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Code of Federal Regulations > TITLE 45 -- PUBLIC WELFARE > SUBTITLE A -- DEPARTMENT OF HEALTH AND HUMAN SERVICES > SUBCHAPTER B -- REQUIREMENTS RELATING TO HEALTH CARE ACCESS > PART 146 -- REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET > SUBPART C -- REQUIREMENTS RELATED TO BENEFITS

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) General-- (i) General parity requirement. A group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that provides both medical/surgical benefits and mental health or substance use disorder benefits must comply with paragraph (b)(2), (b)(3), or (b)(5) of this section.

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

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

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

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

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

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

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

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

(B) Impose an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is no less than an average limit calculated for medical/surgical benefits in the following manner. The average limit is calculated by taking into account the weighted average of the aggregate lifetime or annual dollar limits, as appropriate, that are applicable to the categories of medical/surgical benefits. Limits based on delivery systems, such as inpatient/outpatient treatment or normal treatment of common, low-cost conditions (such as treatment of normal births), do not constitute categories for purposes of this paragraph (b)(5)(i)(B). In addition, for purposes of determining weighted averages, any benefits that are not within a category that is subject to a separately-designated dollar limit under the plan are taken into account as a single separate category by using an estimate of the upper limit on the dollar amount that a plan may reasonably be expected to incur with respect to such benefits, taking into account any other applicable restrictions under the plan.

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

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

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

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

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

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

(ii) Classifications of benefits used for applying rules --(A) In general. If a plan (or health insurance coverage) provides mental health or substance use disorder benefits in any classification of benefits described in this paragraph (c)(2)(ii), mental health or substance use disorder benefits must be provided in every classification in which medical/surgical benefits are

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

- (1)**Inpatient, in-network. Benefits furnished on an inpatient basis and within a network of providers established or recognized under a plan or health insurance coverage. See special rules for plans with multiple network tiers in paragraph (c)(3)(iii) of this section.
- (2)**Inpatient, out-of-network. Benefits furnished on an inpatient basis and outside any network of providers established or recognized under a plan or health insurance coverage. This classification includes inpatient benefits under a plan (or health insurance coverage) that has no network of providers.
- (3)**Outpatient, in-network. Benefits furnished on an outpatient basis and within a network of providers established or recognized under a plan or health insurance coverage. See special rules for office visits and plans with multiple network tiers in paragraph (c)(3)(iii) of this section.
- (4)**Outpatient, out-of-network. Benefits furnished on an outpatient basis and outside any network of providers established or recognized under a plan or health insurance coverage. This classification includes outpatient benefits under a plan (or health insurance coverage) that has no network of providers. See special rules for office visits in paragraph (c)(3)(iii) of this section.
- (5)**Emergency care. Benefits for emergency care.
- (6)**Prescription drugs. Benefits for prescription drugs. See special rules for multi-tiered prescription drug benefits in paragraph (c)(3)(iii) of this section.

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

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

Example 1.

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

(ii)Conclusion. In this Example 1, because the plan has no network of providers, all benefits provided are out-of-network. Because inpatient, out-of-network medical/surgical benefits are subject to separate financial requirements from outpatient, out-of-network medical/surgical benefits, the rules of this paragraph (c)

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apply separately with respect to any financial requirements and treatment limitations, including the deductible, in each classification.

Example 2.

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

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

Example 3.

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

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

(A)Benefits in the emergency care classification; and

(B)All other benefits.

Example 4.

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

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

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

(B)All other benefits.

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

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

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

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

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

(D)Clarifications for certain threshold requirements. For any deductible, the dollar amount of plan payments includes all plan payments with respect to claims that would be subject to the deductible if it had not been satisfied. For any out-of-pocket maximum, the dollar amount of plan payments includes all plan payments associated with out-of-pocket payments that are taken into account towards the out-of-pocket maximum as well as all plan payments associated with out-of-pocket payments that would have been made towards the out-of-pocket maximum if it had not been satisfied. Similar rules apply for any other thresholds at which the rate of plan payment changes. (See also PHS Act section 2707(b) and Affordable Care Act section 1302(c), which establish limitations on annual deductibles for non-grandfathered health plans in the small group market and annual limitations on out-of-pocket maximums for all non-grandfathered health plans.)

