# HEALTH & WELFARE PLAN LUNCH GROUP

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# INDEX

1. Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act (MHPAEA)

2. [Proposed] FAQs About Mental Health and Substance Use Disorder Parity Implementation and the 21st Century Cures Act Part XX

3. Risk Analyses vs. Gap Analyses – What is the difference?

# Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act (MHPAEA)

## About This Tool

The goal of this self-compliance tool is to help group health plans, plan sponsors, plan administrators, group and individual market health insurance issuers, State regulators and other parties determine whether a group health plan or health insurance issuer complies with the Mental Health Parity and Addiction Equity Act (MHPAEA), and additional, related requirements that apply to Employer Retirement Income Security Act of 1975 (ERISA) group health plans. The requirements described in this tool generally apply to group health plans, group health insurance issuers, and individual market health insurance issuers. However, requirements that do not apply as broadly are noted.

This tool is does not provide legal advice. Rather, it gives the user a basic understanding of MHPAEA to assist in evaluating compliance with its requirements. For more information on MHPAEA, or related guidance issued by the Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury (collectively, the Departments), please visit https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/mental-health-and-substance-use-disorder-parity.

Furthermore, as directed by Section 13001(a) of the 21st Century Cures Act, this publicly available tool is as a compliance program guidance document to improve compliance with MHPAEA. The Department will update the self-compliance tool biennially to provide additional guidance on MHPAEA's requirements, as appropriate.

MHPAEA, as a Federal law, sets minimum standards for group health plans and issuers with respect to parity requirements. However, many States have enacted their own laws to advance parity between mental health and substance use disorder benefits and medical/surgical benefits by supplementing the requirements of MHPAEA. Insured group health plans and issuers should check with their State regulators to understand the full scope of applicable parity requirements. Increased public awareness and commitment to successful implementation of MHPAEA and State parity laws has led to the creation of private partnerships among different advocacy groups that may be a helpful resource regarding parity implementation.

## Introduction

MHPAEA, as amended by the Patient Protection and Affordable Care Act (the Affordable Care Act), generally requires that group health plans and health insurance issuers offering group or individual health insurance coverage ensure that the financial requirements and treatment limitations on mental health or substance use disorder (MH/SUD) benefits they provide are no more restrictive than those on medical or surgical benefits. This is commonly referred to as providing MH/SUD benefits in parity with medical/surgical benefits.

MHPAEA generally applies to group health plans and group and individual health insurance issuers that provide coverage for mental health or substance use disorder and benefits in addition to medical/surgical benefits. DOL has primary enforcement authority with regard to MHPAEA over private sector employment-based group health plans, while HHS has primary enforcement authority over non-Federal governmental plans, such as those sponsored by State and local government employers. HHS also directly enforces MHPAEA over issuers in states that have notified HHS's Centers for Medicare & Medicaid Services' that they do not have the authority to enforce or are not otherwise enforcing MHPAEA. In all other States, the State is directly enforcing MHPAEA with respect to issuers.

Unless a plan is otherwise exempt, MHPAEA generally applies to both grandfathered and non-grandfathered group health plans and large group health insurance coverage. Also note that the Affordable Care Act requires plans and issuers offering coverage in the individual and small group markets to cover certain essential health benefits (EHB), including MH/SUD benefits. Final rules issued by HHS implementing EHB requirements specify that MH/SUD benefits must be offered consistent with the requirements of the MHPAEA regulations. *See 45 CFR 156.115(a)(3).*

Under the MHPAEA regulations, if a plan or issuer provides any classification of MH/SUD benefits described in the MHPAEA final regulation, MH/SUD benefits must be provided in every classification in which medical/surgical benefits are provided. Under PHS Act section 2713, as added by the Affordable Care Act, non-grandfathered group health plans and group and individual health insurance plans are required to provide coverage for certain preventive services with no cost-sharing, which includes, among other things, alcohol misuse screening and counseling, depression screening, and tobacco use screening. However, the MHPAEA regulations does not require a group health plan or a health insurance issuer that provides MH/SUD benefits only to the extent required under PHS Act section 2713, to provide additional MH/SUD benefits in any classification. *See 29 CFR 2590.712(e)(3)(ii), 45 CFR 146.136(e)(3)(ii), 26 CFR 54.9812-1(e)(3)(ii)*

## Definitions

***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 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 for any coverage unit.

***Cumulative financial requirements*** are financial requirements that determine whether or to what extent benefits are provided based on certain accumulated amounts, and they 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 certain 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 not including mental health or substance use disorder benefits. Any condition defined by the plan or coverage as being or as not being a medical/surgical condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the International Classification of Diseases (ICD) or State guidelines).

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

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

***Treatment limitations*** include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations (QTLs), which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations (NQTLs), 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.

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## SECTION A. APPLICABILITY

**Question 1.** **Is the group health plan or group or individual health insurance coverage exempt from MHPAEA? If so, please indicate the reason (e.g. retiree-only plan, excepted benefits, small employer exception, increased cost exception).**

| Comments: |
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If a group health plan or group or individual health insurance coverage provides either mental health or substance use disorder benefits, in addition to medical/surgical benefits, the plan may be subject to the MH/SUD parity provisions. However, **retiree-only group health plans**, self-insured non-Federal governmental plans that have obtained a waiver and group health plans and group or individual health insurance coverage offering only **excepted benefits**, are generally not subject to the MH/SUD parity provisions. (***Note***: if under an arrangement(s) to provide medical care benefits by an employer or employee organization, any participant or beneficiary can simultaneously receive coverage for medical/surgical benefits and MH/SUD benefits, the MH/SUD parity requirements apply separately with respect to each combination of medical/surgical benefits and MH/SUD benefits and all such combinations are considered to be a single group health plan. *See 26 CFR 54.9812-1(e), 29 CFR 2590.712(e), 45 CFR 146.136(e)*).

Under ERISA, the MHPAEA requirements do not apply to **small employers**, defined as employers who employed an average of at least 2 but not more than 50 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. *See 26 CFR 54.9812-1(f)(1), 29 CFR 2590.712(f)(1), 45 CFR 146.136(f)(1).* However, under HHS final rules governing the Affordable Care Act requirement to provide EHBs, non-grandfathered health insurance coverage in the individual and small group markets must provide all categories of EHBs, including MH/SUD benefits. *45 CFR 147.150(a).* The final EHB rules require that such benefits be provided in compliance with the requirements of the MHPAEA rules. *45 CFR 156.115(a)(3); See also ACA Implementation FAQs Part XVII, Q6, available at: https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xvii.pdf.*

MHPAEA also contains an **increased cost exemption** available to group health plans and issuers that meet the requirements for the exemption. The final rules establish standards and procedures for claiming an increased cost exemption under MHPAEA. *See 26 CFR 54.9812-1(g), 29 CFR 2590.712(g), 45 CFR 146.136(g).*

Sponsors of self-funded, non-Federal governmental plans are permitted to elect to exempt those plans from, or "opt out of," certain provisions of the Public Health Service (PHS) Act, including MHPAEA. This election was authorized under section 2722(a)(2) of the PHS Act (42 USC § 300gg-21(a)(2)).

**Question 2.** **If not exempt, does the group health plan or group or individual health insurance coverage provide MH/SUD benefits in addition to providing medical/surgical benefits?**

| Comments: |
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**Unless the group health plan or group or individual health insurance coverage is exempt or does not provide MH/SUD benefits, continue to the following sections to examine compliance with requirements under MHPAEA.**

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## SECTION B. COVERAGE IN ALL CLASSIFICATIONS

**Question 3.** **Does the group health plan or group or individual health insurance coverage provide MH/SUD benefits in every classification in which medical/surgical benefits are provided?**

| Comments: |
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Under the MHPAEA regulations, if a plan or issuer provides mental health or substance use disorder benefits in any classification described in the MHPAEA final regulation, mental health or substance use disorder benefits must be provided in every classification in which medical/surgical benefits are provided. *See 26 CFR 54.9812-1(c)(2)(ii)(A), 29 CFR 2590.712(c)(2)(ii)(A), 45 CFR 146.136(c)(2)(ii)(A).*

**Under the MHPAEA regulations, the six classifications* of benefits are:**

1) inpatient, in-network;
2) inpatient, out-of-network;
3) outpatient, in-network;
4) outpatient, out-of-network;
5) emergency care; and
6) prescription drugs.

*See 26 CFR 54.9812-1(c)(2)(ii), 29 CFR 2590.712(c)(2)(ii), 45 CFR 146.136(c)(2)(ii).*

**See special rules related to the classifications discussed below.*

***ILLUSTRATION:*** Plan X provides medical/surgical benefits as well as MH/SUD benefits. While the Plan covers medical/surgical benefits in all benefit classifications, it does not cover outpatient services for MH/SUD benefits for either in-network or out-of-network providers. In this example, since the Plan fails to provide MH/SUD benefits in outpatient, in-network and outpatient, out-of-network classifications in which medical/surgical benefits are provided, the Plan fails to meet MHPAEA's parity requirements.

