV

29 CFR Part 2590 is amended as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

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

Authority: 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 1–2011, 77 FR 1088 (January 9, 2012).

■ 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 with respect to items or services for medical conditions or surgical procedures, as defined under the terms of the plan or health insurance coverage and in accordance with applicable Federal and State law, but does not include mental health or substance use disorder benefits. Any condition defined by the plan or coverage 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 items or services for mental health conditions, as defined under the terms of the plan or health insurance coverage and in accordance with applicable Federal and State law. Any condition defined by the plan or coverage 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 items or services for substance use disorders, as defined under the terms of the plan or health insurance coverage 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 or coverage. (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 for purposes of this definition.

(b) *Parity requirements with respect to aggregate lifetime and annual dollar limits.* This paragraph (b) details the application of the parity requirements with respect to aggregate lifetime and annual dollar limits. This paragraph (b) does not address the provisions of PHS Act section 2711, as incorporated in ERISA section 715 and Code section 9815, which prohibit imposing lifetime and annual limits on the dollar value of essential health benefits. For more information, see 29 CFR 2590.715–2711.

(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)(5) 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) *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.

(5) *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)(5)(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)(5), the weighting applicable to any category of medical/surgical benefits is determined in the manner set forth in paragraph (b)(4) of this section for determining one-third or two-thirds of all medical/surgical benefits.

(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 (illustrated in examples in paragraph (c)(2)(ii)(C) of this section). 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. See special rules for plans with multiple network tiers in paragraph (c)(3)(iii) of this section.

(*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. See special rules for office visits and plans with multiple network tiers in paragraph (c)(3)(iii) of this section.

(*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. See special rules for office visits in paragraph (c)(3)(iii) of this section.

(*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 care, 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 care 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. (See also PHS Act section 2707(b) and Affordable Care Act section 1302(c), which establish limitations on annual deductibles for non-grandfathered health plans in the small group market and annual limitations on out-of-pocket maximums for all non-grandfathered health plans.)

(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 rules*—(A) *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.

(B) *Multiple network tiers.* If a plan (or health insurance coverage) provides benefits through multiple tiers of in-network providers (such as an in-network tier of preferred providers with more generous cost-sharing to participants than a separate in-network tier of participating providers), the plan may divide its benefits furnished on an in-network basis into sub-classifications that reflect network tiers, if the tiering is based on reasonable factors determined in accordance with the rules in paragraph (c)(4)(i) of this section (such as quality, performance, and market standards) and without regard to whether a provider provides services with respect to medical/surgical benefits or mental health or substance use disorder benefits. After the sub-classifications are established, the plan or issuer may not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in the sub-

classification using the methodology set forth in paragraph (c)(3)(i) of this section.

(C) *Sub-classifications permitted for office visits, separate from other outpatient services.* For purposes of applying the financial requirement and treatment limitation rules of this paragraph (c), a plan or issuer may divide its benefits furnished on an outpatient basis into the two sub-classifications described in this paragraph (c)(3)(iii)(C). After the sub-classifications are established, the plan or issuer may not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (c)(3)(i) of this section. Sub-classifications other than these special rules, such as separate sub-classifications for generalists and specialists, are not permitted. The two sub-classifications permitted under this paragraph (c)(3)(iii)(C) are:

(*1*) Office visits (such as physician visits), and

(*2*) All other outpatient items and services (such as outpatient surgery, facility charges for day treatment centers, laboratory charges, or other medical items).

(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).

Example 5. (i) *Facts.* A plan has two-tiers of network of providers: a preferred provider tier and a participating provider tier. Providers are placed in either the preferred tier or participating tier based on reasonable factors determined in accordance with the rules in paragraph (c)(4)(i) of this section, such as accreditation, quality and performance measures (including customer feedback), and relative reimbursement rates. Furthermore, provider tier placement is determined without regard to whether a provider specializes in the treatment of mental health conditions or substance use disorders, or medical/surgical conditions. The plan divides the in-network classifications into two sub-classifications (in-network/preferred and in-network/participating). The plan does not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(ii) *Conclusion.* In this *Example 5,* the division of in-network benefits into sub-classifications that reflect the preferred and participating provider tiers does not violate the parity requirements of this paragraph (c)(3).

Example 6. (i) *Facts.* With respect to outpatient, in-network benefits, a plan imposes a $25 copayment for office visits and a 20 percent coinsurance requirement for outpatient surgery. The plan divides the outpatient, in-network classification into two sub-classifications (in-network office visits and all other outpatient, in-network items and services). The plan or issuer does not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(ii) *Conclusion.* In this *Example 6,* the division of outpatient, in-network benefits into sub-classifications for office visits and all other outpatient, in-network items and services does not violate the parity requirements of this paragraph (c)(3).

Example 7. (i) *Facts.* Same facts as *Example 6,* but for purposes of determining parity, the plan divides the outpatient, in-network classification into outpatient, in-network generalists and outpatient, in-network specialists.

(ii) *Conclusion.* In this *Example 7,* the division of outpatient, in-network benefits into any sub-classifications other than office visits and all other outpatient items and services violates the requirements of paragraph (c)(3)(iii)(C) of this section.

(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.

(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) For plans with multiple network tiers (such as preferred providers and participating providers), network tier design;

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

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

(F) 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);

(G) Exclusions based on failure to complete a course of treatment; and

(H) Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the plan or coverage.

(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 plan requires prior authorization from the plan's utilization reviewer that a treatment is medically necessary for all inpatient medical/surgical benefits and for all inpatient mental health and substance use disorder benefits. In practice, inpatient benefits for medical/surgical conditions are routinely approved for seven days, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan. On the other hand, for inpatient mental health and substance use disorder benefits, routine approval is given only for one day, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan.

(ii) *Conclusion.* In this Example 1, the plan violates the rules of this paragraph (c)(4) because it is applying a stricter nonquantitative treatment limitation in practice to mental health and substance use disorder benefits than is applied to medical/surgical benefits.

