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

(a) *Purpose and meaning of terms*—(1) *Purpose.* This section and § 146.137 set forth rules to ensure parity in aggregate lifetime and annual dollar limits, financial requirements, and quantitative and nonquantitative treatment limitations between mental health and substance use disorder benefits and medical/surgical benefits, as required under PHS Act section 2726. A fundamental purpose of PHS Act section 2726, this section, and § 146.137 is to ensure that participants and beneficiaries in a group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that offers mental health or substance use disorder benefits are not subject to more restrictive aggregate lifetime or annual dollar limits, financial requirements, or treatment limitations with respect to those benefits than the predominant dollar limits, financial requirements, or treatment limitations that are applied to substantially all medical/surgical benefits covered by the plan or coverage in the same classification, as further provided in this section and § 146.137. Accordingly, in complying with the provisions of PHS Act section 2726, this section, and § 146.137, plans and issuers must not design or apply financial requirements and treatment limitations that impose a greater burden on access (that is, are more restrictive) to mental health or substance use disorder benefits under the plan or coverage than they impose on access to medical/surgical benefits in the same classification of benefits. The provisions of PHS Act section 2726, this section, and § 146.137 should be interpreted in a manner that is consistent with the purpose described in this paragraph (a)(1).

(2) *Meaning of terms.* For purposes of this section and § 146.137, 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.

DSM means the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders. For the purpose of this definition, the most current version of the DSM as of November 22, 2024, is the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition,

Text Revision published in March 2022. A subsequent version of the DSM published after November 22, 2024, will be considered the most current version beginning on the first day of the plan year that is one year after the date the subsequent version is published.

Evidentiary standards are any evidence, sources, or standards that a group health plan (or health insurance issuer offering coverage in connection with such a plan) considered or relied upon in designing or applying a factor with respect to a nonquantitative treatment limitation, including specific benchmarks or thresholds. Evidentiary standards may be empirical, statistical, or clinical in nature, and include: sources acquired or originating from an objective third party, such as recognized medical literature, professional standards and protocols (which may include comparative effectiveness studies and clinical trials), published research studies, payment rates for items and services (such as publicly available databases of the "usual, customary and reasonable" rates paid for items and services), and clinical treatment guidelines; internal plan or issuer data, such as claims or utilization data or criteria for assuring a sufficient mix and number of network providers; and benchmarks or thresholds, such as measures of excessive utilization, cost levels, time or distance standards, or network participation percentage thresholds.

Factors are all information, including processes and strategies (but not evidentiary standards), that a group health plan (or health insurance issuer offering coverage in connection with such a plan) considered or relied upon to design a nonquantitative treatment limitation, or to determine whether or how the nonquantitative treatment limitation applies to benefits under the plan or coverage. Examples of factors include, but are not limited to: provider discretion in determining a diagnosis or type or length of treatment; clinical efficacy of any proposed treatment or service; licensing and accreditation of providers; claim types with a high percentage of fraud; quality measures; treatment outcomes; severity or chronicity of condition; variability in the cost of an episode of treatment; high cost growth; variability in cost and quality; elasticity of demand; and geographic location.

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

ICD means the World Health Organization's International Classification of Diseases adopted by the Department of Health and Human Services through § 162.1002 of this subtitle. For the purpose of this definition, the most current version of the ICD as of November 22, 2024, is the International Classification of Diseases, 10th Revision, Clinical Modification adopted for the period beginning on October 1, 2015. Any subsequent version of the ICD adopted through § 162.1002 of this subtitle after November 22, 2024, will be considered the most current version beginning on the first day of the plan year that is one year after the date the subsequent version is adopted.

Medical/surgical benefits means benefits with respect to items or services for medical conditions or surgical procedures, as defined under the terms of the group health plan (or health insurance coverage offered by an issuer in connection with such a plan) and in accordance with applicable Federal and State law, but does not include mental health benefits or substance use disorder benefits. Notwithstanding the preceding sentence, any condition or procedure defined by the plan or coverage as being or as not being a medical condition or surgical procedure must be defined

consistent with generally recognized independent standards of current medical practice (for example, the most current version of the ICD). To the extent generally recognized independent standards of current medical practice do not address whether a condition or procedure is a medical condition or surgical procedure, plans and issuers may define the condition or procedure in accordance with applicable Federal and State law.

Mental health benefits means benefits with respect to items or services for mental health conditions, as defined under the terms of the group health plan (or health insurance coverage offered by an issuer in connection with such a plan) and in accordance with applicable Federal and State law, but does not include medical/surgical benefits or substance use disorder benefits. Notwithstanding the preceding sentence, any condition defined by the plan or coverage as being or as not being a mental health condition must be defined consistent with generally recognized independent standards of current medical practice. For the purpose of this definition, to be consistent with generally recognized independent standards of current medical practice, the definition must include all conditions covered under the plan or coverage, except for substance use disorders, that fall under any of the diagnostic categories listed in the mental, behavioral, and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed in the most current version of the DSM. To the extent generally recognized independent standards of current medical practice do not address whether a condition is a mental health condition, plans and issuers may define the condition in accordance with applicable Federal and State law.

Processes are actions, steps, or procedures that a group health plan (or health insurance issuer offering coverage in connection with such a plan) uses to apply a nonquantitative treatment limitation, including actions, steps, or procedures established by the plan or issuer as requirements in order for a participant or beneficiary to access benefits, including through actions by a participant's or beneficiary's authorized representative or a provider or facility. Examples of processes include, but are not limited to: procedures to submit information to authorize coverage for an item or service prior to receiving the benefit or while treatment is ongoing (including requirements for peer or expert clinical review of that information); provider referral requirements that are used to determine when and how a participant or beneficiary may access certain services; and the development and approval of a treatment plan used in a concurrent review process to determine whether a specific request should be granted or denied. Processes also include the specific procedures used by staff or other representatives of a plan or issuer (or the service provider of a plan or issuer) to administer the application of nonquantitative treatment limitations, such as how a panel of staff members applies the nonquantitative treatment limitation (including the qualifications of staff involved, number of staff members allocated, and time allocated), consultations with panels of experts in applying the nonquantitative treatment limitation, and the degree of reviewer discretion in adhering to criteria hierarchy when applying a nonquantitative treatment limitation.