***Classifying benefits***. In determining the classification in which a particular benefit belongs, a group health plan or group or individual market health insurance issuer must apply the same standards to medical/surgical benefits as to MH/SUD benefits. *See 26 CFR 54.9812-1(c)(2)(ii)(A), 29 CFR 2590.712(c)(2)(ii)(A), 45 CFR 146.136(c)(2)(ii)(A)* This rule also applies to intermediate services provided under the plan or coverage. Plans and issuers must assign covered intermediate MH/SUD benefits (such as residential treatment, partial hospitalization and intensive outpatient treatment) to the existing six classifications in the same way that they assign intermediate medical/surgical benefits to these classifications. For example, if a plan classifies care in skilled nursing facilities and rehabilitation hospitals for medical/surgical benefits as inpatient benefits, it must classify covered care in residential treatment facilities for MH/SUD benefits as inpatient benefits. If a plan treats home health care as an outpatient benefit, then any covered intensive outpatient MH/SUD services and partial hospitalization must be considered outpatient benefits as well. A plan or issuer must also comply with MHPAEA's nonquantitative treatment limitations (NQTL) rules, discussed in Section F, in assigning any benefits to a particular classification. *See 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), 45 CFR 146.136(c)(4).*

### Medication Assisted Treatment (MAT) is subject to MHPAEA

Plans and issuers that offer MAT benefits to treat opioid use disorder are subject to MHPAEA requirements, including the special rule for multi-tiered prescription drug benefits which apply to the medication component of MAT. The behavioral health services components of MAT should be treated as outpatient benefits and/or inpatient benefits as appropriate for purposes of MHPAEA. Ensure that there are NO impermissible QTLs, such as visit limits, or impermissible NQTLs, such as limits on treatment dosage and duration.

> ***ILLUSTRATION:*** An issuer did not cover methadone for opioid addiction though it did cover methadone for pain management. The issuer failed to demonstrate that the processes, strategies, evidentiary standards, and other factors used to develop the methadone treatment exclusion for opioid addiction are comparable to and applied no more stringently than those used for medical/surgical conditions. The issuer re-evaluated the medical necessity of methadone-maintenance treatment programs and developed medical-necessity criteria that mirrors Federal guidelines for opioid treatment programs to replace the methadone-maintenance treatment exclusion.

### Treatment for eating disorders is subject to MHPAEA

Eating disorders are mental health conditions, and treatment of an eating disorder is a mental health benefit within the meaning of that term as defined by MHPAEA. *See ACA Implementation FAQs Part 38, Q1, available at* https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-38.pdf. Section 13007 of the Cures Act provides that if a plan or an issuer provides coverage for eating disorders, including residential treatment, they must provide these benefits in accordance with the requirements under MHPAEA.

## Compliance Tips

- If the plan or issuer does not contract with a network of providers, all benefits are out-of-network. If a plan or issuer that has no network imposes a financial requirement or treatment limitation on inpatient or outpatient benefits, the plan or issuer is imposing the requirement or limitation within classifications (inpatient, out-of-network or outpatient, out-of-network), and the rules for parity will be applied separately for the different classifications. *See 26 CFR 54.9812-1(c)(2)(ii)(C), 29 CFR 2590.712(c)(2)(ii)(C), 45 CFR 146.136(c)(2)(ii)(C) Example 1.*
- If a plan or issuer covers the full range of medical/surgical benefits (in all classifications, both in-network and out-of-network), beware of exclusions on out-of-network MH/SUD benefits.
- Benefits for intermediate services (such as non-hospital inpatient and partial hospitalization) must be assigned to classifications using a comparable methodology across medical/surgical benefits and MH/SUD benefits.

***NOTE*: Special rules related to classifications**

1. **Special rule for outpatient sub-classifications:**

- For purposes of determining parity for outpatient benefits (in-network and out-of-network), a plan or issuer may divide its benefits furnished on an outpatient basis into two sub-classifications: (1) office visits; and (2) all other outpatient items and services, for purposes of applying the financial requirement and treatment limitation rules. *26 CFR 54.9812-1(c)(3)(iii);* 29 CFR 2590.712(c)(3)(iii) 45 CFR 146.136(c)(3)(iii).
  - After the sub-classifications are established, the plan or issuer may not impose any financial requirement or QTL on MH/SUD benefits in any sub-classification (i.e., office visits or non-office visits) 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 the final rules. *See 26 CFR 54.9812-1(c)(3)(i), 29 CFR 2590.712(c)(3)(i), 45 CFR 146.136(c)(3)(i), and 45 CFR 146.136(c)(3)(iii).*
- Other than as explicitly permitted under the final rules, sub-classifications are not permitted when applying the financial requirement and treatment limitation rules under MHPAEA. Accordingly, separate sub-classifications for generalists and specialists are not permitted.

2. **Special rule for prescription drug benefits:**

- There is a special rule for multi-tiered prescription drug benefits. Multi-tiered drug formularies involve different levels of drugs that are classified based primarily on cost, the lowest-tier (Tier 1) drugs having the lowest cost-sharing. If a plan or issuer applies different levels of financial requirements to different tiers of prescription drug benefits, the plan complies with the mental health parity provisions if it establishes the different levels of financial requirements based on reasonable factors determined in accordance with

the rules for NQTLs and without regard to whether a drug is generally prescribed for medical/surgical or MH/SUD benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up. *See 26 CFR54.9812-1(c)(3)(iii), 29 CFR 2590.712(c)(3) (iii),45 CFR 146.136(c)(3)(iii).*

3. **Special rule for multiple network tiers:**

- There is a special rule for multiple network tiers. If a plan or issuer provides benefits through multiple tiers of in-network providers (such as in-network preferred and in-network participating providers), the plan or issuer 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 for NQTLs (such as quality, performance, and market standards) and without regard to whether a provider provides services with respect to medical/surgical benefits or MH/SUD benefits. After the tiers are established, the plan or issuer may not impose any financial requirement or treatment limitation on MH/SUD benefits in any tier that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/ surgical benefits in the tier.

***NOTE*:** As explained in the Introduction to this section, nothing in MHPAEA requires a non-grandfathered group health plan or health insurance coverage that provides MH/SUD benefits only to the extent required under PHS Act section 2713 to provide additional MH/SUD benefits in any classification.

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## SECTION C. LIFETIME AND ANNUAL LIMITS

**Question 4. Does the group health plan or group or individual market health insurance issuer comply with the mental health parity requirements regarding lifetime and annual dollar limits on MH/SUD benefits?**

| Comments: |
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A plan or issuer generally may not impose a lifetime dollar limit or an annual dollar limit on MH/SUD benefits that is lower than the lifetime or annual dollar limit imposed on medical/ surgical benefits. *See 26 CFR 9812-1(b), 29 CFR 2590.712(b), 45 CFR 146.136(b).* (This prohibition applies only to dollar limits on what the plan would pay, and not to dollar limits on what an individual may be charged.) If a plan or issuer does not include an aggregate lifetime or annual dollar limit on any medical/surgical benefits, or it includes one that applies to less than one-third of all medical/surgical benefits, it may not impose an aggregate lifetime or annual dollar limit on MH/SUD benefits. 26 CFR 54.9812-1(b)(2), *29 CFR 2590.712(b)(2), 45 CFR 146.136(b)(2).*

***ILLUSTRATION:*** Plan Z limits outpatient substance use disorder treatments to a maximum of $1,000,000 per calendar year. With the exception of a $500,000 per year limit on chiropractic services, (which applies to less than one-third of all medical/surgical benefits), the Plan does not impose such annual dollar limits with respect to other outpatient medical/surgical benefits. In this example, the Plan is in violation of MHPAEA since the outpatient substance use disorder dollar limit is not in parity with outpatient medical/surgical dollar limits.

**Compliance Tip**

- There is a different rule for cumulative limits other than aggregate lifetime or annual dollar limits discussed later in this checklist at **Question 6.** A plan or issuer may impose annual out-of-pocket dollar limits on participants and beneficiaries if that is done in accordance with the rule regarding cumulative limits.

***NOTE:*** These provisions are affected by section 2711 of the PHS Act, as amended by the Affordable Care Act. Specifically, PHS Act section 2711 generally prohibits lifetime and annual dollar limits on EHB, which includes MH/SUD services. Accordingly, the parity requirements regarding lifetime and annual dollar limits only apply to the provision of MH/SUD benefits that are not EHBs.

Note also that, for plan years beginning in 2018, the annual limitation on an individual's maximum out-of-pocket (MOOP) costs in effect under the Affordable Care Act is $7,350 for self-only coverage and $14,700 for coverage other than self-only coverage *See 26 CFR 54.9812-1(c)(3)(i)(D), 29 CFR 2590.712(c)(3)(i)(D); 45 CFR 156.130.* The annual limitation on out-of-pocket costs is increased annually by the premium adjustment percentage described under Affordable Care Act section 1302(c)(4), this updated amount is detailed each year in regulations issues by the Department of Health and Human Services.