Example 2. (i) *Facts.* A plan applies concurrent review to inpatient care where there are high levels of variation in length of stay (as measured by a coefficient of variation exceeding 0.8). In practice, the application of this standard affects 60 percent of mental health conditions and substance use disorders, but only 30 percent of medical/surgical conditions.

(ii) *Conclusion.* In this *Example 2,* the plan complies with the rules of this paragraph (c)(4) because the evidentiary standard used by the plan is applied no more stringently for mental health and substance use disorder benefits than for medical/surgical benefits, even though it results in an overall difference in the application of concurrent review for mental health conditions or substance use disorders than for medical/surgical conditions.

Example 3. (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 and uses comparable criteria in determining whether a course of treatment is medically necessary. 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 3,* 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, it is not applied in a comparable way. 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 4. (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 is based on clinically appropriate standards of care for a condition.

(ii) *Conclusion.* In this *Example 4,* the plan complies with the rules of this paragraph (c)(4) because the processes for developing the evidentiary standards used to determine medical appropriateness and the application of these standards 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 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 5. (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 5,* the plan violates the rules of this paragraph (c)(4). Although the standard for applying a nonquantitative treatment limitation is the same for both mental health and substance use disorder benefits and medical/surgical benefits—whether a drug has a black box warning—it is not applied in a comparable manner. 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 6. (i) *Facts.* An employer maintains both a major medical plan 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 plan 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 plan.

(ii) *Conclusion.* In this *Example 6,* 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.

Example 7. (i) *Facts.* Training and State licensing requirements often vary among types of providers. A plan applies a general standard that any provider must meet the highest licensing requirement related to supervised clinical experience under applicable State law in order to participate in the plan's provider network. Therefore, the plan requires master's-level mental health therapists to have post-degree, supervised clinical experience but does not impose this requirement on master's-level general medical providers because the scope of their licensure under applicable State law does require clinical experience. In addition, the plan does not require post-degree, supervised clinical experience for psychiatrists or Ph.D. level psychologists since their licensing already requires supervised training.

(ii) *Conclusion.* In this *Example 7,* the plan complies with the rules of this paragraph (c)(4). The requirement that master's-level mental health therapists must have supervised clinical experience to join the network is permissible, as long as the plan consistently applies the same standard to all providers even though it may have a disparate impact on certain mental health providers.

Example 8. (i) *Facts.* A plan considers a wide array of factors in designing medical management techniques for both mental health and substance use disorder benefits and medical/surgical benefits, such as cost of treatment; high cost growth; variability in cost and quality; elasticity of demand; provider discretion in determining diagnosis, or type or length of treatment; clinical efficacy of any proposed treatment or service; licensing and accreditation of providers; and claim types with a high percentage of fraud. Based on application of these factors in a comparable fashion, prior authorization is required for some (but not all) mental health and substance use disorder benefits, as well as for some medical/surgical benefits, but not for others. For example, the plan requires prior authorization for: outpatient surgery; speech, occupational, physical, cognitive and behavioral therapy extending for more than six months; durable medical equipment; diagnostic imaging; skilled nursing visits; home infusion therapy; coordinated home care; pain management; high-risk prenatal care; delivery by cesarean section; mastectomy; prostate cancer treatment; narcotics prescribed for more than seven days; and all inpatient services beyond 30 days. The evidence considered in developing its medical management techniques includes consideration of a wide array of recognized medical literature and professional standards and protocols (including comparative effectiveness studies and clinical trials). This evidence and how it was used to develop these medical management techniques is also well documented by the plan.

(ii) *Conclusion.* In this *Example 8,* the plan complies with the rules of this paragraph (c)(4). Under the terms of the plan as written and in operation, the processes, strategies, evidentiary standards, and other factors considered by the plan in implementing its prior authorization requirement with respect to mental health and substance use disorder benefits are comparable to, and applied no more stringently than, those applied with respect to medical/surgical benefits.

Example 9. (i) *Facts.* A plan generally covers medically appropriate treatments. The plan automatically excludes coverage for inpatient substance use disorder treatment in any setting outside of a hospital (such as a freestanding or residential treatment center). For inpatient treatment outside of a hospital for other conditions (including freestanding or residential treatment centers prescribed for mental health conditions, as well as for medical/surgical conditions), the plan will provide coverage if the prescribing physician obtains authorization from the plan that the inpatient treatment is medically appropriate for the individual, based on clinically appropriate standards of care.

(ii) *Conclusion.* In this *Example 9,* 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 substance use disorder treatment in any setting outside of a hospital is not comparable to the conditional exclusion of inpatient treatment outside of a hospital for other conditions.

Example 10. (i) *Facts.* A plan generally provides coverage for medically appropriate medical/surgical benefits as well as mental health and substance use disorder benefits. The plan excludes coverage for inpatient, out-of-network treatment of chemical dependency when obtained outside of the State where the policy is written. There is no similar exclusion for medical/surgical benefits within the same classification.

(ii) *Conclusion.* In this Example 10, the plan violates the rules of this paragraph (c)(4). The plan is imposing a nonquantitative treatment limitation that restricts benefits based on geographic location. Because there is no comparable exclusion that applies to medical/surgical benefits, this exclusion may not be applied to mental health or substance use disorder benefits.

Example 11. (i) *Facts.* A plan requires prior authorization for all outpatient mental health and substance use disorder services after the ninth visit and will only approve up to five additional visits per authorization. With respect to outpatient medical/surgical benefits, the plan allows an initial visit without prior authorization. After the initial visit, the plan pre-approves benefits based on the individual treatment plan recommended by the attending provider based on that individual's specific medical condition. There is no explicit, predetermined cap on the amount of additional visits approved per authorization.

(ii) *Conclusion.* In this *Example 11,* the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation—prior authorization to determine medical appropriateness—is applied to both mental health and substance use disorder benefits and medical/surgical benefits for outpatient services, it is not applied in a comparable way. While the plan is more generous with respect to the number of visits initially provided without pre-authorization for mental health benefits, treating all mental health conditions and substance use disorders in the same manner, while providing for individualized treatment of medical conditions, is not a comparable application of this nonquantitative treatment limitation.