Strategies are practices, methods, or internal metrics that a plan (or health insurance issuer offering coverage in connection with such a plan) considers, reviews, or uses to design a nonquantitative treatment limitation. Examples of strategies include, but are not limited to: the development of the clinical rationale used in approving or denying benefits; the method of

determining whether and how to deviate from generally accepted standards of care in concurrent reviews; the selection of information deemed reasonably necessary to make medical necessity determinations; reliance on treatment guidelines or guidelines provided by third-party organizations in the design of a nonquantitative treatment limitation; and rationales used in selecting and adopting certain threshold amounts to apply a nonquantitative treatment limitation, professional standards and protocols to determine utilization management standards, and fee schedules used to determine provider reimbursement rates, used as part of a nonquantitative treatment limitation. Strategies also include the method of creating and determining the composition of the staff or other representatives of a plan or issuer (or the service provider of a plan or issuer) that deliberates, or otherwise makes decisions, on the design of nonquantitative treatment limitations, including the plan's or issuer's methods for making decisions related to the qualifications of staff involved, number of staff members allocated, and time allocated; breadth of sources and evidence considered; consultations with panels of experts in designing the nonquantitative treatment limitation; and the composition of the panels used to design a nonquantitative treatment limitation.

Substance use disorder benefits means benefits with respect to items or services for substance use disorders, as defined under the terms of the group health plan (or health insurance coverage offered by an issuer in connection with such a plan) and in accordance with applicable Federal and State law, but does not include medical/surgical benefits or mental health benefits. Notwithstanding the preceding sentence, any disorder defined by the plan or coverage as being or as not being a substance use disorder must be defined consistent with generally recognized independent standards of current medical practice. For the purpose of this definition, to be consistent with generally recognized independent standards of current medical practice, the definition must include all disorders covered under the plan or coverage that fall under any of the diagnostic categories listed as a mental or behavioral disorder due to psychoactive substance use (or equivalent category) in the mental, behavioral, and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed as a Substance-Related and Addictive Disorder (or equivalent category) in the most current version of the DSM. To the extent generally recognized independent standards of current medical practice do not address whether a disorder is a substance use disorder, plans and issuers may define the disorder in accordance with applicable Federal and State law.

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 (such as standards related to network composition), 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, non-exhaustive list of nonquantitative treatment limitations.) A complete 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, non-exhaustive 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. A plan or issuer may not impose any financial requirement or treatment limitation that is applicable only with respect to mental health or substance use disorder benefits and not to any medical/surgical benefits in the same benefit classification. 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 any benefits for a mental health condition or substance use disorder in any classification of benefits described in this paragraph (c)(2)(ii), it must provide meaningful benefits for that mental health condition or substance use disorder in every classification in which medical/surgical benefits are provided. For purposes of this paragraph (c)(2)(ii)(A), whether the benefits provided are meaningful benefits is determined in comparison to the benefits provided for medical conditions and surgical procedures in the classification and requires, at a minimum, coverage of benefits for that condition or disorder in each classification in which the plan (or coverage) provides benefits for one or more medical conditions or surgical procedures. A plan (or coverage) does not provide meaningful benefits under this paragraph (c)(2)(ii)(A) unless it provides benefits for a core treatment for that condition or disorder in each classification in which the plan (or coverage) provides benefits for a core treatment for one or more medical conditions or surgical procedures. For purposes of this paragraph (c)(2)(ii)(A), a core treatment for a condition or disorder is a standard treatment or course of treatment, therapy, service, or intervention indicated by generally recognized independent standards of current medical practice. If there is no core treatment for a covered mental health condition or substance use disorder with respect to a classification, the plan (or coverage) is not required to provide benefits for a core treatment for such condition or disorder in that classification (but must provide benefits for such condition or disorder 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), in addition to the permissible sub-classifications described in paragraph (c)(3)(iii) of this section:

(*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. With regard to the examples in this paragraph (c)(2)(ii)(C), references to any particular core treatment are included for illustrative purposes only. Plans and issuers must consult generally recognized independent standards of current medical practice to determine the applicable core treatment, therapy, service, or intervention for any covered condition or disorder.

(*1*) *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 paragraph (c)(2)(ii)(C)(*1*) (*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.

(*2*) *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 paragraph (c)(2)(ii)(C)(*2*) (*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.

(*3*) *Example 3*—(*i*) *Facts.* Same facts as in paragraph (c)(2)(ii)(C)(*2*)(*i*) of this section (*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 paragraph (c)(2)(ii)(C)(*3*) (*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 benefits in the emergency care classification and all other benefits.

(*4*) *Example 4*—(*i*) *Facts.* Same facts as in paragraph (c)(2)(ii)(C)(*2*)(*i*) of this section (*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 paragraph (c)(2)(ii)(C)(*4*) (*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 inpatient, out-of-network benefits and all other benefits.

(*5*) *Example 5*—(*i*) *Facts.* A plan covers treatment for autism spectrum disorder (ASD), a mental health condition, and covers outpatient, out-of-network developmental screenings for ASD but excludes all other benefits for outpatient treatment for ASD, including applied behavior analysis (ABA) therapy, when provided on an out-of-network basis. The plan generally covers the full range of outpatient treatments (including core treatments) and treatment settings for medical conditions and surgical procedures when provided on an out-of-network basis. Under the generally recognized independent standards of current medical practice consulted by the plan, developmental screenings alone do not constitute a core treatment for ASD.

(*ii*) *Conclusion.* In this paragraph (c)(2)(ii)(C)(*5*) (*Example 5*), the plan violates the rules of this paragraph (c)(2)(ii). Although the plan covers benefits for ASD in the outpatient, out-of-network classification, it only covers developmental screenings, so it does not cover a core treatment for ASD in the classification. Because the plan generally covers the full range of medical/surgical benefits, including a core treatment for one or more medical conditions or surgical procedures in

the classification, it fails to provide meaningful benefits for treatment of ASD in the classification.

(*6*) *Example 6*—(*i*) *Facts.* Same facts as in paragraph (c)(2)(ii)(C)(*5*) of this section (*Example 5*), except that the plan is an HMO that does not cover the full range of medical/surgical benefits including a core treatment for any medical conditions or surgical procedures in the outpatient, out-of-network classification (except as required under PHS Act sections 2799A-1 and 2799A-2), but covers benefits for medical conditions and surgical procedures in the inpatient, in-network; outpatient, in-network; emergency care; and prescription drug classifications.

(*ii*) *Conclusion.* In this paragraph (c)(2)(ii)(C)(*6*) (*Example 6*), the plan does not violate the rules of this paragraph (c)(2)(ii). Because the plan does not provide meaningful benefits including for a core treatment for any medical condition or surgical procedure in the outpatient, out-of-network classification (except as required under PHS Act sections 2799A-1 and 2799A-2), the plan is not required to provide meaningful benefits for any mental health conditions or substance use disorders in that classification. Nevertheless, the plan must provide meaningful benefits for each mental health condition and substance use disorder for which the plan provides benefits in every classification in which meaningful medical/surgical benefits are provided as required under paragraph (c)(2)(ii)(A) of this section. This example does not address whether the plan has complied with other applicable requirements of this section in excluding coverage of ABA therapy in the outpatient, out-of-network classification.