## SECTION D. FINANCIAL REQUIREMENTS AND QUANTITATIVE TREATMENT LIMITATIONS

**Question 5.** **Does the group health plan or group or individual market health insurance issuer comply with the mental health parity requirements regarding financial requirements or QTLs on MH/SUD benefits?**

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- A plan or issuer may not impose a financial requirement or QTL applicable to MH/SUD benefits in any classification that is more restrictive than the predominant financial requirement or QTL of that type that is applied to substantially all medical/surgical benefits in the same classification. *See 26 CFR 54.9812-1(c)(2), 29 CFR 2590.712(c)(2), 45 CFR 146.136(c)(2).*
  - Types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. *See 26 CFR 54.9812-1(c)(1)(ii), 29 CFR 2590.712(c)(1)(ii), 45 CFR 146.136(c)(1)(ii).*
  - Types of QTLs include annual, episode, and lifetime day and visit limits, for example, number of treatments, visits, or days of coverage. *See 26 CFR 54.9812-1(c)(1)(ii), 29 CFR 2590.712(c)(1)(ii), 45 CFR 146.136(c)(1)(ii).*

- The six classifications and the subclassifications outlined in Section B, above, are the only classifications that may be used when determining the predominant financial requirements or QTLs that apply to substantially all medical/surgical benefits. *See 26 CFR 54.9812-*

*1(c)(2)(ii), 29 CFR 2590.712(c)(2)(ii), 45 CFR 146.136(c)(2)(ii).* A plan or issuer may not use a separate sub-classification under these classifications for generalists and specialists. *See 26 CFR 54.9812-1(c)(3)(iii)(C), 29 CFR 2590.712(c)(3)(iii)(C), 45 CFR 146.136(c)(3)(iii)(C).*

**Compliance Tips**

- Ensure that the plan or issuer does not impose cost-sharing requirements or QTLs that are applicable **only** to mental health/ substance use disorder benefits.
- Identify **all** benefit packages and health insurance coverage to which parity applies.

**Detailed steps for applying this rule:**

- To determine compliance, each type of financial requirement or QTL within a coverage unit must be analyzed separately within each classification. *See 26 CFR 54.9812-1(c)(2)(i), 29 CFR 2590.712(c)(2)(i), 45 CFR 146.136(c)(2)(i).* Coverage unit refers to the way in which a plan groups individuals for purposes of determining benefits, or premiums or contributions, for example, self-only, family, or employee plus spouse. *See 26 CFR 54.9812-1(c)(1)(iv), 29 CFR 2590.712(c)(1)(iv), 45 CFR 146.136..* If a plan applies different levels of a financial requirement or QTL to different coverage units in a classification of medical/surgical benefits (for example, a $15 copayment for self-only and a $20 copayment for family coverage), the predominant level is determined separately for each coverage unit. *See 26 CFR 54.9812-1(c)(3)(ii), 29 CFR 2590.712(c)(3)(ii), 45 CFR 146.136(c)(3)(ii).*

- **Step One ("substantially all" test):** First determine if a particular type of financial requirement or QTL applies to substantially all medical/surgical benefits in the relevant classification of benefits.
  - Generally, a financial requirement or QTL is considered to apply to substantially all medical/surgical benefits if it applies to at least two-thirds of the medical/surgical benefits in the classification. *See 26 CFR 9812-1(c)(3)(i)(A), 29 CFR 2590.712(c)(3)(i)(A), 45 CFR 146.136(c)(3)(i)(A).* This two-thirds calculation is generally based on the dollar amount of plan payments expected to be paid for the plan year within the classification. *See 26 CFR 54.9812-1(c)(3)(i)(C), 29 CFR 2590.712(c)(3)(i)(C), 45 CFR 146.136(c)(3)(i)(C).* (Any reasonable method can be used for this calculation. *See 26 CFR 54.9812-1(c)(3)(i)(E), 29 CFR 2590.712(c)(3)(i)(E), 45 CFR 146.136(c)(3)(i)(E).*

- **Step Two ("predominant" test):** If the type of financial requirement or QTL applies to at least two-thirds of medical/surgical benefits in that classification, then determine the predominant level of that type of financial requirement or QTL that applies to the medical/surgical benefits that are subject to that type of financial requirement or QTL in that classification of benefits. (***Note*: If the type of financial requirement or QTL does not apply to at least two-thirds of medical/surgical benefits in that classification, it cannot apply to MH/SUD benefits in that classification.)

- Generally, the level of a financial requirement or QTL that is considered the predominant level of that type is the level that applies to more than one-half of the medical/surgical benefits in that classification subject to the financial requirement or QTL. *See 26 CFR 54.9812-1(c)(3)(i)(B)(1), 29 CFR 2590.712(c)(3)(i)(B)(1), 45 CFR 146.136(c)(3)(i)(B)(1).* If 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 can combine levels until the combination of levels applies to more than one-half of medical/surgical benefits subject to the financial requirement or QTL in the classification. In that case, the least restrictive level within the combination is considered the predominant level. *See 26 CFR 54.9812-1(c)(3)(i)(B)(2), 29 CFR 2590.712(c)(3)(i)(B)(2), 45 CFR 146.136(c)(3)(i)(B)(2).* For a simpler method of compliance, a plan may treat the least restrictive level of financial requirement or treatment limitation applied to medical/surgical benefits as predominant.

**Compliance Tip: Book of Business**

- When performing the "substantially all" and "predominant" tests for financial requirements and QTLs, basing the analysis on an issuer's entire book of business is generally not a reasonable method if a plan or issuer has sufficient claims data for a reasonable projection of future claims costs for the substantially all and predominant analysis. However, there may be insufficient reliable claims data for a group health plan, in which case the analyses will require utilizing reasonable data from outside the group health plan. A plan or issuer must always use appropriate and sufficient data to perform the analysis in compliance with applicable Actuarial Standards of Practice. *See ACA Implementation FAQs Part 34, Q3, available at* https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-34.pdf.

***ILLUSTRATION:*** Plan Z requires copayments for out-patient, in-network MH/SUD benefits. In order to determine if the plan meets the parity requirements:

1. **STEP ONE: Determine if the particular type of financial requirement applies to substantially all (that is, 2/3 of) medical /surgical benefits in the relevant classification.**

   Based on its prior claims experience, Plan Z expects $1 million in medical/surgical benefits to be paid in the outpatient, in-network classification and $700,000 of those benefits are expected to be subject to copayments. Because the amount of medical/surgical benefits expected to be subject to a copayment, which is $700,000, is at least 2/3 of the $1 million total medical/surgical benefits expected to be paid, a copayment can be applied to outpatient, in-network MH/SUD benefits.

2. **STEP TWO: Determine what level of the financial requirement is predominant (that is, the level that applies to more than half the medical/surgical benefits subject to the financial requirement in the relevant classification).**

   In the outpatient, in-network classification where $1 million in medical/surgical benefits is expected to be paid, $700,000 of those benefits are expected to be subject to copayments. Out of the $700,000, Plan Z expects that 25% will be subject to a $15 copayment and 75% will be

subject to a $30 copayment. Since 75% is more than half, the $30 copayment is the predominant level.

3. **CONCLUSION:** Plan Z cannot impose a copayment to MH/SUD benefits in this classification that is higher than $30.

### Compliance Tips

- Ensure that when conducting the predominant/substantially all tests, the dollar amount of all plan payments for medical/surgical benefits expected to be paid in that classification for the relevant plan year are analyzed.
- A plan may be able to impose the specialist level of a financial requirement or QTL to MH/SUD benefits in a classification (or an office visit sub-classification) if it is the predominant level that applies to substantially all medical/surgical benefits within the office visit sub-classification. For example, if the specialist level of copay is the predominant level of copay that applies to substantially all medical/surgical benefits in the office visit, in-network sub-classification, the plan may apply the specialist level copay to MH/SUD benefits in the office visit, in-network sub-classification. *See 26 CFR 54.9812-1(c)(3), 29 CFR 2590.712(c)(3).*

## SECTION E. CUMULATIVE FINANCIAL REQUIREMENTS AND TREATMENT LIMITATIONS

**Question 6.** **Does the group health plan or group or individual market health insurance issuer comply with the mental health parity requirements regarding cumulative financial requirements or cumulative QTLs for MH/SUD benefits?**

| Comments: |
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- A plan or issuer may not apply any cumulative financial requirement or cumulative QTL for MH/SUD benefits in a classification that accumulates separately from any cumulative financial requirement or QTL established for medical/surgical benefits in the same classification. *See 26 CFR 54.9812-1(c)(3)(v), 29 CFR 2590.712(c)(3)(v), 45 CFR 146.136(c)(3)(v).* For example, a plan may not impose an annual $250 deductible on medical/surgical benefits in a classification and a separate $250 deductible on MH/SUD benefits in the same classification.

  - 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 (but do not include aggregate lifetime or annual dollar limits because these two terms are excluded from the meaning of financial requirements). *See 26 CFR 54.9812-1(a), 29 CFR 2590.712(a), 45 CFR 146.136(a).*

- Cumulative QTLs 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. *See* ***26 CFR 54.9812-1(a),*** *29 CFR 2590.712(a), 45 CFR 146.136(a).*

***ILLUSTRATION:*** Plan Y offers three benefit options all of which provide medical/surgical as well as MH/SUD benefits. For all three benefit options, the plan provides for in-network treatment limitations of 30 days per year with respect to inpatient mental health services, and in-network treatment limitations of 20 visits per year with respect to outpatient mental health services. No such limitations are imposed on outpatient or inpatient, in-network medical/surgical benefits in any of the three benefit options.