(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 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 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 requirements of § 2560.503–1 of this chapter for group health plans.

(3) *Provisions of other law.* Compliance with the disclosure requirements in paragraphs (d)(1) and (d)(2) of this section is not determinative of compliance with any other provision of applicable Federal or State law. In particular, in addition to those disclosure requirements, provisions of other applicable law require disclosure of information relevant to medical/surgical, mental health, and substance use disorder benefits. For example, ERISA section 104 and § 2520.104b–1 of this chapter provide that, for plans subject to ERISA, instruments under which the plan is established or operated must generally be furnished to plan participants within 30 days of request. Instruments under which the plan is established or operated include documents with information on medical necessity criteria for both medical/surgical benefits and mental health and substance use disorder benefits, as well as the processes, strategies, evidentiary standards, and other factors used to

apply a nonquantitative treatment limitation with respect to medical/surgical benefits and mental health or substance use disorder benefits under the plan. In addition, §§ 2560.503–1 and 2590.715–2719 of this chapter set forth rules regarding claims and appeals, including the right of claimants (or their authorized representative) upon appeal of an adverse benefit determination (or a final internal adverse benefit determination) to be provided upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the claimant's claim for benefits. This includes documents with information on medical necessity criteria for both medical/surgical benefits and mental health and substance use disorder benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply a nonquantitative treatment limitation with respect to medical/surgical benefits and mental health or substance use disorder benefits under the plan.

(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;

(ii) Require a group health plan (or health insurance issuer offering coverage in connection with a group health plan) that provides coverage for mental health or substance use disorder benefits only to the extent required under PHS Act section 2713 to provide additional mental health or substance use disorder benefits in any classification in accordance with this section; or

(iii) 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.

(4) *Coordination with EHB requirements.* Nothing in paragraph (f) or (g) of this section changes the requirements of 45 CFR 147.150 and 45 CFR 156.115, providing that a health insurance issuer offering non-grandfathered health insurance coverage in the individual or small group market providing mental health and substance use disorder services, including behavioral health treatment services, as part of essential health benefits required under 45 CFR 156.110(a)(5) and 156.115(a), must comply with the provisions of 45 CFR 146.136 to satisfy the requirement to provide essential health benefits.

(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), 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*—(1) *In general.* If the application of this section to a group health plan (or health insurance coverage offered in connection with such plans) results in an increase for the plan year involved of the actual total cost of coverage with respect to medical/surgical benefits and mental health and substance use disorder benefits as determined and certified under paragraph (g)(3) of this section by an amount that exceeds the applicable percentage described in paragraph (g)(2) of this section of the actual total plan costs, the provisions of this section shall not apply to such plan (or coverage) during the following plan year, and such exemption shall apply to the plan (or coverage) for one plan year. An employer or issuer may elect to continue to provide mental health and substance use disorder benefits in compliance with this section with respect to the plan or coverage involved regardless of any increase in total costs.

(2) *Applicable percentage.* With respect to a plan or coverage, the applicable percentage described in this paragraph (g) is—

(i) 2 percent in the case of the first plan year in which this section is applied to the plan or coverage; and

(ii) 1 percent in the case of each subsequent plan year.

(3) *Determinations by actuaries*—(i) Determinations as to increases in actual costs under a plan or coverage that are attributable to implementation of the requirements of this section shall be made and certified by a qualified and licensed actuary who is a member in good standing of the American Academy of Actuaries. All such determinations must be based on the formula specified in paragraph (g)(4) of

this section and shall be in a written report prepared by the actuary.

(ii) The written report described in paragraph (g)(3)(i) of this section shall be maintained by the group health plan or health insurance issuer, along with all supporting documentation relied upon by the actuary, for a period of six years following the notification made under paragraph (g)(6) of this section.

(4) *Formula.* The formula to be used to make the determination under paragraph (g)(3)(i) of this section is expressed mathematically as follows:

$[(E_1 - E_0)/T_0] - D > k$

(i) E_1 is the actual total cost of coverage with respect to mental health and substance use disorder benefits for the base period, including claims paid by the plan or issuer with respect to mental health and substance use disorder benefits and administrative costs (amortized over time) attributable to providing these benefits consistent with the requirements of this section.

(ii) E_0 is the actual total cost of coverage with respect to mental health and substance use disorder benefits for the length of time immediately before the base period (and that is equal in length to the base period), including claims paid by the plan or issuer with respect to mental health and substance use disorder benefits and administrative costs (amortized over time) attributable to providing these benefits.

(iii) T_0 is the actual total cost of coverage with respect to all benefits during the base period.

(iv) k is the applicable percentage of increased cost specified in paragraph (g)(2) of this section that will be expressed as a fraction for purposes of this formula.

(v) D is the average change in spending that is calculated by applying the formula $(E_1 - E_0)/T_0$ to mental health and substance use disorder spending in each of the five prior years and then calculating the average change in spending.

(5) *Six month determination.* If a group health plan or health insurance issuer seeks an exemption under this paragraph (g), determinations under paragraph (g)(3) of this section shall be made after such plan or coverage has complied with this section for at least the first 6 months of the plan year involved.

(6) *Notification.* A group health plan or health insurance issuer that, based on the certification described under paragraph (g)(3) of this section, qualifies for an exemption under this paragraph (g), and elects to implement the exemption, must notify participants and beneficiaries covered under the plan, the Secretary, and the appropriate State agencies of such election.

(i) *Participants and beneficiaries*—(A) *Content of notice.* The notice to participants and beneficiaries must include the following information:

(*1*) A statement that the plan or issuer is exempt from the requirements of this section and a description of the basis for the exemption.

(*2*) The name and telephone number of the individual to contact for further information.