(*7*) *Example 7*—(*i*) *Facts.* A plan provides extensive benefits, including for core treatments for many medical conditions and surgical procedures in the outpatient, in-network classification, including nutrition counseling for diabetes and obesity. The plan also generally covers diagnosis and treatment for eating disorders, which are mental health conditions, including coverage for nutrition counseling to treat eating disorders in the outpatient, in-network classification. Nutrition counseling is a core treatment for eating disorders, in accordance with generally recognized independent standards of current medical practice consulted by the plan.

(*ii*) *Conclusion.* In this paragraph (c)(2)(ii)(C)(*7*) (*Example 7*), the plan does not violate the rules of this paragraph (c)(2)(ii). The coverage of diagnosis and treatment for eating disorders, including nutrition counseling, in the outpatient, in-network classification results in the plan providing meaningful benefits for the treatment of eating disorders in the classification, as determined in comparison to the benefits provided for medical conditions or surgical procedures in the classification.

(*8*) *Example 8*—(*i*) *Facts.* A plan provides extensive benefits for the core treatments for many medical conditions and surgical procedures in the outpatient, in-network and prescription drug classifications. The plan provides coverage for diagnosis and treatment for opioid use disorder, a substance use disorder, in the outpatient, in-network classification, by covering counseling and behavioral therapies and, in the prescription drug classification, by covering medications to treat opioid use disorder (MOUD). Counseling and behavioral therapies and MOUD, in combination, are one of the core treatments for opioid use disorder, in accordance with generally recognized independent standards of current medical practice consulted by the plan.

(*ii*) *Conclusion.* In this paragraph (c)(2)(ii)(C)(*8*) (*Example 8*), the plan does not violate the rules of this paragraph (c)(2)(ii). The coverage of counseling and behavioral therapies and MOUD, in combination, in the outpatient, in-network classification and prescription drug classification, respectively, results in the plan providing meaningful benefits for the treatment of opioid use disorder in the outpatient, in-network and prescription drug classifications.

(3) *Financial requirements and quantitative treatment limitations*—(i) *Determining "substantially all" and "predominant"*—(A) *Substantially all.* For purposes of this paragraph (c)(3), 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 purposes of this paragraph (c)(3)(i)(A), 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)(3), 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. The rules of this paragraph (c)(3)(i)(D) apply for any other thresholds at which the rate of plan payment changes. (See also PHS Act section 2707 and Affordable Care Act section 1302(c), which establish 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.* Unless specifically permitted under this paragraph (c)(3)(iii), sub-classifications are not permitted when applying the rules of paragraph (c)(3) of this section.

(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) 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) 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) through (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.

(A) *Example 1—*(*1*) *Facts.* (*i*) 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:

Table 1 to Paragraph (c)(3)(iv)(A)(1)(i)

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)	

(*ii*) 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.

(*2*) *Conclusion.* In this paragraph (c)(3)(iv)(A) (*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.

(B) *Example 2*—(*1*) *Facts.* (*i*) 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:

Table 2 to Paragraph (c)(3)(iv)(B)(1)(i)

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)	

(*ii*) 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.

(*2*) *Conclusion.* In this paragraph (c)(3)(iv)(B) (*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.

(C) *Example 3*—(*1*) *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.

(*2*) *Conclusion.* In this paragraph (c)(3)(iv)(C) (*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.

(D) *Example 4*—(*1*) *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) of this section (relating to requirements for nonquantitative treatment limitations).

Table 3 to Paragraph (c)(3)(iv)(D)(1)

	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%.

(*2*) *Conclusion.* In this paragraph (c)(3)(iv)(D) (*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).

(E) *Example 5*—(*1*) *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) 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.

(*2*) *Conclusion.* In this paragraph (c)(3)(iv)(E) (*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).

(F) *Example 6*—(*1*) *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.

(*2*) *Conclusion.* In this paragraph (c)(3)(iv)(F) (*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).

(G) *Example 7*—(*1*) *Facts.* Same facts as in paragraph (c)(3)(iv)(F)(*1*) of this section (*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.

(*2*) *Conclusion.* In this paragraph (c)(3)(iv)(G) (*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 subject to deductible**	**Percent**
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.* Consistent with paragraph (a)(1) of this section, a group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) may not impose any nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification that is more restrictive, as written or in operation, than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification. For purposes of this paragraph (c)(4), a nonquantitative treatment limitation is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification if the plan or issuer fails to meet the requirements of paragraph (c)(4)(i) or (iii) of this section. In such a case, the plan (or health insurance coverage) will be considered to violate PHS Act section 2726 (a)(3)(A)(ii), and the nonquantitative treatment limitation may not be imposed by the plan (or health insurance coverage) with respect to mental health or substance use disorder benefits in the classification.

(i) *Requirements related to design and application of a nonquantitative treatment limitation*—(A) *In general.* A 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 designing and 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 designing and applying the limitation with respect to medical/surgical benefits in the classification.

(B) *Prohibition on discriminatory factors and evidentiary standards.* For purposes of determining comparability and stringency under paragraph (c)(4)(i)(A) of this section, a plan (or health insurance coverage) may not rely upon discriminatory factors or evidentiary standards to design a nonquantitative treatment limitation to be imposed on mental health or substance use disorder benefits. A factor or evidentiary standard is discriminatory if the information, evidence, sources, or standards on which the factor or evidentiary standard are based are biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits.

(*1*) Information, evidence, sources, or standards are considered to be biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits if, based on all the relevant facts and circumstances, the information, evidence, sources, or standards systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. For purposes of this paragraph (c)(4)(i)(B)(*1*), relevant facts and circumstances may include, but are not limited to, the reliability of the source of the information, evidence, sources, or standards, including any underlying data; the independence of the information, evidence, sources, and standards relied upon; the analyses and methodologies employed to select the information and the consistency of their application; and any known safeguards deployed to prevent reliance on skewed data or metrics. Information, evidence, sources, or standards are not considered biased or not objective for this purpose if the plan or issuer has taken the steps necessary to correct, cure, or supplement any information, evidence, sources, or standards that would have been biased or not objective in the absence of such steps.

(*2*) For purposes of this paragraph (c)(4)(i)(B), historical plan data or other historical information from a time when the plan or coverage was not subject to PHS Act section 2726 or was not in compliance with PHS Act section 2726 are considered to be biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits, if the historical plan data or other historical information systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits, and the plan or issuer has not taken the steps necessary to correct, cure, or supplement the data or information.

(*3*) For purposes of this paragraph (c)(4)(i)(B), generally recognized independent professional medical or clinical standards and carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate mental health and substance use disorder benefits are not information, evidence, sources, or standards that are biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits. However, plans and issuers must comply with the other requirements in this paragraph (c)(4), as

applicable, with respect to such standards or measures that are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation.