In this example, the plan improperly imposes cumulative treatment limitations on the number of visits for outpatient and inpatient, in-network and out-of-network mental health benefits in all three benefit options.

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## SECTION F. NONQUANTITATIVE TREATMENT LIMITATIONS

**Question 7.** **Does the group health plan or group or individual market health insurance issuer comply with the mental health parity requirements regarding NQTLs on MH/SUD benefits?**

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An NQTL is generally a limitation on the scope or duration of benefits for treatment. The MHPAEA regulations prohibits a plan or an issuer from imposing NQTLs on MH/SUD benefits in any classification unless, under the terms of the plan or coverage as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, those used in applying the limitation with respect to medical/surgical benefits in the same classification. *See 26 CFR 54.9812-1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), 45 CFR 146.136(c)(4)(i).*

The following is an illustrative, non-exhaustive list of NQTLs:

- Medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;
- Prior authorization or ongoing authorization requirements;
- Concurrent review standards;
- **Formulary design for prescription drugs;**
- **For plans with multiple network tiers (such as preferred providers and** participating providers), network tier design;
- **Standards for provider admission to participate in a network, including** reimbursement rates;
- **Plan or issuer methods for determining usual, customary, and reasonable charges;**
- Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as "fail-first" policies or "step therapy" protocols);
- Exclusions of specific treatments for certain conditions;
- Restrictions on applicable provider billing codes;

- Standards for providing access to out-of-network providers;
- **Exclusions based on failure to complete a course of treatment; and**
- Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the plan or coverage.

*See 26 CFR 54.9812-1(c)(4)(ii), 29 CFR 2590.712(c)(4)(ii), 45 CFR 146.136(c)(4)(ii).* For additional examples of plan provisions that may operate as NQTLs see *Warning Signs, available at* https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/mental-health-parity/warning-signs-plan-or-policy-nqtls-that-require-additional-analysis-to-determine-mhpaea-compliance.pdf.

While NQTLs are generally defined as treatment limitations that are not expressed numerically, the application of an NQTL in a numerical way does not modify its nonquantitative character. For example, standards for provider admission to participate in a network are NQTLs because such standards are treatment limitations that typically are not expressed numerically. *See 29 CFR 2590.712 (c)(4)(ii), 45 CFR 146.136(c)(4)(ii).* Nevertheless, these standards sometimes rely on numerical standards, for example, numerical reimbursement rates. In this case, the numerical expression of reimbursement rates does not modify the nonquantitative character of the provider admission standards; accordingly, standards for provider admission, including associated reimbursement rates to which a participating provider must agree, are to be evaluated in accordance with the rules for NQTLs.

A group health plan or issuer may consider a wide array of factors in designing medical management techniques for both MH/SUD 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 or other factors in a comparable fashion, an NQTL, such as prior authorization, may be required for some (but not all) MH/SUD benefits, as well as for some (but not all) medical/surgical benefits. *See 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), 45 CFR 146.136(c)(4), Example 8.*

**In order to determine compliance with MHPAEA, the following analysis should be applied to each NQTL identified under the plan or coverage:**

**Step One:**

- Identify the NQTL.

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Identify in the plan documents all the services (both MH/SUD and medical/surgical) to which the NQTL applies in each classification.

**NOTE**: NQTLs may also be included in other documents, such as internal guidelines or provider contracts.

### Compliance Tips

- Ask for information about what medical/surgical benefits are also subject to these requirements or restrictions.
- If a benefit includes multiple components (e.g., outpatient and prescription drug classifications), and each component is subject to a different type of NQTL (e.g., prior authorization and limits on treatment dosage or duration), each NQTL must be analyzed separately.
- Find out how these requirements are implemented, who makes the decisions and what the decision-maker's qualifications are.

Determine which benefits are treated as medical/surgical and which are treated as MH/SUD, and analyze the NQTLs under each benefit classification. Plans and issuers should clearly define which benefits are treated as medical/surgical and which benefits are treated as MH/SUD under the plan. Benefits (such as inpatient treatment at a skilled nursing facility or other non-hospital facility and partial hospitalization) must be assigned to classifications using a comparable methodology across medical/surgical benefits and MH/SUD benefits.

### Compliance Tip

- Any separate NQTL that applies to only the MH/SUD benefits within any particular classification does not comply with MHPAEA.

**Step Two:**

- Identify the factors considered in the design of the NQTL.

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*Examples of factors include but are not limited to*:

- Excessive utilization;
- Recent medical cost escalation;
- Provider discretion in determining diagnosis;
- Lack of clinical efficiency of treatment or service;
- High variability in cost per episode of care;
- High levels of variation in length of stay;
- Lack of adherence to quality standards;
- Claim types with high percentage of fraud;
- Current and projected demand for services.

### Compliance Tips

- If only certain benefits are subject to an NQTL, such as meeting a fail-first protocol or requiring preauthorization, plans and issuers should have information available to substantiate how the applicable factors were used to apply the specific NQTL to medical/surgical and MH/SUD benefits.
- Determine whether any factors were given more weight than others and the reason(s) for doing so.

**Step Three:**

- Identify the sources (including any processes, strategies, evidentiary standards) used to define the factors identified above to design the NQTL.

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*Examples of sources of factors include, but are not limited to:*

- Internal claims analysis;
- Medical expert reviews;
- State and Federal requirements;
- National accreditation standards;
- Internal market and competitive analysis;
- Medicare physician fee schedules;
- Evidentiary standards, including any published standards as well as internal plan or issuer standards, relied upon to define the factors triggering the application of an NQTL to benefits.

If these factors are utilized, they must be applied comparably to MH/SUD and medical/surgical benefits.

### Compliance Tips

- Evidentiary standards and processes that a plan or issuer relies upon may include any evidence that a plan or issuer considers in developing its medical management techniques, including recognized medical literature and professional standards and protocols (including comparative effectiveness studies and clinical trials), and published research studies.
- If there is any variation in the application of a guideline or standard being relied upon by the plan or issuer, the plan or issuer should explain the process and factors relied upon for establishing that variation.

**NOTE**: When identifying the sources of the factors considered in designing the NQTL, also identify any threshold at which each factor will implicate the NQTL. For example, if high cost is identified as a factor used in designing a prior authorization requirement, the threshold dollar amount at which prior authorization will be required for any service, should also be identified.

*Examples of how factors identified based on evidentiary standards may be defined to set applicable thresholds for NQTLs include, but are not limited to:*

- Excessive utilization as a factor to design the NQTL when utilization is two standard deviations above average utilization per episode of care.
- Recent medical cost escalation may be considered as a factor based on internal claims data showing that medical cost for certain services increased 10 percent or more per year for two years.
- Lack of adherence to quality standards may be considered as a factor when deviation from generally accepted national quality standards for a specific disease category occurs more than 30 percent of the time based on clinical chart reviews.
- High level of variation in length of stay may be considered as a factor when claims data shows that 25 percent of patients stayed longer than the median length of stay for acute hospital episodes of care.
- High variability in cost per episode may be considered as a factor when episodes of outpatient care are two standard deviations higher in total cost than the average cost per episode 20 percent of the time in a 12-month period.
- Lack of clinical efficiency may be considered as a factor when more than 50 percent of outpatient episodes of care for specific diseases are not based on evidence-based interventions (as defined by nationally accepted best practices) in a 12-month sample of claims data.

**Step Four:**

- Is the processes, strategies, and evidentiary standards used in applying the NQTL comparable and no more stringently applied to MH/SUD and medical/surgical benefits, both as written and in operation?

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Plans and issuers should demonstrate any methods, analyses, or other evidence used to determine that any factor used, evidentiary standard relied upon, and process employed in developing and applying the NQTL for MH/SUD services and medical/surgical services are comparable.

**Compliance Tips**

- If utilization review (UR) is conducted by different entities or individuals for medical/surgical and MH/SUD benefits provided under the plan or coverage, ensure that there are measures in place to ensure comparable application of UR policies.
- Determine what consequences or penalties apply to the benefits when the NQTL requirement is not met.

*Examples of methods/analyses substantiating that factors, evidentiary standards and processes are comparable:*

- Internal claims database analysis demonstrates that the applicable factors (such as excessive utilization or recent increased costs) were implicated for all MH/SUD and medical/surgical benefits subject to the NQTL.
- Review of published literature on rapidly increasing cost for services for MH/SUD and medical/surgical conditions and a determination that a key factor(s) was present with similar frequency with respect to specific MH/SUD and medical/surgical benefits subject to the NQTL.
- A consistent methodology for analyzing which MH/SUD and medical/surgical benefits had "high cost variability" and were therefore subject to the NQTL.
- Analysis that the methodology for setting usual and customary provider rates for both MH/SUD and medical/surgical benefits were the same, both as developed and applied.