(*3*) The plan or issuer name and plan number (PN).

(*4*) The plan administrator's name, address, and telephone number.

(*5*) For single-employer plans, the plan sponsor's name, address, and telephone number (if different from paragraph (g)(6)(i)(A)(*3*) of this section) and the plan sponsor's employer identification number (EIN).

(*6*) The effective date of such exemption.

(*7*) A statement regarding the ability of participants and beneficiaries to contact the plan administrator or health insurance issuer to see how benefits may be affected as a result of the plan's or issuer's election of the exemption.

(*8*) A statement regarding the availability, upon request and free of charge, of a summary of the information on which the exemption is based (as required under paragraph (g)(6)(i)(D) of this section).

(B) *Use of summary of material reductions in covered services or benefits.* A plan or issuer may satisfy the requirements of paragraph (g)(6)(i)(A) of this section by providing participants and beneficiaries (in accordance with paragraph (g)(6)(i)(C) of this section) with a summary of material reductions in covered services or benefits consistent with § 2520.104b–3(d) of this chapter that also includes the information specified in paragraph (g)(6)(i)(A) of this section. However, in all cases, the exemption is not effective until 30 days after notice has been sent.

(C) *Delivery.* The notice described in this paragraph (g)(6)(i) is required to be provided to all participants and beneficiaries. The notice may be furnished by any method of delivery that satisfies the requirements of section 104(b)(1) of ERISA (29 U.S.C. 1024(b)(1)) and its implementing regulations (for example, first-class mail). If the notice is provided to the participant and any beneficiaries at the participant's last known address, then the requirements of this paragraph (g)(6)(i) are satisfied with respect to the participant and all beneficiaries residing at that address. If a beneficiary's last known address is different from the participant's last known address, a separate notice is required to be provided to the beneficiary at the beneficiary's last known address.

(D) *Availability of documentation.* The plan or issuer must make available to participants and beneficiaries (or their representatives), on request and at no charge, a summary of the information on which the exemption was based. (For purposes of this paragraph (g), an individual who is not a participant or beneficiary and who presents a notice described in paragraph (g)(6)(i) of this section is considered to be a representative. A representative may request the summary of information by providing the plan a copy of the notice provided to the participant under paragraph (g)(6)(i) of this section with any personally identifiable information redacted.) The summary of information must include the incurred expenditures, the base period, the dollar amount of claims incurred during the base period that would have been denied under the terms of the plan or coverage absent amendments required to comply with paragraphs (b) and (c) of this section, the administrative costs related to those claims, and other administrative costs attributable to complying with the requirements of this section. In no event should the summary of information include any personally identifiable information.

(ii) *Federal agencies*—(A) *Content of notice.* The notice to the Secretary must include the following information:

(*1*) A description of the number of covered lives under the plan (or coverage) involved at the time of the notification, and as applicable, at the time of any prior election of the cost exemption under this paragraph (g) by such plan (or coverage);

(*2*) For both the plan year upon which a cost exemption is sought and the year prior, a description of the actual total costs of coverage with respect to medical/surgical benefits and mental health and substance use disorder benefits; and

(*3*) For both the plan year upon which a cost exemption is sought and the year prior, the actual total costs of coverage with respect to mental health and substance use disorder benefits under the plan.

(B) *Reporting.* A group health plan, and any health insurance coverage offered in connection with a group health plan, must provide notice to the Department of Labor. This requirement is satisfied if the plan sends a copy, to the address designated by the Secretary in generally applicable guidance, of the notice described in paragraph (g)(6)(ii)(A) of this section identifying

the benefit package to which the exemption applies.

(iii) *Confidentiality.* A notification to the Secretary under this paragraph (g)(6) shall be confidential. The Secretary shall make available, upon request and not more than on an annual basis, an anonymous itemization of each notification that includes—

(A) A breakdown of States by the size and type of employers submitting such notification; and

(B) A summary of the data received under paragraph (g)(6)(ii) of this section.

(iv) *Audits.* The Secretary may audit the books and records of a group health plan or a health insurance issuer relating to an exemption, including any actuarial reports, during the 6 year period following notification of such exemption under paragraph (g)(6) of this section. A State agency receiving a notification under paragraph (g)(6) of this section may also conduct such an audit with respect to an exemption covered by such notification.

(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, this section applies to group health plans and health insurance issuers offering group health insurance coverage on the first day of the first plan year beginning on or after July 1, 2014. Until the applicability date, plans and issuers are required to continue to comply with the corresponding sections of 29 CFR 2590.712 contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2013.

(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 date on which the last of the collective bargaining agreements terminates (determined without regard to any extension agreed to after October 3, 2008).

■ 3. Section 2590.715–2719 is amended by adding a sentence to the end of the introductory text of paragraph (d) and revising paragraph (d)(1)(i) to read as follows:

§ 2590.712 Internal claims and appeals and external review processes.

* * * * *

(d) * * * A Multi State Plan or MSP, as defined by 45 CFR 800.20, must provide an effective Federal external review process in accordance with this paragraph (d).

(1) * * *

(i) *In general.* Subject to the suspension provision in paragraph (d)(1)(ii) of this section and except to the extent provided otherwise by the Secretary in guidance, the Federal external review process established pursuant to this paragraph (d) applies, at a minimum, to any adverse benefit determination or final internal adverse benefit determination (as defined in paragraphs (a)(2)(i) and (a)(2)(v) of this section), except that a denial, reduction, termination, or a failure to provide payment for a benefit based on a determination that a participant or beneficiary fails to meet the requirements for eligibility under the terms of a group health plan is not eligible for the Federal external review process under this paragraph (d).