(ii) *Illustrative, non-exhaustive list of nonquantitative treatment limitations.* Nonquantitative treatment limitations include—

(A) Medical management standards (such as prior authorization) 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 related to network composition, including but not limited to, standards for provider and facility admission to participate in a network or for continued network participation, including methods for determining reimbursement rates, credentialing standards, and procedures for ensuring the network includes an adequate number of each category of provider and facility to provide services under the plan or coverage;

(E) Plan or issuer methods for determining out-of-network rates, such as allowed amounts; usual, customary, and reasonable charges; or application of other external benchmarks for out-of-network rates;

(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) *Required use of outcomes data*—(A) *In general.* To ensure that a nonquantitative treatment limitation applicable to mental health or substance use disorder benefits in a classification, in operation, is no more restrictive than the predominant nonquantitative treatment limitation applied to substantially all medical/surgical benefits in the classification, a plan or issuer must collect and evaluate relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits and carefully consider the impact as part of the plan's or issuer's evaluation. As part of its evaluation, the plan or issuer may not disregard relevant outcomes data that it knows or reasonably should know suggest that a nonquantitative treatment limitation is associated with material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits. The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, may specify in guidance the type, form, and manner of collection and evaluation for the data required under this paragraph (c)(4)(iii)(A).

(*1*) *Relevant data generally.* For purposes of this paragraph (c)(4)(iii)(A), relevant data could include, as appropriate, but are not limited to, the number and percentage of claims denials and any other data relevant to the nonquantitative treatment limitation required by State law or private accreditation standards.

(*2*) *Relevant data for nonquantitative treatment limitations related to network composition.* In addition to the relevant data set forth in paragraph (c)(4)(iii)(A)(*1*) of this section, relevant data for nonquantitative treatment limitations related to network composition could include, as appropriate, but are not limited to, in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (for comparable services and as benchmarked to a reference standard).

(*3*) *Unavailability of data.* (*i*) If a plan or issuer newly imposes a nonquantitative treatment limitation for which relevant data is initially temporarily unavailable and the plan or issuer therefore cannot comply with this paragraph (c)(4)(iii)(A), the plan or issuer must include in its comparative analysis, as required under § 146.137(c)(5)(i)(C), a detailed explanation of the lack of relevant data, the basis for the plan's or issuer's conclusion that there is a lack of relevant data, and when and how the data will become available and be collected and analyzed. Such a plan or issuer also must comply with this paragraph (c)(4)(iii)(A) as soon as practicable once relevant data becomes available.

(*ii*) If a plan or issuer imposes a nonquantitative treatment limitation for which no data exist that can reasonably assess any relevant impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, the plan or issuer must include in its comparative analysis, as required under § 146.137(c)(5)(i)(D), a reasoned justification as to the basis for the conclusion that there are no data that can reasonably assess the nonquantitative treatment limitation's impact, why the nature of the nonquantitative treatment limitation prevents the plan or issuer from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure the nonquantitative treatment limitation complies with this section. If a plan or issuer becomes aware of data that can reasonably assess any relevant impact of the nonquantitative treatment limitation, the plan or issuer must comply with this paragraph (c)(4)(iii)(A) as soon as practicable.

(*iii*) Consistent with paragraph (a)(1) of this section, paragraphs (c)(4)(iii)(A)(*3*)(*i*) and (*ii*) of this section shall only apply in very limited circumstances and, where applicable, shall be construed narrowly.

(B) *Material differences.* To the extent the relevant data evaluated under paragraph (c)(4)(iii)(A) of this section suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in a classification, such differences will be considered a strong indicator that the plan or issuer violates this paragraph (c)(4).

(*1*) Where the relevant data suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in a classification, the plan or issuer must take reasonable action, as necessary, to address the material differences to ensure compliance, in operation, with this paragraph (c)(4) and must document the actions that have been or are being taken by the plan or issuer to address material differences in access to mental health or substance use disorder benefits, as compared to medical/surgical benefits, as required by § 146.137(c)(5)(iv).

(*2*) For purposes of this paragraph (c)(4)(iii)(B), relevant data are considered to suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits if, based on all relevant facts and circumstances, and taking into account the considerations outlined in this paragraph (c)(4)(iii)(B)(*2*), the difference in the data suggests that the nonquantitative treatment limitation is likely to have a negative impact on access to mental health or substance use disorder benefits as compared to medical/surgical benefits.

(*i*) Relevant facts and circumstances, for purposes of this paragraph (c)(4)(iii)(B)(*2*), may include, but are not limited to, the terms of the nonquantitative treatment limitation at issue, the quality or limitations of the data, causal explanations and analyses, evidence as to the recurring or non-recurring nature of the results, and the magnitude of any disparities.

(*ii*) Differences in access to mental health or substance use disorder benefits attributable to generally recognized independent professional medical or clinical standards or carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate mental health and substance use disorder benefits, which are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation, are not considered to be material for purposes of this paragraph (c)(4)(iii)(B). To the extent a plan or issuer attributes any differences in access to the application of such standards or measures, the plan or issuer must explain the bases for that conclusion in the documentation prepared under § 146.137(c)(5)(iv)(A).

(C) *Nonquantitative treatment limitations related to network composition.* For purposes of applying paragraph (c)(4)(iii)(A) of this section with respect to nonquantitative treatment limitations related to network composition, a plan or issuer must collect and evaluate relevant data in a manner reasonably designed to assess the aggregate impact of all such nonquantitative treatment limitations on access to mental health and substance use disorder benefits and medical/surgical benefits. Examples of possible actions that a plan or issuer could take to comply with the requirement under paragraph (c)(4)(iii)(B)(*1*) of this section to take reasonable action, as necessary, to address any material differences in access with respect to nonquantitative treatment limitations related to network composition, to ensure compliance with this paragraph (c)(4), include, but are not limited to:

(*1*) Strengthening efforts to recruit and encourage a broad range of available mental health and substance use disorder providers and facilities to join the plan's or issuer's network of providers, including taking actions to increase compensation or other inducements, streamline credentialing

processes, or contact providers reimbursed for items and services provided on an out-of-network basis to offer participation in the network;

(*2*) Expanding the availability of telehealth arrangements to mitigate any overall mental health and substance use disorder provider shortages in a geographic area;

(*3*) Providing additional outreach and assistance to participants and beneficiaries enrolled in the plan or coverage to assist them in finding available in-network mental health and substance use disorder providers and facilities; and

(*4*) Ensuring that provider directories are accurate and reliable.

(iv) *Prohibition on separate nonquantitative treatment limitations applicable only to mental health or substance use disorder benefits.* Consistent with paragraph (c)(2)(i) of this section, a group health plan (or health insurance coverage offered by an issuer in connection with such a plan) may not apply any nonquantitative treatment limitation that is applicable only with respect to mental health or substance use disorder benefits and does not apply with respect to any medical/surgical benefits in the same benefit classification.