**Compliance Tips**

- Look for compliance as written **AND IN OPERATION.**
- Determine whether there are exception processes available and when they may be applied.
- Determine how much discretion is allowed in applying the NQTL and whether such discretion is afforded comparably for processing MH/SUD benefit claims and medical/surgical benefits claims.
- Determine who makes denial determinations and if the decision-makers have comparable expertise with respect to MH/SUD and medical/surgical benefits.
- Determine average denial rates and appeal overturn rates for concurrent review and assess the parity between these rates for MH/SUD benefits and medical/surgical benefits.
- Document your analysis, as a best practice.

**NOTE**: While outcomes are NOT determinative of compliance, rates of denials may be reviewed as a warning sign, or indicator of a potential operational parity noncompliance. For example, if a plan has a 34% denial rate on concurrent reviews of psychiatric hospital stays in a 12 month period and a 5% denial rate on concurrent review for medical hospital stays in that same 12 month period, the concurrent review process for both psychiatric and medical hospital stays should be carefully examined to ensure that the concurrent review standard is not being applied more stringently to MH/SUD benefits than to medical/surgical benefits in operation.

## ILLUSTRATIONS

Set forth below are additional illustrations of how differences in a plan's or coverage's NQTLs may be permissible. Whether an NQTL complies with the Departments' regulations is based on the facts and circumstances involved:

- Plan X covers neuropsychological testing but excludes such testing for certain conditions. In such situations, look to see whether the exclusion is based on evidence addressing, for example, clinical efficacy of such testing for different conditions and the degree to which such testing is used for educational purposes with regard to different conditions. Does the plan rely on criteria and evidence from comparable sources with respect to

medical/surgical and mental health conditions? Does the plan have documentation indicating the criteria used and evidence supporting the plan's determination of the diagnoses for which the plan will cover this service and the rationale for excluding certain diagnoses? The result may be that the plan permissibly covers neuropsychological testing for some medical/surgical or mental health conditions, but not for all.

**Conclusion**: This outcome may be permissible to the extent the plan has based the exclusion of this testing for certain conditions on clinical efficacy and/or other factors if the factors are designed and applied in a comparable manner with respect to, the conditions for which testing is covered and those for which it is excluded.

### Compliance Tip

- **Do not focus on results.** Look at the **underlying processes and strategies** used in applying NQTLs. Are there arbitrary or discriminatory differences in how the plan or issuer is applying those processes and strategies to medical/surgical benefits versus MH/SUD benefits?

- Plan Y uses diagnosis related group (DRG) codes in their standard utilization review process to actively manage hospitalization utilization. For all non-DRG hospitalizations (whether due to an underlying medical/surgical condition or a MH/SUD condition), the plan requires precertification for hospital admission and incremental concurrent review. The precertification and concurrent review processes review unique clinical presentation, condition severity, expected course of recovery, quality and efficiency. The evidentiary standards and other factors used in the development of the concurrent review process are comparable across medical/surgical benefits and MH/SUD benefits, and are well documented. These evidentiary standards and other factors are available to participants and beneficiaries free of charge upon request.

  **Conclusion**: In this example, it appears that, under the terms of the plan as written and in practice, the processes, strategies, evidentiary standards, and other factors considered by the plan in implementing its precertification and concurrent review of hospitalizations are comparable and applied no more stringently with respect to MH/SUD benefits than those applied with respect to medical/surgical benefits.

- Plan Z classifies care in skilled nursing facilities or rehabilitation hospitals for medical/surgical conditions as inpatient benefits and likewise treats any covered care in residential treatment facilities for MH/SUD as an inpatient benefit. In addition, the plan treats home health care as an outpatient benefit and treats intensive outpatient and partial hospitalization for MH/SUD services as outpatient benefits.

  **Conclusion**: In this example, the plan assigns covered intermediate mental health and substance use disorder benefits to the six classifications in the same way that it assigns comparable intermediate medical/surgical benefits to the classifications.

- Master's degree training and state licensing requirements often vary among provider types. Plan Z consistently applies its standard that any provider must meet the most stringent licensing requirement standard in the applicable State related to supervised clinical experience requirements in order to participate in the network. Therefore, Plan Z requires master's-level therapists to have post-degree, supervised clinical experience in order to join its provider network. There is no parallel requirement for master's-level general medical providers because their licensing requires supervised clinical experience. In addition, the plan does not require post-degree, supervised clinical experience for psychiatrists or PhD level psychologists since their licensing already requires supervised training.

  **Conclusion**: The requirement that master's-level therapists must have supervised clinical experience to join the network is permissible, as the plan consistently applies the same standard to all providers even though it may have a disparate impact on certain mental health providers whose State licensing does not require this experience.

- A patient with chronic depression has not responded to five different anti-depressant medications and therefore, was referred for outpatient treatment with repetitive transcranial magnetic stimulation (rTMS). This specific treatment has been approved by the FDA and has been the subject of more than six randomized controlled trials published in peer reviewed journals. The plan denies the treatment as experimental. The plan states that it used the same criteria to deny the rTMS as it does to approve or deny any MH/SUD or medical/surgical benefits under the plan. The plan identifies its standard for both medical/surgical benefits and MH/SUD benefits as requiring that at least two randomized controlled trials showing efficacy of a treatment be published in peer reviewed journals for any new treatment for either medical or behavioral conditions to be covered by the plan. However, the plan indicates that while more than two randomized controlled trials regarding rTMS have been published in peer reviewed journals, a committee of medical experts involved in plan utilization management reviews reviewed the journals and determined that only one of the articles provided sufficient evidence of efficacy. The plan did not identify what specific standards were used to assess whether a peer review had adequately evidenced efficacy and what the qualifications of the plan's experts are. Lastly, the plan does not impose this additional level of scrutiny with respect to reviewing medical/surgical treatments beyond the initial requirement that the treatment has been the subject of the requisite number and type of trials.

  **Conclusion**: The plan's exclusion fails to comply with MHPAEA's NQTL requirements because, in practice, the plan applies an additional level of scrutiny with respect to MH/SUD benefits and therefore the NQTL more stringently to mental health benefits than to medical/surgical benefits without additional justification.

Examples of MHPAEA enforcement actions that EBSA has undertaken may be found in the MHPAEA Enforcement Fact Sheets, available at https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/fact-sheets/mhpaea-enforcement-2016.pdf and https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/fact-sheets/fsmhpaeaenforcement.pdf. Examples of MHPAEA enforcement actions that HHS has taken may be found in the Department of Health and Human Services' MHPAEA Report at https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/HHS-2008-MHPAEA-Enforcement-Period.pdf

**Group health plans and group and individual market health insurance issuers should be prepared to provide:**

- A list of the NQTLs that apply to MH/SUD and/or medical/surgical benefits offered under the plan or coverage.
- Records documenting NQTL processes and how the NQTLs are being applied to both medical/surgical as well as MH/SUD benefits to ensure they can demonstrate compliance with the law. Such records may also be helpful to plans and issuers in responding to inquiries from participants, beneficiaries, enrollees, and dependents regarding benefits under the plan or coverage. ( *See a more detailed discussion of disclosure requirements in the following section.)*
- All appropriate documentation including any guidelines or other standards that the plan or issuer relied upon as the basis for its compliance with the requirement that any NQTL applicable to MH/SUD benefits was comparable to and applied no more stringently than the NQTL as applied to medical/surgical benefits. This should include details as to how the standards were applied, and any internal testing, review or analysis done by the plan or issuer to support the rationale that the NQTL is being applied comparably and no more stringently to MH/SUD benefits and medical/surgical benefits. If the standards that are applied to MH/SUD are more stringent than those in nationally recognized medical guidelines, but the standards that are applied to medical/surgical benefits are not, an explanation of the reason for the application of the more stringent standard for MH/SUD benefits.
- For the period of coverage under review, plans and issuers should be prepared to provide a record of all claims (MH/SUD and medical/surgical) submitted and the number of those denied within each classification of benefits.

## SECTION G. DISCLOSURE REQUIREMENTS

**Question 8. Does the group health plan or group or individual health insurance issuer comply with the MHPAEA disclosure requirements?**

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- The plan administrator (or the health insurance issuer) must make **available the criteria for medical necessity determinations** made under a group health plan or group or individual health insurance coverage with respect to MH/SUD benefits to any current or potential participant, beneficiary, enrollee, or contracting provider **upon request**. *See 29 CFR 2590.712(d)(1), ,45 CFR 146.136 (d)(1).*

  The plan administrator (or health insurance issuer) must make available **the reason for any denial** under a group health plan or group or individual health insurance coverage of reimbursement or payment for services with respect to MH/SUD benefits to any participant, beneficiary, enrollee, , and may do so in a form and manner consistent with the rules in 29 CFR 2560.503-1 (the DOL claims procedure rule) and 29 CFR 2590.715-2719 (internal claims and appeals and external review processes).