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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 adopts as final the interim final rule with comment period amending 45 CFR part 146, which was published on February 2, 2010, in the **Federal Register** at 75 FR 5410, with the following changes, and further amends part 147 as set forth below:

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, 2711 through 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 with respect to items or services for medical conditions or surgical procedures, as defined under the terms of the plan or health insurance coverage and in accordance with applicable Federal and State law, but does not include mental health or substance use disorder benefits. Any condition defined by the plan or coverage 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 items or services for mental health conditions, as defined under the terms of the plan or health insurance coverage and in accordance with applicable Federal and State law. Any condition defined by the plan or coverage 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 items or services for substance use disorders, as defined under the terms of the plan or health insurance coverage 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 or coverage. (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 for purposes of this definition.

(b) *Parity requirements with respect to aggregate lifetime and annual dollar limits.* This paragraph (b) details the application of the parity requirements with respect to aggregate lifetime and annual dollar limits. This paragraph (b) does not address the provisions of PHS Act section 2711, which prohibit imposing lifetime and annual limits on the dollar value of essential health benefits. For more information, see § 147.126 of this subchapter.

(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)(5) 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) *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.

(5) *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)(5)(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)(5), the weighting applicable to any category of medical/surgical benefits is determined in the manner set forth in paragraph (b)(4) of this section for determining one-third or two-thirds of all medical/surgical benefits.

(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 (illustrated in examples in paragraph (c)(2)(ii)(C) of this section). 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. See special rules for plans with multiple network tiers in paragraph (c)(3)(iii) of this section.

(*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. See special rules for office visits and plans with multiple network tiers in paragraph (c)(3)(iii) of this section.

(*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. See special rules for office visits in paragraph (c)(3)(iii) of this section.

(*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 care, 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 care 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. (See also PHS Act section 2707(b) and Affordable Care Act section 1302(c), which establish limitations on annual deductibles for non-grandfathered health plans in the small group market and annual limitations on out-of-pocket maximums for all non-grandfathered health plans.)

(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 rules*—(A) *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.

(B) *Multiple network tiers.* If a plan (or health insurance coverage) provides benefits through multiple tiers of in-network providers (such as an in-network tier of preferred providers with more generous cost-sharing to participants than a separate in-network tier of participating providers), the plan may divide its benefits furnished on an in-network basis into sub-classifications that reflect network tiers, if the tiering is based on reasonable factors determined in accordance with the rules in paragraph (c)(4)(i) of this section (such as quality, performance, and market standards) and without regard to whether a provider provides services with respect to medical/surgical benefits or mental health or substance use disorder benefits. After the sub-classifications are established, the plan or issuer may not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (c)(3)(i) of this section.

(C) *Sub-classifications permitted for office visits, separate from other outpatient services.* For purposes of applying the financial requirement and treatment limitation rules of this paragraph (c), a plan or issuer may divide its benefits furnished on an outpatient basis into the two sub-classifications described in this paragraph (c)(3)(iii)(C). After the sub-classifications are established, the plan or issuer may not impose any financial

requirement or quantitative treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (c)(3)(i) of this section. Sub-classifications other than these special rules, such as separate sub-classifications for generalists and specialists, are not permitted. The two sub-classifications permitted under this paragraph (c)(3)(iii)(C) are:

(*1*) Office visits (such as physician visits), and

(*2*) All other outpatient items and services (such as outpatient surgery, facility charges for day treatment centers, laboratory charges, or other medical items).

(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).

Example 5. (i) *Facts.* A plan has two-tiers of network of providers: A preferred provider tier and a participating provider tier. Providers are placed in either the preferred tier or participating tier based on reasonable factors determined in accordance with the rules in paragraph (c)(4)(i) of this section, such as accreditation, quality and performance measures (including customer feedback), and relative reimbursement rates. Furthermore, provider tier placement is determined without regard to whether a provider specializes in the treatment of mental health conditions or substance use disorders, or medical/surgical conditions. The plan divides the in-network classifications into two sub-classifications (in-network/preferred and in-network/participating). The plan does not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(ii) *Conclusion.* In this *Example 5,* the division of in-network benefits into sub-classifications that reflect the preferred and participating provider tiers does not violate the parity requirements of this paragraph (c)(3).

Example 6. (i) *Facts.* With respect to outpatient, in-network benefits, a plan imposes a $25 copayment for office visits and a 20 percent coinsurance requirement for outpatient surgery. The plan divides the outpatient, in-network classification into two sub-classifications (in-network office visits and all other outpatient, in-network items and services). The plan or issuer does not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(ii) *Conclusion.* In this *Example 6,* the division of outpatient, in-network benefits into sub-classifications for office visits and all other outpatient, in-network items and services does not violate the parity requirements of this paragraph (c)(3).

Example 7. (i) *Facts.* Same facts as *Example 6,* but for purposes of determining parity, the plan divides the outpatient, in-network classification into outpatient, in-network generalists and outpatient, in-network specialists.

(ii) *Conclusion.* In this *Example 7,* the division of outpatient, in-network benefits into any sub-classifications other than office visits and all other outpatient items and services violates the requirements of paragraph (c)(3)(iii)(C) of this section.

(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.

(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) For plans with multiple network tiers (such as preferred providers and participating providers), network tier design;

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

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

(F) 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);

(G) Exclusions based on failure to complete a course of treatment; and

(H) Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the plan or coverage.

(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 plan requires prior authorization from the plan's utilization reviewer that a treatment is medically necessary for all inpatient medical/surgical benefits and for all inpatient mental health and substance use disorder benefits. In practice, inpatient benefits for medical/surgical conditions are routinely approved for seven days, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan. On the other hand, for inpatient mental health and substance use disorder benefits, routine approval is given only for one day, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan.

(ii) *Conclusion.* In this Example 1, the plan violates the rules of this paragraph (c)(4) because it is applying a stricter nonquantitative treatment limitation in practice to mental health and substance use disorder benefits than is applied to medical/surgical benefits.

Example 2. (i) *Facts.* A plan applies concurrent review to inpatient care where there are high levels of variation in length of stay (as measured by a coefficient of variation exceeding 0.8). In practice, the application of this standard affects 60 percent of mental health conditions and substance use disorders, but only 30 percent of medical/surgical conditions.