(v) *Effect of final determination of noncompliance under § 146.137.* (A) If a group health plan (or health insurance issuer offering coverage in connection with a group health plan) receives a final determination from the Secretary or applicable State authority that the plan or issuer is not in compliance with the requirements of PHS Act section 2726(a)(8) or § 146.137 with respect to a nonquantitative treatment limitation, the nonquantitative treatment limitation violates this paragraph (c)(4) and the Secretary or applicable State authority may direct the plan or issuer not to impose the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the relevant classification, unless and until the plan or issuer demonstrates to the Secretary or applicable State authority compliance with the requirements of this section or takes appropriate action to remedy the violation.

(B) A determination by the Secretary of whether to require cessation of a nonquantitative treatment limitation under this paragraph (c)(4)(v) will be based on an evaluation of the relevant facts and circumstances involved in the specific final determination and the nature of the underlying nonquantitative treatment limitation and will take into account the interest of plan participants and beneficiaries and feedback from the plan or issuer.

(vi) *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.

(A) *Example 1 (not comparable and more stringent factors for reimbursement rate methodology, in operation)—*(*1*) *Facts.* A plan's reimbursement rate methodology for outpatient, in-network providers is based on a variety of factors. As written, for mental health, substance use disorder, and medical/surgical benefits, all reimbursement rates for physicians and non-physician practitioners for the same Current Procedural Terminology (CPT) code are based on a combination of factors, such as the nature of the service, duration of the service, intensity and specialization of training, provider licensure and type, number of providers qualified to provide

the service in a given geographic area, and market need (demand). In operation, the plan utilizes an additional strategy to further reduce reimbursement rates for mental health and substance use disorder non-physician providers from those paid to mental health and substance use disorder physicians by the same percentage for every CPT code, but does not apply the same reductions for non-physician medical/surgical providers.

(*2*) *Conclusion.* In this paragraph (c)(4)(vi)(A) (*Example 1*), the plan violates the rules of this paragraph (c)(4). Because the plan reimburses non-physician providers of mental health and substance use disorder services by reducing their reimbursement rate from the rate for physician providers of mental health and substance use disorder services by the same percentage for every CPT code but does not apply the same reductions to non-physician providers of medical/surgical services from the rate for physician providers of medical/surgical services, in operation, the factors used in designing and applying the nonquantitative treatment limitation to mental health and substance use disorder benefits in the outpatient, in-network classification are not comparable to, and are applied more stringently than, the factors used in designing and applying the limitation with respect to medical/surgical benefits in the same classification. As a result, the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the outpatient, in-network classification is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(B) *Example 2 (strategy for exclusion for experimental or investigative treatment more stringently applied to ABA therapy in operation)*—(*1*) *Facts.* A plan, as written, generally excludes coverage for all treatments that are experimental or investigative for both medical/surgical benefits and mental health and substance use disorder benefits in the outpatient, in-network classification. As a result, the plan generally excludes, as experimental, a treatment or procedure when no professionally recognized treatment guidelines include the treatment or procedure as a clinically appropriate standard of care for the condition or disorder and fewer than two randomized controlled trials are available to support the treatment's use with respect to the given condition or disorder. The plan provides benefits for the treatment of ASD, which is a mental health condition, but, in operation, the plan excludes coverage for ABA therapy to treat children with ASD, deeming it experimental. More than one professionally recognized treatment guideline defines clinically appropriate standards of care for ASD and more than two randomized controlled trials are available to support the use of ABA therapy as one intervention to treat certain children with ASD.

(*2*) *Conclusion.* In this paragraph (c)(4)(vi)(B) (*Example 2*), the plan violates the rules of this paragraph (c)(4). As written, the plan excludes coverage of experimental treatment of medical conditions and surgical procedures, mental health conditions, and substance use disorders when no professionally recognized treatment guidelines define clinically appropriate standards of care for the condition or disorder as including the treatment or procedure at issue, and fewer than two randomized controlled trials are available to support the treatment's use with respect to the given condition or procedure. However, in operation, the plan deviates from this strategy with respect to ABA therapy because more than one professionally recognized treatment guideline defines clinically appropriate standards of care for ASD as including ABA therapy to treat certain

children with ASD and more than two randomized controlled trials are available to support the use of ABA therapy to treat certain children with ASD. Therefore, in operation, the strategy used to design the nonquantitative treatment limitation for benefits for the treatment of ASD, which is a mental health condition, in the outpatient, in-network classification is not comparable to, and is applied more stringently than, the strategy used to design the nonquantitative treatment limitation for medical/surgical benefits in the same classification. As a result, the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the outpatient, in-network classification is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(C) *Example 3 (step therapy protocol with exception for severe or irreversible consequences, discriminatory factor)*—(*1*) *Facts.* A plan's written terms include a step therapy protocol that requires participants and beneficiaries who are prescribed certain drugs to try and fail a generic or preferred brand name drug before the plan will cover the drug originally prescribed by a participant's or beneficiary's attending provider. The plan provides an exception to this protocol that was developed solely based on a methodology developed by an external third-party organization. The third-party organization's methodology, which is not based on a generally recognized independent professional medical or clinical standard, identifies instances in which a delay in treatment with a drug prescribed for a medical condition or surgical procedure could result in either severe or irreversible consequences. However, with respect to a drug prescribed for a mental health condition or a substance use disorder, the third-party organization's methodology only identifies instances in which a delay in treatment could result in both severe *and* irreversible consequences, and the plan does not take any steps to correct, cure, or supplement the methodology.

(*2*) *Conclusion.* In this paragraph (c)(4)(vi)(C) (*Example 3*), the plan violates the rules of paragraph (c)(4)(i)(B) of this section. The source upon which the factor used to apply the step therapy protocol is based is biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits because it addresses instances in which a delay in treatment with a drug prescribed for a medical condition or surgical procedure could result in either severe or irreversible consequences, but only addresses instances in which a delay in treatment with a drug prescribed for a mental health condition or substance use disorder could result in both severe and irreversible consequences, and the plan fails to take the steps necessary to correct, cure, or supplement the methodology so that it is not biased and is objective. Based on the relevant facts and circumstances, this source systematically disfavors access or is specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. Therefore, the factor used to apply the step therapy protocol is discriminatory for purposes of determining comparability and stringency under paragraph (c)(4)(i)(A) of this section, and may not be relied upon by the plan.