- Pursuant to the internal claims and appeals and external review rules under the Affordable Care Act applicable to all non-grandfathered group health plans and to all non-grandfathered group and individual health insurance coverage, claims related to medical judgment (including mental health/substance use disorder) are eligible for external review. The **internal claims and appeals** rules include the right of claimants (or their authorized representative) 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 about the **processes, strategies, evidentiary standards, and other factors used to apply an NQTL** with respect to medical/surgical benefits and MH/SUD benefits under the plan. *See 26 CFR 54.9812-1(d)(3), 29 CFR 2560.5301- 2590.712(d)(3), 45 CFR 146.136(d)(3 147.136(b).).*

- With respect to group health plans that are subject to ERISA, if coverage is denied based on medical necessity, **medical necessity criteria** for the MH/SUD benefits at issue and for medical/surgical benefits in the same classification must be provided **within 30 days of the request** to the participant, beneficiary, or provider or other individual if acting as an authorized representative of the beneficiary or participant. *See 29 CFR 2520.104b-1; 29 CFR 2590.712(d)(1).*

- If a plan or a plan administrator or health insurance issuer fails to provide these documents, a court may hold it liable for up to $110 a day from the date of failure to provide these documents.

**Compliance Tips**

- The reason for benefit denials include applicable medical necessity criteria as applied to that participant, beneficiary, enrollee.
- Under ERISA, Plans and issuers cannot refuse to disclose information necessary for the parity analysis on the basis that the information is proprietary or has commercial value.
- Under ERISA, Plans and issuers can provide summary descriptions of the medical necessity criteria in a layperson's terms.

**Make Showing Compliance Simple**

**Documents or Plan Instruments Participants and Beneficiaries or DOL may request:**

Under ERISA section 104(b), participants and beneficiaries may request documents and plan instruments regarding whether the plan is providing benefits in accordance with MHPAEA and copies must be furnished within 30 days of request. This may include documentation that illustrates how the health plan has determined that any financial requirement, QTL, or NQTL is in compliance with MHPAEA. For example, participants and beneficiaries may ask for:

- An analysis showing that the plan meets the predominant/substantially all tests. The plan may need to provide information regarding the amount of medical/surgical claims subject to a certain type of QTL, such as a co-payment, in the prior year in a classification or its basis for calculating claims expected to be subject to a certain type of QTL in the current

plan year in a classification, for purposes of determining the plan's compliance with the predominant/substantially all tests.

- A description of an applicable requirement or limitation, such as preauthorization or concurrent review, that the plan applies for MH/SUD benefits and medical/surgical benefits within the relevant classification (in- or out-of-network, in- or outpatient). These might include references to specific plan documents, for example provisions as stated on specified pages of the Summary Plan Description (SPD), or other underlying guidelines or criteria not included in the SPD that the Plan has consulted or relied upon;
- Information regarding factors, such as cost or recommended standards of care, that are relied upon by a plan for determining which medical/surgical or MH/SUD benefits are subject to a specific requirement or limitation. These might include references to specific related factors or guidelines, such as applicable utilization review criteria;
- A description of the applicable requirement or limitation that the plan believes has been used in any given MH/SUD service adverse benefit determination (ABD) within the relevant classification;
- Medical necessity guidelines relied upon for in and out-of-network medical/surgical and MH/SUD benefits.

**Compliance Tips**

- Find out how the plan administrator handles general information requests about coverage limitations as well as specific information or disclosure requests with respect to denied benefit claims.
- Pull a sample of appeals files and examine what was disclosed to participants, including the criteria for medical necessity determinations and reasons for claim denials.
- Determine how long it took the plan or the plan administrator to furnish requested documents to participants.

As directed by the 21st Century Cures Act, and in response to comments received from the regulated community, the Departments continue to issue additional guidance regarding disclosures, in particular with respect to NQTLs. Based on requests from various stakeholders for model MHPAEA disclosure forms and for guidance on processes for requesting disclosures in a more uniform, streamlined, or otherwise simpli ed way, the Departments issued a draft model disclosure request form (available at https://www.dol.gov/sites/default/files/ebsa/laws-and-regulations/laws/mental-health-parity/mhpaea-disclosure-template-draft.pdf). Based on the feedback received on the draft model form, the Departments have issued a revised draft model disclosure request form available at https://www.dol.gov/sites/default/files/ebsa/laws-and-regulations/laws/mental-health-parity/mhpaea-disclosure-template-draft-revised.pdf. For the most current version of the form please visit the Department's dedicated MH/SUD parity webpage, available at https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/mental-health-and-substance-use-disorder-parity.

This form can, but is not required to, be used to request MHPAEA-related information from group plans and group and individual health insurance issuers, including general information about coverage limitations or specific information that may have resulted in denial of MH/SUD benefit claims.

## Compliance Tips

- Participants, beneficiaries, enrollees, dependents, and contracting providers may request information to determine whether benefits under a plan are being provided in parity even in the absence of any specific ABD.
- Group health plans may need to work with insurance issuers providing coverage on behalf of an insured group health plan or with third party administrators administering the plan to ensure that such service providers either directly or in coordination with the plan are providing participants and beneficiaries any documents or information to which they are entitled.
- If a group health plan or group or individual health insurance issuer uses mental health and substance use disorder vendors and carve-out service providers, the plan must ensure that all combinations of benefits comport with parity, therefore vendors and carve out providers should provide documentation of the necessary information to the plan to ensure that all combination of benefits comport with parity.

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***NOTE:*** Compliance with the disclosure requirements of MHPAEA is not determinative of compliance with any other provision or other applicable Federal or State law. Be sure that the plan or issuer, in addition to these disclosure requirements, is disclosing information relevant to medical/surgical, mental health, and substance use disorder benefits as required pursuant to other applicable provisions of law.

****Set out below is PROPOSED guidance regarding nonquantitative treatment limitations and disclosure requirements in connection with the Mental Health Parity and Addiction Equity Act (MHPAEA). This guidance was developed consistent with section 13001(b) of the 21st Century Cures Act. Public comments are invited and should be submitted by June 22, 2018 to E-OHPSCA-FAQ39@dol.gov. All comments will be shared among the Departments.****

# [PROPOSED] FAQS ABOUT MENTAL HEALTH AND SUBSTANCE USE DISORDER PARITY IMPLEMENTATION AND THE 21ST CENTURY CURES ACT PART XX

[Date will be inserted upon finalization]

Below are responses to additional frequently asked questions (FAQs) regarding implementation of the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), as amended by the Affordable Care Act, the 21st Century Cures Act (Cures Act), and the Employee Retirement Income Security Act (ERISA). These FAQs have been prepared jointly by the Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury (collectively, "the Departments"). As with previously issued FAQs (available at www.dol.gov/ebsa/healthreform/index.html and www.cms.gov/cciio/resources/fact-sheets-and-faqs/index.html), these FAQs are designed to help people understand and benefit from the law, as intended.

## Mental Health Parity and Addiction Equity Act of 2008 and the 21st Century Cures Act

In general, MHPAEA requires that the financial requirements (such as coinsurance and copays) and treatment limitations (such as visit limits) imposed on mental health or substance use disorder (MH/SUD) benefits cannot be more restrictive than the predominant financial requirements and treatment limitations that apply to substantially all medical/surgical benefits in a classification.

With regard to any nonquantitative treatment limitation (NQTL), the MHPAEA final regulations provide that a group health plan or health insurance issuer may not impose an NQTL with respect to MH/SUD 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 NQTL to MH/SUD 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 to medical/surgical benefits in the same

classification. MHPAEA also imposes certain disclosure requirements on group health plans and health insurance issuers.

**Q1: What are the Departments doing to promote understanding of and compliance with MHPAEA as required under the 21st Century Cures Act?**

The Departments work with plans, issuers, and service providers to help them understand and comply with MHPAEA, and ensure that individuals receive the benefits to which they are entitled. The Departments also coordinate with State regulators (both individually and through the National Association of Insurance Commissioners (NAIC)) to issue guidance to address frequently asked questions from stakeholders in an effort to increase understanding and compliance. Compliance assistance is a high priority and, thus, the Departments emphasize assisting plans and issuers that are working to comply with the law's requirements.

The Cures Act, enacted December 13, 2016, requires the Departments to, among other requirements, solicit feedback and issue guidance regarding the disclosure and NQTL requirements of MHPAEA. Section 13001(b) of the Cures Act requires that the Departments issue clarifying information and illustrative examples of methods that a plan or issuer offering group or individual health insurance coverage can use to disclose information in compliance with MHPAEA. Section 13001(b) also directs the Departments to issue clarifying information and illustrative examples of methods, processes, strategies, evidentiary standards, and other factors that plans and issuers may use regarding the development and application of NQTLs such as:

1. Medical management standards based on medical necessity or appropriateness, or whether a treatment is experimental or investigative;
2. Limitations with respect to prescription drug formulary design, and use of "step therapy" protocols or "fail-first" policies;
3. Network admission standards (such as credentialing);
4. Factors used in provider reimbursement methodologies (such as service type, geographic market, demand for services, and provider supply, practice size, training, experience, and licensure) as such factors apply to network adequacy; and
5. Examples of sources of information that may serve as evidentiary standards for the purposes of making determinations regarding the development and application of NQTLs.