(ii) *Conclusion.* In this *Example 2,* the plan complies with the rules of this paragraph (c)(4) because the evidentiary standard used by the plan is applied no more stringently for mental health and substance use disorder benefits than for medical/surgical benefits, even though it results in an overall difference in the application of concurrent review for mental health conditions or substance use disorders than for medical/surgical conditions.

Example 3. (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 and uses comparable criteria in determining whether a course of treatment is medically necessary. 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 3,* 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, it is not applied in a comparable way. 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 4. (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 is based on clinically appropriate standards of care for a condition.

(ii) *Conclusion.* In this *Example 4,* the plan complies with the rules of this paragraph (c)(4) because the processes for developing the evidentiary standards used to determine medical appropriateness and the application of these standards 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 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 5. (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 5,* the plan violates the rules of this paragraph (c)(4). Although the standard for applying a nonquantitative treatment limitation is the same for both mental health and substance use disorder benefits and medical/surgical benefits—whether a drug has a black box warning—it is not applied in a comparable manner. 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 6. (i) *Facts.* An employer maintains both a major medical plan 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 plan 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 plan.

(ii) *Conclusion.* In this *Example 6,* 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.

Example 7. (i) *Facts.* Training and State licensing requirements often vary among types of providers. A plan applies a general standard that any provider must meet the highest licensing requirement related to supervised clinical experience under applicable State law in order to participate in the plan's provider network. Therefore, the plan requires master's-level mental health therapists to have post-degree, supervised clinical experience but does not impose this requirement on master's-level general medical providers because the scope of their licensure under applicable State law does require clinical experience. In addition, the plan does not require post-degree, supervised clinical experience for psychiatrists or Ph.D. level psychologists since their licensing already requires supervised training.

(ii) *Conclusion.* In this *Example 7,* the plan complies with the rules of this paragraph (c)(4). The requirement that master's-level mental health therapists must have supervised clinical experience to join the network is permissible, as long as the plan consistently applies the same standard to all providers even though it may have a disparate impact on certain mental health providers.

Example 8. (i) *Facts.* A plan considers a wide array of factors in designing medical management techniques for both mental health and substance use disorder benefits and medical/surgical benefits, such as cost of treatment; high cost growth; variability in cost and quality; elasticity of demand; provider discretion in determining diagnosis, or type or length of treatment; clinical efficacy of any proposed treatment or service; licensing and accreditation of providers; and claim types with a high percentage of fraud. Based on application of these factors in a comparable fashion, prior authorization is required for some (but not all) mental health and substance use disorder benefits, as well as for some medical/surgical benefits, but not for others. For example, the plan requires prior authorization for: Outpatient surgery; speech, occupational, physical, cognitive and behavioral therapy extending for more than six months; durable medical equipment; diagnostic imaging; skilled nursing visits; home infusion therapy; coordinated home care; pain management; high-risk prenatal care; delivery by cesarean section; mastectomy; prostate cancer treatment; narcotics prescribed for more than seven days; and all inpatient services beyond 30 days. The evidence considered in developing its medical management techniques includes consideration of a wide array of recognized medical literature and professional standards and protocols (including comparative effectiveness studies and clinical trials). This evidence and how it was used to develop these medical management techniques is also well documented by the plan.

(ii) *Conclusion.* In this *Example 8,* the plan complies with the rules of this paragraph (c)(4). Under the terms of the plan as written and in operation, the processes, strategies, evidentiary standards, and other factors considered by the plan in implementing its prior authorization requirement with respect to mental health and substance use disorder benefits are comparable to, and applied no more stringently than, those applied with respect to medical/surgical benefits.

Example 9. (i) *Facts.* A plan generally covers medically appropriate treatments. The plan automatically excludes coverage for inpatient substance use disorder treatment in any setting outside of a hospital (such as a freestanding or residential treatment center). For inpatient treatment outside of a hospital for other conditions (including freestanding or residential treatment centers prescribed for mental health conditions, as well as for medical/surgical conditions), the plan will provide coverage if the prescribing physician obtains authorization from the plan that the inpatient treatment is medically appropriate for the individual, based on clinically appropriate standards of care.

(ii) *Conclusion.* In this *Example 9,* 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 substance use disorder treatment in any setting outside of a hospital is not comparable to the conditional exclusion of inpatient treatment outside of a hospital for other conditions.

Example 10. (i) *Facts.* A plan generally provides coverage for medically appropriate medical/surgical benefits as well as mental health and substance use disorder benefits. The plan excludes coverage for inpatient, out-of-network treatment of chemical dependency when obtained outside of the State where the policy is written. There is no similar exclusion for medical/surgical benefits within the same classification.

(ii) *Conclusion.* In this Example 10, the plan violates the rules of this paragraph (c)(4). The plan is imposing a nonquantitative treatment limitation that restricts benefits based on geographic location. Because there is no comparable exclusion that applies to medical/surgical benefits, this exclusion may not be applied to mental health or substance use disorder benefits.

Example 11. (i) *Facts.* A plan requires prior authorization for all outpatient mental health and substance use disorder services after the ninth visit and will only approve up to five additional visits per authorization. With respect to outpatient medical/surgical benefits, the plan allows an initial visit without prior authorization. After the initial visit, the plan pre-approves benefits based on the individual treatment plan recommended by the attending provider based on that individual's specific medical condition. There is no explicit, predetermined cap on the amount of additional visits approved per authorization.

(ii) *Conclusion.* In this *Example 11,* the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation—prior authorization to determine medical appropriateness—is applied to both mental health and substance use disorder benefits and medical/surgical benefits for outpatient services, it is not applied in a comparable way. While the plan is more generous with respect to the number of visits initially provided without pre-authorization for mental health benefits, treating all mental health conditions and substance use disorders in the same manner, while providing for individualized treatment of medical conditions, is not a comparable application of this nonquantitative treatment limitation.

(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 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 by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary. 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).