(D) *Example 4 (use of historical plan data and plan steps to correct, cure, or supplement)*—(*1*) *Facts.* A plan's methodology for calculating provider reimbursement rates relies only on historical plan data on total plan spending for each specialty, divided between mental health and substance use disorder providers and medical/surgical providers, from a time when the plan was not subject

to PHS Act section 2726. The plan has used these historical plan data for many years to establish base reimbursement rates in all provider specialties for which it provides medical/surgical, mental health, and substance use disorder benefits in the inpatient, in-network classification. In evaluating the use of these historical plan data in the design of the methodology for calculating provider reimbursement rates, the plan determined, based on all the relevant facts and circumstances, that the historical plan data systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. To ensure this information about historical reimbursement rates is not biased and is objective, the plan supplements its methodology to develop the base reimbursement rates for mental health and substance use disorder providers in accordance with additional information, evidence, sources, and standards that reflect the increased demand for mental health and substance use disorder benefits in the inpatient, in-network classification and to attract sufficient mental health and substance use disorder providers to the network, so that the relevant facts and circumstances indicate the supplemented information, evidence, sources, or standards do not systematically disfavor access and are not specifically designed to disfavor access to mental health and substance use disorder benefits as compared to medical/surgical benefits.

(*2*) *Conclusion.* In this paragraph (c)(4)(vi)(D) (*Example 4*), the plan does not violate the rules of paragraph (c)(4)(i)(B) of this section with respect to the plan's methodology for calculating provider reimbursement rates in the inpatient, in-network classification. The relevant facts and circumstances indicate that the plan's use of only historical plan data to design its methodology for calculating provider reimbursement rates in the inpatient, in-network classification would otherwise be considered to be biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits under paragraph (c)(4)(i)(B)(*2*) of this section, since the historical data systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. However, the plan took the steps necessary to supplement the information, evidence, sources, and standards to reasonably reflect the increased demand for mental health and substance use disorder benefits in the inpatient, in-network classification, and adjust the methodology to increase reimbursement rates for those benefits, thereby ensuring that the information, evidence, sources, and standards relied upon by the plan for this purpose are not biased and are objective. Therefore, the factors and evidentiary standards used to design the plan's methodology for calculating provider reimbursement rates in the inpatient, in-network classification are not discriminatory.

(E) *Example 5 (generally recognized independent professional medical or clinical standards and more stringent prior authorization requirement in operation)*—(*1*) *Facts.* The provisions of a plan state that it relies on, and does not deviate from, generally recognized independent professional medical or clinical standards to inform the factor used to design prior authorization requirements for both medical/surgical and mental health and substance use disorder benefits in the prescription drug classification. The generally recognized independent professional medical standard for treatment of opioid use disorder that the plan utilizes—in this case, the American Society of Addiction Medicine national practice guidelines—does not support prior authorization every 30 days for buprenorphine/naloxone. However, in operation, the plan requires prior authorization for buprenorphine/naloxone combination for treatment of opioid use disorder, every

30 days, which is inconsistent with the generally recognized independent professional medical standard on which the factor used to design the limitation is based. The plan's factor used to design prior authorization requirements for medical/surgical benefits in the prescription drug classification relies on, and does not deviate from, generally recognized independent professional medical or clinical standards.

(*2*) *Conclusion.* In this paragraph (c)(4)(vi)(E) (*Example 5*), the plan violates the rules of this paragraph (c)(4). The American Society of Addiction Medicine national practice guidelines on which the factor used to design prior authorization requirements for substance use disorder benefits is based are generally recognized independent professional medical or clinical standards that are not considered to be biased or not objective in a manner that discriminates against mental health and substance use disorder benefits under paragraph (c)(4)(i)(B)(*3*) of this section. However, the plan must comply with other requirements in this paragraph (c)(4), as applicable, with respect to such standards or measures that are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation. In operation, the plan's factor used to design and apply prior authorization requirements with respect to substance use disorder benefits is not comparable to, and is applied more stringently than, the same factor used to design and apply prior authorization requirements for medical/surgical benefits, because the factor relies on, and does not deviate from, generally recognized independent professional medical or clinical standards for medical/surgical benefits, but deviates from the relevant guidelines for substance use disorder benefits. As a result, the nonquantitative treatment limitation with respect to substance use disorder benefits in the prescription drug classification is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(F) *Example 6 (plan claims no data exist to reasonably assess impact of nonquantitative treatment limitation on access; medical necessity criteria)*—(*1*) *Facts.* A plan approves or denies claims for mental health and substance use disorder benefits and for medical/surgical benefits in the inpatient, in-network and outpatient, in-network classifications based on medical necessity criteria. The plan states in its comparative analysis that no data exist that can reasonably assess any relevant impact of the medical necessity criteria nonquantitative treatment limitation on relevant outcomes related to access to mental health or substance use disorder benefits as compared to the plan's medical necessity criteria nonquantitative treatment limitation's impact on relevant outcomes related to access to medical/surgical benefits in the relevant classifications, without further explanation.

(*2*) *Conclusion.* In this paragraph (c)(4)(vi)(F) (*Example 6*), the plan violates this paragraph (c)(4). The plan does not comply with paragraph (c)(4)(iii)(A)(*3*)(*ii*) of this section because the plan did not include in its comparative analysis, as required under § 146.137(c)(5)(i)(D), a reasoned justification as to the basis for its conclusion that there are no data that can reasonably assess the nonquantitative treatment limitation's impact, an explanation of why the nature of the nonquantitative treatment limitation prevents the plan from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure the nonquantitative treatment limitation complies with this paragraph (c)(4). Data that could reasonably assess the medical necessity criteria nonquantitative

treatment limitation's impact might include, for example, the number and percentage of claims denials, or the number and percentage of claims that were approved for a lower level of care than the level requested on the initial claim. Therefore, because the plan has not collected and evaluated relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits in the relevant classifications, the plan violates the requirements of paragraph (c)(4)(iii) of this section, and violates the requirements under § 146.137(c)(5)(i)(D) because it did not include sufficient information in its comparative analysis with respect to the lack of relevant data.

(G) *Example 7 (concurrent review data collection; no material difference in access)*—(*1*) *Facts.* A plan follows a written process to apply a concurrent review nonquantitative treatment limitation to all medical/surgical benefits and mental health and substance use disorder benefits within the inpatient, in-network classification. Under this process, a first-level review is conducted in every instance in which concurrent review applies and an authorization request is approved by the first-level reviewer only if the clinical information submitted by the facility meets the plan's criteria for a continued stay. If the first-level reviewer is unable to approve the authorization request because the clinical information submitted by the facility does not meet the plan's criteria for a continued stay, it is sent to a second-level reviewer who will either approve or deny the request. The plan collects relevant data, including the number of referrals to second-level review, and the number of denials of claims for medical/surgical benefits and mental health and substance use disorder benefits subject to concurrent review as compared to the total number of claims subject to concurrent review, in the inpatient, in-network classification. The plan also collects and evaluates the number of denied claims for medical/surgical benefits and mental health and substance use disorder benefits that are overturned on appeal in the inpatient, in-network classification. The plan evaluates the relevant data and determines that, based on the relevant facts and circumstances, the data do not suggest that the concurrent review nonquantitative treatment limitation contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits in the classification. Upon requesting the plan's comparative analysis for the concurrent review nonquantitative treatment limitation and reviewing the relevant data, the Secretary does not request additional data and agrees that the data do not suggest material differences in access.