Accordingly, on June 16, 2017, the Departments issued additional MHPAEA compliance assistance guidance regarding benefits for eating disorder treatment, and solicited feedback from stakeholders as to whether additional clarification was needed regarding how the requirements of MHPAEA apply to treatment for eating disorders.[1] The Departments also released a draft model

[1] See FAQs about Mental Health and Substance Use Disorder Parity Implementation and the 21st Century Cures Act Part 38, available at https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-38.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQ-Part-38.pdf.

disclosure request form for comment and solicited feedback as to how disclosure processes may be improved.[2] Comments were due by September 13, 2017 and are available at https://www.dol.gov/agencies/ebsa/laws-and-regulations/rules-and-regulations/public-comments/faq-38. Based on the feedback received through that solicitation, the Departments have revised the draft model form. A copy of the revised draft model form can be found at https://www.reginfo.gov/public/do/PRAICList?ref_nbr=201706-1210-001.

The Departments have submitted the revised form to the Office of Management and Budget (OMB) as required by the Paperwork Reduction Act. OMB is requesting comments on the revised form. Comments are requested on any aspect of the draft model form, including ways to reduce burden on individuals, families, health care providers, States, group health plans, health insurance issuers, and other stakeholders.

Please send comments on these disclosure issues to: Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL-EBSA, Office of Management and Budget, Room 10235, 725 17th Street, N.W., Washington, DC 20503; by Fax: 202-395-5806 (this is not a toll-free number); or by email: OIRA_submission@omb.eop.gov. Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue, N.W., Washington, D.C. 20210; or by email: DOL_PRA_PUBLIC@dol.gov. Commenters should submit their views by June 22, 2018 to ensure consideration. Comments should reference control number 1210-0138.

In addition, based on the comments and other information received, including written and oral comments received in connection with the HHS-sponsored listening session on mental health parity that occurred on July 27, 2017,[3] the Departments understand that additional compliance information is needed. Some of that information is contained in these FAQs. Other information will be issued by the Departments on a rolling basis, including revised compliance program documents and updated enforcement data. In addition, the Departments are aware that increased public awareness of MHPAEA and commitment to its successful implementation has led to the creation of partnerships among different advocacy groups that focus on developing accreditation programs that seek to advance understanding of and compliance with the law. The Departments

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[2] A copy of that draft model form, as well as instructions, can be found at https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html or https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/mental-health-and-substance-use-disorder-parity.

[3] *See* 82 FR 30876 (July 3, 2017), available at https://www.gpo.gov/fdsys/pkg/FR-2017-07-03/pdf/2017-13959.pdf. *See also* Achieving Parity in Health Insurance Coverage: 21st Century Cures Act Parity Listening Session; available at https://www.hhs.gov/programs/topic-sites/mental-health-parity/achieving-parity/cures-act-parity-listening-session/index.html. The Departments also reviewed DOL compliance reviews, consumer complaints and feedback from States and other stakeholders during the Substance Abuse and Mental Health Admininistration policy forums, among other information. *See* Implementation of the Mental Health Parity and Addiction Equity Act (MHPAEA), available at https://www.samhsa.gov/health-financing/implementation-mental-health-parity-addiction-equity-act.

are considering how such accreditation programs can be utilized as a best practice to help increase compliance with MHPAEA. For the most current information on MHPAEA and the Cures Act implementation, see https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/mental-health-and-substance-use-disorder-parity and https://www.hhs.gov/mental-health-and-addiction-insurance-help/index.html.

**Q2. My health plan document states that it excludes treatment that is experimental or investigative for both medical/surgical benefits and for MH/SUD services. For both medical/surgical benefits and MH/SUD services, the plan generally follows current medical evidence and professionally recognized treatment guidelines on the efficacy of treatment. With respect to both medical/surgical benefits and MH/SUD services, the plan's documents state that the plan denies a treatment as experimental for a given condition when no professionally recognized treatment guidelines define clinically appropriate standards of care for the condition, and fewer than two randomized controlled trials are available to support the treatment's use with respect to the condition.**

**The plan defines Autism Spectrum Disorder as a mental health condition. More than one professionally recognized treatment guideline and more than two controlled randomized trials support the use of Applied Behavioral Analysis (ABA) therapy to treat certain children with Autism Spectrum Disorder. For the most recent plan year, the plan denied all claims for ABA therapy to treat children with Autism Spectrum Disorder under the rationale that the treatment is experimental or investigative. With respect to medical/surgical conditions, the plan approved treatment when supported by one or more professionally recognized treatment guidelines and two or more controlled randomized trials. Is this permissible?**

No. A medical management standard limiting or excluding benefits based on whether a treatment is experimental or investigative is an NQTL under MHPAEA.[4] A group health plan may impose an NQTL if, 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 the NQTL are comparable to and are applied no more stringently than the processes, strategies, evidentiary standards, and other factors used in applying the NQTL to medical/surgical benefits in the same classification. Although the plan as written purports to exclude experimental or investigative treatment for both MH/SUD and medical/surgical benefits using the same standards, in practice, it imposes this exclusion more stringently on MH/SUD benefits, as the plan denies all claims for ABA therapy, despite the fact that professionally recognized treatment guidelines and the requisite number of randomized controlled trials support the use of ABA therapy to treat children with Autism Spectrum Disorder. Accordingly, because the plan applies

[4] MHPAEA regulations at 26 CFR 54.9812-1(c)(4)(ii); 29 CFR 2590.712(c)(4)(ii); and 45 CFR 146.136(c)(4)(ii) contain an illustrative list of NQTLs that includes, among other things, medical management standards limiting or excluding benefits based on medical necessity; formulary design for prescription drugs; network tier design; and plan methods for determining usual, customary, and reasonable charges.

the NQTL more stringently to mental health benefits than to medical/surgical benefits, the plan's exclusion of ABA therapy as experimental does not comply with MHPAEA.

**Q3: My health plan generally excludes treatment that is experimental or investigative for both medical/surgical benefits and for MH/SUD services. The plan defines experimental or investigative treatments as those with a rating below "B" in the Hayes Medical Technology Directory. However, the plan reviews and covers certain treatments for medical/surgical conditions that have a rating of "C" on a treatment-by-treatment basis, while denying all benefits for MH/SUD treatment that have a rating of "C" or below, without reviewing the treatments to determine whether exceptions are appropriate. Is this permissible under MHPAEA?**

No. A medical management standard that limits or excludes benefits based on whether a treatment is experimental or investigative is an NQTL under MHPAEA.[5] A plan may impose an NQTL on MH/SUD benefits if, 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 exclusion with respect to MH/SUD benefits are comparable to and applied no more stringently than, those used in applying the NQTL requirement with respect to medical/surgical benefits in the same classification. Here, although the text of the plan sets forth the same evidentiary standard for defining experimental as the Hayes Medical Directory ratings below "B," the plan applies a different evidentiary standard, which is more stringent for MH/SUD benefits than for medical surgical benefits because the unconditional exclusion of treatments with a "C" rating for MH/SUD benefits is not comparable to the conditional exclusion of those treatments with a "C" rating for medical/surgical benefits. Because of the discrepant application of the evidentiary standard used by the plan, the fact that the plan ultimately denies some medical/surgical benefits that have a rating of "C" does not justify the total exclusion of treatments with a "C" rating for MH/SUD. Accordingly, the plan does not comply with MHPAEA.

**Q4: My health plan documents state that the plan follows professionally-recognized treatment guidelines when setting dosage limits for prescription medications, but the dosage limit set by my plan for buprenorphine to treat opioid use disorder is less than what professionally-recognized treatment guidelines generally recommend. The dosage limits set by my plan with respect to medical/surgical benefits are not less than the limits such treatment guidelines recommend. Is this permissible under MHPAEA?**

No. Medical management standards that limit or exclude benefits based on medical necessity, medical appropriateness, or other factors are NQTLs.[6] Plans and issuers may impose dosage

[5] 26 CFR 54.9812-1(c)(4)(ii); 29 CFR 2590.712(c)(4)(ii); 45 CFR 146.136(c)(4)(ii).
[6] *See* 26 CFR 54.9812-1(c)(4)(ii)(A); 29 CFR 2590.712(c)(4)(ii)(A); 45 CFR 146.136(c)(4)(ii)(A).

limits as a medical management technique with respect to prescription drug coverage under the plan. Even though these medical management techniques may result in numerically expressed limitations (such as dosage limits), the techniques are nevertheless NQTLs. The Departments' regulations require that the processes, strategies, evidentiary standards, or other factors used in applying an NQTL to MH/SUD prescription drug benefits (in this case, a dosage limit on buprenorphine to treat opioid use disorder) must be comparable to and applied no more stringently than the processes, strategies, evidentiary standards, or other factors used in applying dosage limits to prescription drugs to treat medical/surgical conditions. If the plan follows the dosage recommendations in professionally-recognized treatment guidelines to set dosage limits for prescription drugs in its formulary to treat medical/surgical conditions, it must also follow comparable treatment guidelines, and apply them no more stringently, in setting dosage limits for prescription drugs, including buprenorphine, to treat MH/SUD conditions.