(3) *Provisions of other law.* Compliance with the disclosure requirements in paragraphs (d)(1) and (d)(2) of this section is not determinative of compliance with any other provision of applicable Federal or State law. In particular, in addition to those disclosure requirements, provisions of other applicable law require disclosure of information relevant to medical/surgical, mental health, and substance use disorder benefits. For example, § 147.136 of this subchapter sets forth rules regarding claims and appeals, including the right of claimants (or their authorized representative) upon appeal of an adverse benefit determination (or a final internal adverse benefit determination) to be provided upon request and free of charge, reasonable access to and copies

of all documents, records, and other information relevant to the claimant's claim for benefits. This includes documents with information on medical necessity criteria for both medical/surgical benefits and mental health and substance use disorder benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply a nonquantitative treatment limitation with respect to medical/surgical benefits and mental health or substance use disorder benefits under the plan.

(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;

(ii) Require a group health plan (or health insurance issuer offering coverage in connection with a group health plan) that provides coverage for mental health or substance use disorder benefits only to the extent required under PHS Act section 2713 to provide additional mental health or substance use disorder benefits in any classification in accordance with this section; or

(iii) 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.

(4) *Coordination with EHB requirements.* Nothing in paragraph (f) or (g) of this section changes the requirements of §§ 147.150 and 156.115 of this subchapter, providing that a health insurance issuer offering non-grandfathered health insurance coverage in the individual or small group market providing mental health and substance use disorder services, including behavioral health treatment services, as part of essential health benefits required under §§ 156.110(a)(5) and 156.115(a) of this subchapter, must comply with the provisions of this section to satisfy the requirement to provide essential health benefits.

(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 (as defined in section 2791 of the PHS Act).

(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 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*—(1) *In general.* If the application of this section to a group health plan (or health insurance coverage offered in connection with such plans) results in an increase for the plan year involved of the actual total cost of coverage with respect to medical/surgical benefits and mental health and substance use disorder benefits as determined and certified under paragraph (g)(3) of this section by an amount that exceeds the applicable percentage described in paragraph (g)(2) of this section of the actual total plan costs, the provisions of this section shall not apply to such plan (or coverage) during the following plan year, and such exemption shall apply to the plan (or coverage) for one plan year. An employer or issuer may elect to continue to provide mental health and substance use disorder benefits in compliance with this section with respect to the plan or coverage involved regardless of any increase in total costs.

(2) *Applicable percentage.* With respect to a plan or coverage, the applicable percentage described in this paragraph (g) is—

(i) 2 percent in the case of the first plan year in which this section is applied to the plan or coverage; and

(ii) 1 percent in the case of each subsequent plan year.

(3) *Determinations by actuaries*—(i) Determinations as to increases in actual costs under a plan or coverage that are attributable to implementation of the requirements of this section shall be made and certified by a qualified and licensed actuary who is a member in good standing of the American Academy of Actuaries. All such determinations must be based on the formula specified in paragraph (g)(4) of this section and shall be in a written report prepared by the actuary.

(ii) The written report described in paragraph (g)(3)(i) of this section shall be maintained by the group health plan or health insurance issuer, along with all supporting documentation relied upon by the actuary, for a period of six years following the notification made under paragraph (g)(6) of this section.

(4) *Formula.* The formula to be used to make the determination under paragraph (g)(3)(i) of this section is expressed mathematically as follows: $[(E_1 - E_0)/T_0] - D > k$

(i) E_1 is the actual total cost of coverage with respect to mental health and substance use disorder benefits for the base period, including claims paid by the plan or issuer with respect to mental health and substance use disorder benefits and administrative costs (amortized over time) attributable to providing these benefits consistent with the requirements of this section.

(ii) E_0 is the actual total cost of coverage with respect to mental health and substance use disorder benefits for the length of time immediately before the base period (and that is equal in

length to the base period), including claims paid by the plan or issuer with respect to mental health and substance use disorder benefits and administrative costs (amortized over time) attributable to providing these benefits.

(iii) T_0 is the actual total cost of coverage with respect to all benefits during the base period.

(iv) k is the applicable percentage of increased cost specified in paragraph (g)(2) of this section that will be expressed as a fraction for purposes of this formula.

(v) D is the average change in spending that is calculated by applying the formula $(E_1 - E_0)/T_0$ to mental health and substance use disorder spending in each of the five prior years and then calculating the average change in spending.

(5) *Six month determination.* If a group health plan or health insurance issuer seeks an exemption under this paragraph (g), determinations under paragraph (g)(3) of this section shall be made after such plan or coverage has complied with this section for at least the first 6 months of the plan year involved.

(6) *Notification.* A group health plan or health insurance issuer that, based on the certification described under paragraph (g)(3) of this section, qualifies for an exemption under this paragraph (g), and elects to implement the exemption, must notify participants and beneficiaries covered under the plan, the Secretary, and the appropriate State agencies of such election.

(i) *Participants and beneficiaries*—(A) *Content of notice.* The notice to participants and beneficiaries must include the following information:

(*1*) A statement that the plan or issuer is exempt from the requirements of this section and a description of the basis for the exemption.

(*2*) The name and telephone number of the individual to contact for further information.

(*3*) The plan or issuer name and plan number (PN).

(*4*) The plan administrator's name, address, and telephone number.

(*5*) For single-employer plans, the plan sponsor's name, address, and telephone number (if different from paragraph (g)(6)(i)(A)(*3*) of this section) and the plan sponsor's employer identification number (EIN).

(*6*) The effective date of such exemption.

(*7*) A statement regarding the ability of participants and beneficiaries to contact the plan administrator or health insurance issuer to see how benefits may be affected as a result of the plan's or issuer's election of the exemption.

(*8*) A statement regarding the availability, upon request and free of charge, of a summary of the information on which the exemption is based (as required under paragraph (g)(6)(i)(D) of this section).