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

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

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

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paragraph (c) with respect to prescription drug benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up.

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

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

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

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

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

Example 1.

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

Co-insurance 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	N/A	12.5%	56.25%	12.5%	18.75%	
		(100x/	(450x/	(100x/	(150x/	

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

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

Example 2.

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

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

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

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

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substance use disorder benefits that is more restrictive than the least restrictive copayment in the combination, the \$ 15 copayment.

Example 3.

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

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

Example 4.

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

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

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

Example 5.

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

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

Example 6.

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

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

Example 7.

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

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

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

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

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Example 1.

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

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

Example 2.

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

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

Example 3.

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

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

Example 4.

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

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

(ii)Conclusion. In this Example 4, the two-thirds threshold of the substantially all standard is met with respect to each classification except

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

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

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

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

(B) Formulary design for prescription drugs;

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

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

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

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

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

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

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

Example 1.

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

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

Example 2.

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

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

Example 3.

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

(ii)Conclusion. In this Example 3, the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation--medical necessity--is applied both to mental health and substance use disorder benefits and to medical/surgical benefits for outpatient, in-network services, it is not applied in a comparable way. The penalty for failure to obtain prior approval for mental health and substance use disorder benefits is not comparable to the penalty for failure to obtain prior approval for medical/surgical benefits.

Example 4.

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

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

Example 5.

(i)Facts. A plan generally covers medically appropriate treatments. In determining whether prescription drugs are medically appropriate, the plan automatically excludes coverage for antidepressant drugs that are given a

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

(ii)Conclusion. In this Example 5, the plan violates the rules of this paragraph (c)(4). Although the standard for applying a nonquantitative treatment limitation is the same for both mental health and substance use disorder benefits and medical/surgical benefits--whether a drug has a black box warning--it is not applied in a comparable manner. The plan's unconditional exclusion of antidepressant drugs given a black box warning is not comparable to the conditional exclusion for other drugs with a black box warning.

Example 6.

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

(ii)Conclusion. In this Example 6, limiting eligibility for mental health and substance use disorder benefits only after EAP benefits are exhausted is a nonquantitative treatment limitation subject to the parity requirements of this paragraph (c). Because no comparable requirement applies to medical/surgical benefits, the requirement may not be applied to mental health or substance use disorder benefits.

Example 7.

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

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

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

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

Example 9.

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

(ii)Conclusion. In this Example 9, the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation--medical appropriateness--is applied to both mental health and substance use disorder benefits and medical/surgical benefits, the plan's unconditional exclusion of substance use disorder treatment in any setting outside of a hospital is not comparable to the conditional exclusion of inpatient treatment outside of a hospital for other conditions.

Example 10.

(i)Facts. A plan generally provides coverage for medically appropriate medical/surgical benefits as well as mental health and substance use

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disorder benefits. The plan excludes coverage for inpatient, out-of-network treatment of chemical dependency when obtained outside of the State where the policy is written. There is no similar exclusion for medical/surgical benefits within the same classification.

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

Example 11.

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

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

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

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

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

(3)Provisions of other law. Compliance with the disclosure requirements in paragraphs (d)(1) and (d)(2) of this section is not determinative of compliance with any other provision of applicable Federal or State

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law. In particular, in addition to those disclosure requirements, provisions of other applicable law require disclosure of information relevant to medical/surgical, mental health, and substance use disorder benefits. For example, § 147.136 of this subchapter sets forth rules regarding claims and appeals, including the right of claimants (or their authorized representative) upon appeal of an adverse benefit determination (or a final internal adverse benefit determination) to be provided upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the claimant's claim for benefits. This includes documents with information on medical necessity criteria for both medical/surgical benefits and mental health and substance use disorder benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply a nonquantitative treatment limitation with respect to medical/surgical benefits and mental health or substance use disorder benefits under the plan.

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

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

(3)Scope. This section does not--

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

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

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

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

(f)Small employer exemption --(1) In general. The requirements of this section do not apply to a group health plan (or health insurance issuer offering coverage in connection with a group health plan) for a plan year of a small employer (as defined in section 2791 of the PHS Act).