(*2*) *Conclusion.* In this paragraph (c)(4)(vi)(G) (*Example 7*), the plan does not violate the rules of paragraph (c)(4)(iii) of this section. The plan collected and evaluated relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits and considered the impact as part of its evaluation. Because the relevant data evaluated do not suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in the inpatient, in-network classification, under paragraph (c)(4)(iii)(B) of this section, there is no strong indicator that the plan violates this paragraph (c)(4).

(H) *Example 8 (material difference in access for prior authorization requirement with reasonable action)*—(*1*) *Facts.* A plan requires prior authorization that a treatment is medically necessary for

all inpatient, in-network medical/surgical benefits and for all inpatient, in-network mental health and substance use disorder benefits. The plan collects and evaluates relevant data in a manner reasonably designed to assess the impact of the prior authorization requirement on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits in the inpatient, in-network classification. The plan's written process for prior authorization states that the plan approves inpatient, in-network benefits for medical conditions and surgical procedures and mental health and substance use disorder benefits for periods of 1, 3, and 7 days, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan. Approvals for mental health and substance use disorder benefits are most commonly given only for 1 day, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan. The relevant data show that approvals for 7 days are most common for medical conditions and surgical procedures under this plan. Based on all the relevant facts and circumstances, the difference in the relevant data suggests that the nonquantitative treatment limitation is likely to have a negative impact on access to mental health and substance use disorder benefits as compared to medical/surgical benefits. Therefore, the data suggest that the nonquantitative treatment limitation contributes to material differences in access. To address these material differences in access, the plan consults more recent medical guidelines to update the factors that inform its medical necessity nonquantitative treatment limitations. Based on this review, the plan modifies the limitation so that inpatient, in-network prior authorization requests for mental health or substance use disorder benefits are approved for similar periods to what is approved for medical/surgical benefits. The plan includes documentation of this action as part of its comparative analysis.

(*2*) *Conclusion.* In this paragraph (c)(4)(vi)(H) (*Example 8*), the plan does not violate the rules of paragraph (c)(4)(iii) of this section. While relevant data for the plan's prior authorization requirements suggested that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to inpatient, in-network medical/surgical benefits under paragraph (c)(4)(iii)(B) of this section, the plan has taken reasonable action, as necessary, to ensure compliance, in operation, with this paragraph (c)(4) by updating the factors that inform its prior authorization nonquantitative treatment limitation for inpatient, in-network mental health and substance use disorder benefits so that these benefits are approved for similar periods to what is approved for medical/surgical benefits. The plan also documents its action taken to address material differences in access to inpatient, in-network benefits as required by paragraph (c)(4)(iii)(B)(*1*) of this section.

(I) *Example 9 (differences attributable to generally recognized independent professional medical or clinical standards)*—(*1*) *Facts.* A group health plan develops a medical management requirement for all inpatient, out-of-network benefits for both medical/surgical benefits and mental health and substance use disorder benefits to ensure treatment is medically necessary. The factors and evidentiary standards used to design and apply the medical management requirement rely on independent professional medical or clinical standards that are generally recognized by health care providers and facilities in relevant clinical specialties. The processes, strategies, evidentiary standards, and other factors used in designing and applying the medical management requirement to mental health and substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other

factors used in designing and applying the requirement with respect to medical/surgical benefits. The plan collects and evaluates relevant data in a manner reasonably designed to assess the impact of the medical management nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, and considers the impact as part of the plan's evaluation, as required by paragraph (c)(4)(iii)(A) of this section. Within the inpatient, out-of-network classification, the application of the medical management requirement results in a higher percentage of denials for mental health and substance use disorder claims than medical/surgical claims, because the benefits were found to be medically necessary for a lower percentage of mental health and substance use disorder claims. The plan correctly determines that these differences in access are attributable to the generally recognized independent professional medical or clinical standards used as the basis for the factors and evidentiary standards used to design or apply the limitation and adequately explains the bases for that conclusion as part of its comparative analysis.

(*2*) *Conclusion.* In this paragraph (c)(4)(vi)(I) (*Example 9*), the plan does not violate the rules of this paragraph (c)(4). Generally recognized independent professional medical or clinical standards of care are not considered to be information, evidence, sources, or standards that are biased and not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits, and the plan otherwise complies with the requirements in paragraph (c)(4)(i) of this section. Additionally, the plan does not violate paragraph (c)(4)(iii) of this section because it has collected and evaluated relevant data, the differences in access are attributable to the generally recognized independent professional medical or clinical standards that are used as the basis for the factors and evidentiary standards used to design or apply the medical management nonquantitative treatment limitation, and the plan explains the bases for this conclusion in its comparative analysis. As a result, the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the inpatient, out-of-network classification is no more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(J) *Example 10 (material differences in access for standards for provider admission to a network with reasonable action)*—(*1*) *Facts.* A plan applies nonquantitative treatment limitations related to network composition in the inpatient, in-network and outpatient, in-network classifications. The plan's networks are constructed by separate service providers for medical/surgical benefits and mental health and substance use disorder benefits. The processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitations related to network composition for mental health or substance use disorder benefits in the outpatient, in-network and inpatient, in-network classifications are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitations with respect to medical/surgical benefits in the classifications, as required under paragraph (c)(4)(i) of this section. In order to ensure, in operation, that the nonquantitative treatment limitations are no more restrictive than the predominant nonquantitative treatment limitations applied to substantially all medical/surgical benefits in the classification, the plan collects and evaluates relevant data in a manner reasonably designed to assess the aggregate impact of all the

nonquantitative treatment limitations related to network composition on relevant outcomes related to access to mental health and substance use disorder benefits as compared with access to medical/surgical benefits and considers the impact as part of the plan's evaluation. The plan considers relevant data that is known, or reasonably should be known, including metrics relating to the time and distance from plan participants and beneficiaries to network providers in rural and urban regions; the number of network providers accepting new patients; the proportions of mental health and substance use disorder and medical/surgical providers and facilities that provide services in rural and urban regions who are in the plan's network; provider reimbursement rates (for comparable services and benchmarked to a reference standard, as appropriate); and in-network and out-of-network utilization rates (including data related to the dollar value and number of provider claims submissions). The plan determines that the relevant data suggest that the nonquantitative treatment limitations in the aggregate contribute to material differences in access to mental health and substance use disorder benefits compared to medical/surgical benefits in the classifications because, based on all the relevant facts and circumstances, the differences in the data suggest that the nonquantitative treatment limitations related to network composition are likely to have a negative impact on access to mental health or substance use disorder benefits as compared to medical/surgical benefits. The plan takes reasonable actions, as necessary, to address the material differences in access, to ensure compliance, in operation, with this paragraph (c)(4), by strengthening its efforts to recruit and encourage a broad range of available providers and facilities to join the plan's network of providers, including by taking actions to increase compensation and other inducements, streamline credentialing processes, contact providers reimbursed for items and services provided on an out-of-network basis to offer participation in the network, and develop a process to monitor the effects of such efforts; expanding the availability of telehealth arrangements to mitigate overall provider shortages in certain geographic areas; providing additional outreach and assistance to participants and beneficiaries enrolled in the plan to assist them in finding available in-network providers and facilities; and ensuring that the plan's provider directories are accurate and reliable. The plan documents the efforts that it has taken to address the material differences in access that the data revealed, and the plan includes the documentation as part of its comparative analysis submission.