(B) *Use of summary of material reductions in covered services or benefits.* A plan or issuer may satisfy the requirements of paragraph (g)(6)(i)(A) of this section by providing participants and beneficiaries (in accordance with paragraph (g)(6)(i)(C) of this section) with a summary of material reductions in covered services or benefits consistent with 29 CFR 2520.104b–3(d) that also includes the information specified in paragraph (g)(6)(i)(A) of this section. However, in all cases, the exemption is not effective until 30 days after notice has been sent.

(C) *Delivery.* The notice described in this paragraph (g)(6)(i) is required to be provided to all participants and beneficiaries. The notice may be furnished by any method of delivery that satisfies the requirements of section 104(b)(1) of ERISA (29 U.S.C. 1024(b)(1)) and its implementing regulations (for example, first-class mail). If the notice is provided to the participant and any beneficiaries at the participant's last known address, then the requirements of this paragraph (g)(6)(i) are satisfied with respect to the participant and all beneficiaries residing at that address. If a beneficiary's last known address is different from the participant's last known address, a separate notice is required to be provided to the beneficiary at the beneficiary's last known address.

(D) *Availability of documentation.* The plan or issuer must make available to participants and beneficiaries (or their representatives), on request and at no charge, a summary of the information on which the exemption was based. (For purposes of this paragraph (g), an individual who is not a participant or beneficiary and who presents a notice described in paragraph (g)(6)(i) of this section is considered to be a representative. A representative may request the summary of information by providing the plan a copy of the notice provided to the participant under paragraph (g)(6)(i) of this section with any personally identifiable information redacted.) The summary of information must include the incurred expenditures, the base period, the dollar amount of claims incurred during the base period that would have been denied under the terms of the plan or coverage absent amendments required to comply with paragraphs (b) and (c) of this section, the administrative costs related to those claims, and other administrative costs attributable to complying with the requirements of this section. In no event should the summary of information include any personally identifiable information.

(ii) *Federal agencies*—(A) *Content of notice.* The notice to the Secretary must include the following information:

(*1*) A description of the number of covered lives under the plan (or coverage) involved at the time of the notification, and as applicable, at the time of any prior election of the cost exemption under this paragraph (g) by such plan (or coverage);

(*2*) For both the plan year upon which a cost exemption is sought and the year prior, a description of the actual total costs of coverage with respect to medical/surgical benefits and mental health and substance use disorder benefits; and

(*3*) For both the plan year upon which a cost exemption is sought and the year prior, the actual total costs of coverage with respect to mental health and substance use disorder benefits under the plan.

(B) *Reporting by health insurance coverage offered in connection with a church plan.* See 26 CFR 54.9812(g)(6)(ii)(B) for delivery with respect to church plans.

(C) *Reporting by health insurance coverage offered in connection with a group health plans subject to Part 7 of Subtitle B of Title I of ERISA.* See 29 CFR 2590.712(g)(6)(ii) for delivery with respect to group health plans subject to ERISA.

(D) *Reporting with respect to non-Federal governmental plans and health insurance issuers in the individual market.* A group health plan that is a non-Federal governmental plan, or a health insurance issuer offering health insurance coverage in the individual market, claiming the exemption of this paragraph (g) for any benefit package must provide notice to the Department of Health and Human Services. This requirement is satisfied if the plan or issuer sends a copy, to the address designated by the Secretary in generally applicable guidance, of the notice described in paragraph (g)(6)(ii)(A) of this section identifying the benefit package to which the exemption applies.

(iii) *Confidentiality.* A notification to the Secretary under this paragraph (g)(6) shall be confidential. The Secretary shall make available, upon request and not more than on an annual basis, an anonymous itemization of each notification that includes—

(A) A breakdown of States by the size and type of employers submitting such notification; and

(B) A summary of the data received under paragraph (g)(6)(ii) of this section.

(iv) *Audits.* The Secretary may audit the books and records of a group health plan or a health insurance issuer relating to an exemption, including any actuarial reports, during the 6 year period following notification of such exemption under paragraph (g)(6) of this section. A State agency receiving a notification under paragraph (g)(6) of this section may also conduct such an audit with respect to an exemption covered by such notification.

(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, this section applies to group health plans and health insurance issuers offering group health insurance coverage on the first day of the first plan year beginning on or after July 1, 2014. Until the applicability date, plans and issuers are required to continue to comply with the corresponding sections of § 146.136 contained in the 45 CFR, parts 1 to 199, edition revised as of October 1, 2013.

(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 date on which the last of the collective bargaining agreements terminates (determined without regard to any extension agreed to after October 3, 2008).

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKETS

■ 3. The authority citation for part 147 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 4. Section 147.136 is amended by adding a sentence to the end of the introductory text of paragraph (d) and revising paragraph (d)(1)(i) to read as follows:

§ 147.136 Internal claims and appeals and external review processes.

* * * * *

(d) * * * A Multi State Plan or MSP, as defined by 45 CFR 800.20, must provide an effective Federal external review process in accordance with this paragraph (d).

(1) * * *

(i) *In general.* Subject to the suspension provision in paragraph (d)(1)(ii) of this section and except to the extent provided otherwise by the Secretary in guidance, the Federal external review process established pursuant to this paragraph (d) applies, at a minimum, to any adverse benefit determination or final internal adverse benefit determination (as defined in paragraphs (a)(2)(i) and (a)(2)(v) of this section), except that a denial, reduction, termination, or a failure to provide payment for a benefit based on a determination that a participant or beneficiary fails to meet the requirements for eligibility under the terms of a group health plan is not eligible for the Federal external review process under this paragraph (d).

* * * * *

■ 5. Section 147.160 is added to read as follows:

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

(a) *In general.* The provisions of § 146.136 of this subchapter apply to health insurance coverage offered by health insurance issuer in the individual market in the same manner and to the same extent as such provisions apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the large group market.

(b) *Applicability date.* The provisions of this section apply for policy years beginning on or after the applicability dates set forth in § 146.136(i) of this subchapter. This section applies to non-grandfathered and grandfathered health plans as defined in § 147.140.

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