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

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

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

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

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

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

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

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

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

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

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

$$[(E[1] - E[0])/T[0]] - D > k$$

(i) E[1] is the actual total cost of coverage with respect to mental health and substance use disorder benefits for the base period, including claims paid by the plan or issuer with respect to mental health and substance use disorder benefits and administrative costs (amortized over time) attributable to providing these benefits consistent with the requirements of this section.

(ii) E[0] is the actual total cost of coverage with respect to mental health and substance use disorder benefits for the length of time immediately before the base period (and that is equal in length to the base period), including claims paid by the plan or issuer with respect to mental health and substance use disorder benefits and administrative costs (amortized over time) attributable to providing these benefits.

(iii) T[0] is the actual total cost of coverage with respect to all benefits during the base period.

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

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(v)D is the average change in spending that is calculated by applying the formula $(E [1] - E [0]) / T [0]$ to mental health and substance use disorder spending in each of the five prior years and then calculating the average change in spending.

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

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

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

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

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

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

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

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

(6)The effective date of such exemption.

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

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

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

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

(D)Availability of documentation. The plan or issuer must make available to participants and beneficiaries (or their representatives), on request and at no charge, a summary of the information on which the exemption was based. (For purposes of this paragraph (g), an

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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)(iii) 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

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which the plan is exempt from the requirements of this section because the plan meets the requirements of paragraph (f) or (g) of this section.

(i)Applicability dates --(1) In general. Except as provided in paragraph (i)(2) of this section, this section applies to group health plans and health insurance issuers offering group health insurance coverage on the first day of the first plan year beginning on or after July 1, 2014. Until the applicability date, plans and issuers are required to continue to comply with the corresponding sections of § 146.136 contained in the 45 CFR, parts 1 to 199, edition revised as of October 1, 2013.

(2)Special effective date for certain collectively-bargained plans. For a group health plan maintained pursuant to one or more collective bargaining agreements ratified before October 3, 2008, the requirements of this section do not apply to the plan (or health insurance coverage offered in connection with the plan) for plan years beginning before the date on which the last of the collective bargaining agreements terminates (determined without regard to any extension agreed to after October 3, 2008).

Statutory Authority

AUTHORITY NOTE APPLICABLE TO ENTIRE PART:

42 U.S.C. 300gg-1 through 300gg-5, 300gg-11 through 300gg-23, 300gg-91, and 300gg-92.

History

62 FR 66932, 66961, Dec. 22, 1997; 68 FR 38206, 38208, June 27, 2003; 69 FR 43924, 43926, July 23, 2004; 70 FR 42276, 42278, July 22, 2005; 71 FR 25092, 25093, Apr. 28, 2006; 72 FR 41230, 41231, July 27, 2007; 75 FR 5410, 5444, Feb. 2, 2010, as confirmed and revised at 78 FR 68240, 68286, Nov. 13, 2013]

Annotations

Notes

[EFFECTIVE DATE NOTE:

78 FR 68240, 68286, Nov. 13, 2013, revised this section, effective Jan. 13, 2014.]

Case Notes

LexisNexis® Notes

Governments : Legislation : Interpretation
Healthcare Law : Insurance : General Overview
Healthcare Law : Insurance : Experimental Treatment
Healthcare Law : Insurance : Medical Necessity
Pensions & Benefits Law : Employee Retirement Income Security Act (ERISA) : Mental Health Parity Act

Governments : Legislation : Interpretation

[A.F. v. Providence Health Plan, 35 F. Supp. 3d 1298, 2014 U.S. Dist. LEXIS 109507](#) (D Or Aug. 8, 2014).

Overview: Dependents who were beneficiaries of a group health insurance plan were entitled to summary judgment on their claims that insurer violated [29 U.S.C.S. § 1185a](#) and Oregon law when it purported to cover autism under its plan but denied coverage for medically necessary Applied Behavior Analysis therapy through its developmental disability exclusion.