(*2*) *Conclusion.* In this paragraph (c)(4)(vi)(J) (*Example 10*), the plan does not violate the rules of this paragraph (c)(4). The plan's nonquantitative treatment limitations related to network composition comply with the rules of paragraph (c)(4)(i) of this section. Additionally, the plan collects and evaluates relevant data, as required under paragraph (c)(4)(iii)(A) of this section, in a manner reasonably designed to assess the aggregate impact of all such nonquantitative treatment limitations on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, as required under paragraph (c)(4)(iii)(C) of this section. While the data suggest that the nonquantitative treatment limitations contribute to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, the plan has taken reasonable action, as necessary, to ensure compliance with this paragraph (c)(4). The plan also documents the actions that have been and are being taken by the plan to address material differences as required by § 146.137(c)(5)(iv). As a result, the network composition nonquantitative treatment limitations with respect to mental health or substance use disorder benefits in the inpatient, in-network and outpatient, in-network

classifications are no more restrictive than the predominant nonquantitative treatment limitations that apply to substantially all medical/surgical benefits in the same classifications.

(K) *Example 11 (separate EAP exhaustion treatment limitation applicable only to mental health or substance use disorder benefits)*—(*1*) *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, which, together with other benefits provided by the EAP, are not significant benefits in the nature of medical care. 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.

(*2*) *Conclusion.* In this paragraph (c)(4)(vi)(K) (*Example 11*), the requirement that limits eligibility for mental health and substance use disorder benefits under the major medical plan until EAP benefits are exhausted is a nonquantitative treatment limitation subject to the parity requirements of this paragraph (c)(4). Because the limitation does not apply to medical/surgical benefits, it is a separate nonquantitative treatment limitation applicable only to mental health and substance use disorder benefits that violates paragraph (c)(4)(iv) of this section. Additionally, this EAP would not qualify as excepted benefits under § 146.145(b)(3)(vi)(B)(*1*) because participants in the major medical plan are required to use and exhaust benefits under the EAP (making the EAP a gatekeeper) before an individual is eligible for benefits under the plan.

(L) *Example 12 (separate exclusion for treatment in a residential facility applicable only to mental health and substance use disorder benefits)*—(*1*) *Facts.* A plan generally covers inpatient, in-network and inpatient, out-of-network treatment without any limitations on setting, including skilled nursing facilities and rehabilitation hospitals, provided other medical necessity standards are satisfied. The plan has an exclusion for treatment at residential facilities, which the plan defines as an inpatient benefit for mental health and substance use disorder benefits. This exclusion was not generated through any broader nonquantitative treatment limitation (such as medical necessity or other clinical guideline).

(*2*) *Conclusion.* In this paragraph (c)(4)(vi)(L) (*Example 12*), the plan violates the rules of paragraph (c)(4)(iv) of this section. The exclusion of treatment at residential facilities is a separate nonquantitative treatment limitation applicable only to mental health and substance use disorder benefits in the inpatient, in-network and inpatient, out-of-network classifications because the plan does not apply a comparable exclusion with respect to any medical/surgical benefits in the same benefit classification.

(M) *Example 13 (impermissible nonquantitative treatment limitation imposed following a final determination of noncompliance and direction by the Secretary)*—(*1*) *Facts.* Following an initial request by the Secretary for a plan's comparative analysis of the plan's exclusion of mental health and substance use disorder benefits for failure to complete a course of treatment in the inpatient, in-network classification under § 146.137(d), the plan submits a comparative analysis for the nonquantitative treatment limitation. After review of the comparative analysis, as well as additional information submitted by the plan after the Secretary determines that the plan has not

submitted sufficient information to be responsive to the request, the Secretary makes an initial determination that the comparative analysis fails to demonstrate that the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the inpatient, in-network classification are comparable to, and applied no more stringently than, those used in designing and applying the limitation to medical/surgical benefits in the classification. Under § 146.137(d)(3), the plan submits a corrective action plan and additional comparative analyses within 45 calendar days after the initial determination. However, the corrective action plan does not alter or eliminate the exclusion or alter the processes, strategies, evidentiary standards, and other factors used in designing and applying the exclusion. Moreover, the additional comparative analysis still does not include sufficient information. The Secretary then determines that the additional comparative analyses do not demonstrate compliance with the requirements of this paragraph (c)(4). Accordingly, the plan receives a final determination of noncompliance with PHS Act section 2726 (a)(8) and § 146.137 from the Secretary, which concludes that the plan did not demonstrate compliance through the comparative analysis process. After considering the relevant facts and circumstances, and considering the interests of plan participants and beneficiaries, as well as feedback from the plan, the Secretary directs the plan not to impose the nonquantitative treatment limitation by a certain date, unless and until the plan demonstrates compliance to the Secretary or takes appropriate action to remedy the violation. The plan makes no changes to its plan terms by that date and continues to impose the exclusion of benefits for failure to complete a course of treatment in the inpatient, in-network classification.

(*2*) *Conclusion.* In this paragraph (c)(4)(vi)(M) (*Example 13*), by continuing to impose the exclusion of mental health and substance use disorder benefits for failure to complete a course of treatment in the inpatient, in-network classification after the Secretary directs the plan not to impose this nonquantitative treatment limitation, the plan violates the requirements of paragraph (c)(4)(v) of this section.

(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 (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) who have received 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 and the comparative analyses and other applicable information required by § 146.137.

(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 or § 146.137(g) 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 that is required to provide 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 requirements under section 2726 of the PHS Act and its implementing regulations in this section and § 146.137 to satisfy the requirement to provide coverage for mental health and substance use disorder services, including behavioral health treatment, as part of 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:

$[(E1 - E0) / T0] - D > k$

(i) E1 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) E0 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) T0 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 $(E1-E0)/T0$ 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—

(i) 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 January 1, 2025, except that the requirements of paragraphs (c)(2)(ii)(A), (c)(4)(i)(B), and (c)(4)(iii) of this section apply on the first day of the first plan year beginning on or after January 1, 2026.

(ii) Until the applicability date in paragraph (i)(1)(i) of this section, plans and issuers are required to continue to comply with 45 CFR 146.136, revised as of October 1, 2023.

(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).

(j) *Severability.* If any provision of this section is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

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