- The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act ("Federal Parity Act"), [29 U.S.C.S. § 1185a](#) and the related regulations explicitly note that the Federal Parity Act applies to both quantitative and nonquantitative limitations. [45 C.F.R. § 146.136\(a\)](#); [29 C.F.R. § 2590.712\(a\)](#). The principal of ejusdem generis normally only comes into play when a general word follows a list of specific words, i.e., when a drafter has tacked on a catchall phrase at the end of an enumeration of specifics. The Federal Parity Act provides examples of what treatment limitations might be after the term is used. The term "treatment limitations" does not appear as a general term at the end of a list of specifics. [Go To Headnote](#)

Healthcare Law : Insurance : General Overview

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Healthcare Law : Insurance : Experimental Treatment

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Overview: Dependents who were beneficiaries of a group health insurance plan were entitled to summary judgment on their claims that insurer violated [29 U.S.C.S. § 1185a](#) and Oregon law when it purported to cover autism under its plan but denied coverage for medically necessary Applied Behavior Analysis therapy through its developmental disability exclusion.

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- The U.S. Department of Health and Human Services has issued regulations interpreting the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act, [29 U.S.C.S. § 1185a](#). In those regulations, the agency explains that the term "treatment limitations" includes both quantitative and nonquantitative limitations. Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under a plan or coverage. A permanent exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of this definition. [45 C.F.R. § 146.136\(a\)](#); [29 C.F.R. § 2590.712\(a\)](#). Included in the regulations is an illustrative list of nonquantitative treatment limitations which include medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative. [Go To Headnote](#)

Healthcare Law : Insurance : Medical Necessity

[A.F. v. Providence Health Plan, 35 F. Supp. 3d 1298, 2014 U.S. Dist. LEXIS 109507](#) (D Or Aug. 8, 2014).

Overview: *Dependents who were beneficiaries of a group health insurance plan were entitled to summary judgment on their claims that insurer violated [29 U.S.C.S. § 1185a](#) and Oregon law when it purported to cover autism under its plan but denied coverage for medically necessary Applied Behavior Analysis therapy through its developmental disability exclusion.*

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Pensions & Benefits Law : Employee Retirement Income Security Act (ERISA) : Mental Health Parity Act

[A.F. v. Providence Health Plan, 35 F. Supp. 3d 1298, 2014 U.S. Dist. LEXIS 109507](#) (D Or Aug. 8, 2014).

Overview: *Dependents who were beneficiaries of a group health insurance plan were entitled to summary judgment on their claims that insurer violated [29 U.S.C.S. § 1185a](#) and Oregon law when it purported to cover autism under its plan but denied coverage for medically necessary Applied Behavior Analysis therapy through its developmental disability exclusion.*

- The U.S. Department of Health and Human Services has issued regulations interpreting the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act, [29 U.S.C.S. § 1185a](#). In those regulations, the agency explains that the term "treatment limitations" includes both quantitative and nonquantitative limitations. 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

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expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under a plan or coverage. A permanent exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of this definition. [45 C.F.R. § 146.136\(a\)](#); [29 C.F.R. § 2590.712\(a\)](#). Included in the regulations is an illustrative list of nonquantitative treatment limitations which include medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative. [Go To Headnote](#)

- The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act ("Federal Parity Act"), [29 U.S.C.S. § 1185a](#), and the related regulations explicitly note that the Federal Parity Act applies to both quantitative and nonquantitative limitations. [45 C.F.R. § 146.136\(a\)](#); [29 C.F.R. § 2590.712\(a\)](#). The principal of ejusdem generis normally only comes into play when a general word follows a list of specific words, i.e., when a drafter has tacked on a catchall phrase at the end of an enumeration of specifics. The Federal Parity Act provides examples of what treatment limitations might be after the term is used. The term "treatment limitations" does not appear as a general term at the end of a list of specifics. [Go To Headnote](#)

Research References & Practice Aids

NOTES APPLICABLE TO ENTIRE SUBTITLE:

[PUBLISHER'S NOTE: Nomenclature changes to Subtitle A appear at [66 FR 39450, 39452](#), July 31, 2001.]

[PUBLISHER'S NOTE: For Federal Register citations concerning Race to the Top--Early Learning Challenge (RTT-ELC) program, see: [78 FR 53964](#), Aug. 30, 2013.]

NOTES APPLICABLE TO ENTIRE PART:

[PUBLISHER'S NOTE: For Federal Register citations concerning Part 146 Regulation Clarifications, see: [62 FR 67688, 67689](#), Dec. 29, 1997.]

[PUBLISHER'S NOTE: For Federal Register citations concerning Part 146 Final rule, see: [83 FR 19431](#), May 3, 2018.]

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