The Departments are aware that as an alternative to following professionally-recognized treatment guidelines, many plans and issuers use Pharmacy and Therapeutics (P&T) committees to decide how to cover prescription drugs and evaluate whether to follow or deviate from professionally-recognized treatment guidelines for setting dosage limits. Although the use of P&T committees to inform dosage limits for prescription drugs in this manner does not *per se* violate MHPAEA, these processes must comply with MHPAEA's NQTL standard in practice. For example, if the plan deviates from nationally-recognized treatment guidelines for buprenorphine/naloxone to treat opioid use disorder based on P&T committee reports, but does not deviate from such guidelines with respect to covering prescription drugs to treat medical surgical benefits based on the recommendations of the P&T committee, then this deviation should be evaluated for compliance with MHPAEA's NQTL requirements (for instance, by determining (1) whether the expertise of the members of the P&T committee in MH/SUD conditions is comparable to their expertise in medical/surgical conditions, and (2) by determining the whether the committees' evaluation of nationally-recognized treatment guidelines in setting dosage limits for medications for both MH/SUD and medical/surgical conditions is comparable).

**Q5: My large group health plan or large group insurance coverage provides benefits for prescription drugs to treat both medical/surgical and MH/SUD conditions but contains a general exclusion for items and services to treat bipolar disorder, including prescription drugs. Is this permissible under MHPAEA?**

Yes, although if the plan is insured, it would depend on whether State law permits such an exclusion for large group insurance coverage. Generally, MHPAEA requires that treatment limitations imposed on MH/SUD benefits cannot be more restrictive than treatment limitations that apply to medical and surgical benefits. An exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of the definition of "treatment limitations" in the MHPAEA regulations. Small employer group health insurance coverage and individual health insurance coverage are subject to the requirement to provide essential health

benefits, and the determination of whether certain benefits must be covered under the requirements for essential health benefits depends on the benefits in the applicable State's EHB benchmark plan.

**Q6: My health plan requires step therapy for both medical/surgical and MH/SUD in-patient, in-network benefits. The plan requires a participant to have two unsuccessful attempts at outpatient treatment in the past 12 months to be eligible for certain inpatient in-network SUD benefits. However, the plan only requires one unsuccessful attempt at outpatient treatment in the past 12 months to be eligible for inpatient, in-network medical/surgical benefits. Is this permissible under MHPAEA?**

Probably not. Refusing to pay for a higher-cost therapy until it is shown that a lower-cost therapy is not effective (commonly known as "step therapy protocols" or "fail-first policies") is an NQTL.[7] The Departments' regulations require that the processes, strategies, evidentiary standards, or other factors used in applying an NQTL to MH/SUD benefits must be comparable to and applied no more stringently than the processes, strategies, evidentiary standards, or other factors used in applying the NQTL to treat medical/surgical conditions. Although the same NQTL – step therapy – is applied to both MH/SUD benefits and medical/surgical benefits for eligibility for inpatient, in-network services, the requirement for two attempts at outpatient treatment to be eligible for inpatient, in-network SUD benefits is a more stringent application of the NQTL than the requirement for one attempt at outpatient treatment to be eligible for inpatient, in-network medical/surgical benefits. Unless the plan can demonstrate that evidentiary standards or other factors were utilized comparably to develop and apply the differing step therapy requirements for these MH/SUD and medical/surgical benefits, this NQTL does not comply with MHPAEA.

**Q7. My health plan documents state that in-network provider reimbursement rates are determined based on the providers' required training, licensure, and expertise. However, medical/surgical benefits, reimbursement rates are generally the same for physicians and non-physician practitioners. For MH/SUD benefits, the plan pays reduced reimbursement rates for non-physician practitioners. Is this permissible under MHPAEA?**

No. While a plan is not required to pay identical provider reimbursement rates for medical/surgical and MH/SUD providers, a plan's standards for admitting a provider to participate in a network (including the plan's reimbursement rates for providers) is an NQTL. A plan may impose an NQTL if 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 NQTL with respect to MH/SUD services are comparable to and applied no more stringently than those used in applying the NQTL with respect to medical/surgical benefits in the same classification. Here, the plan reduces reimbursement rates for non-physician

[7] *See* 26 CFR 54.9812-1(c)(4)(ii); 29 CFR 2590.712(c)(4)(ii); 45 CFR 146.136(c)(4)(ii).

practitioners providing MH/SUD services. However, the plan does not use a comparable process with respect to reimbursement of non-physician providers of medical/surgical services. Accordingly, the plan's use of this NQTL does not comply with MHPAEA.

**Q8: My health plan meets applicable State and Federal network adequacy standards for MH/SUD services. With respect to medical/surgical providers, the plan exceeds State and Federal network adequacy standards by attempting to ensure that participants and beneficiaries can schedule an appointment with a network provider within 15 days for non-urgent care when the individual has symptoms of a condition. The plan does not utilize a standard relating to availability of appointments in creating its provider network for MH/SUD services. Is this permissible under MHPAEA?**

No. As explained in the preamble to the Departments' final rules implementing MHPAEA, plan standards such as network adequacy (although not specifically enumerated in the illustrative list of NQTLs), must be applied in a manner that complies with the regulations.[8] The Departments' regulations require that the processes, strategies, evidentiary standards, or other factors used in applying an NQTL to MH/SUD benefits must be comparable to and applied no more stringently than the processes, strategies, evidentiary standards, or other factors used in applying the NQTL to treat medical/surgical conditions. Therefore, although a plan may use factors such as distance standards and waiting times for participants and beneficiaries for appointments for services to measure network adequacy, if these factors are used for these purposes they must be applied to medical/surgical and MH/SUD benefits in a comparably manner. Here, while the plan meets applicable State and Federal network adequacy standards, the plan does not consider how long participants and beneficiaries may have to wait for appointments for services as a factor in developing its network of MH/SUD providers, even though the plan considered it in developing the network for medical/surgical providers. Accordingly, the plan does not comply with MHPAEA.

**Q9: My health plan generally covers medically appropriate treatments. The plan covers inpatient, out-of-network treatment outside of a hospital setting for medical/surgical conditions if the prescribing physician obtains authorization from the plan and the treatment is medically appropriate for the individual, based on clinically appropriate standards of care. The plan provides benefits for the treatment of eating disorders but excludes all inpatient, out-of-network treatment outside of a hospital setting for eating disorders, including residential treatment (which it regards as an inpatient benefit). Is this permissible under MHPAEA?**

No. The Departments' regulations implementing MHPAEA define "mental health benefits" as 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.

[8] 78 FR 68239, 68246 (Nov. 13, 2013).

Section 13007 of the 21st Century Cures Act clarified that if a group health plan or health insurance issuer provides coverage for eating disorder benefits, including residential treatment those benefits must be offered consistent with the requirements of MHPAEA. Accordingly, the Departments have clarified that eating disorders are mental health conditions and, therefore, treatment of an eating disorder is a "mental health benefit" within the meaning of that term as defined by MHPAEA.[9]

Plan or coverage restrictions based on facility type are NQTLs under MHPAEA.[10] A plan may impose an NQTL if, 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 exclusion with respect to MH/SUD benefits are comparable to and applied no more stringently than, those used in applying the NQTL to medical/surgical benefits in the same classification. In evaluating an exclusion of an intermediate level of care, including residential treatment, it must be initially determined if the intermediate level of care is assigned to the six benefit classifications in the same way for both medical/surgical and MH/SUD benefits. If so, then the basis for the exclusion (in this case, residential treatment) in the classification must be reviewed to determine if the processes, strategies, evidentiary standards and other factors that are the basis for the exclusion of MH/SUD benefits are comparable to and applied no more stringently than the processes, strategies, evidentiary standards and other factors used in applying the NQTL to medical/surgical benefits in the same classification.

Following this analysis, if a plan can articulate factors that are comparable to and applied no more stringently than to support excluding residential treatment in certain circumstances, the plan may be able to demonstrate that the exclusion is consistent with parity standards will meet its obligation with respect to this limitation under MHPAEA. However, in this example, the plan provides inpatient, out-of-network treatment outside of a hospital for medical/surgical conditions so long as a prescribing physician obtains prior authorization from the plan and the treatment is medically appropriate for the individual, while the plan unequivocally excludes all inpatient, out-of-network treatment outside of a hospital (in this case, residential treatment) for eating disorders. This restriction on residential treatment for eating disorders is not comparable to this plan's coverage restrictions for inpatient treatment outside of a hospital for medical/surgical conditions, which are less stringent. This exclusion does not comply with MHPAEA.

**Q10: My health plan provides benefits for emergency room care. If emergency room care is provided for an acute condition affecting my physical health that arises as a complication of a mental health condition or substance use disorder, are benefits for that care considered MH/SUD benefits for the purposes of MHPAEA?**

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[9] See Frequently Asked Questions about Mental Health and Substance /Use Disorder Parity Implementation and the 21st Century Cures Act Part 38, available at https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-38.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-andFAQs/aca_implementation_faqs38.html

[10] 26 CFR 54.9812-1(c)(4)(ii); 29 CFR 2590.712(c)(4)(ii); 45 CFR 146.136(c)(4)(ii).

It depends. The Departments' regulations implementing MHPAEA define "medical/surgical benefits" as 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 not including mental health or substance use disorder benefits. Similarly, "mental health benefits" and "substance use disorder benefits" are defined as benefits with respect to items or services for mental health conditions or substance use disorders, as defined under the terms of the plan or health insurance coverage and in accordance with applicable Federal and State law. Mental health conditions must be defined to be consistent with generally recognized independent standards of current medical practice.

Despite any underlying MH/SUD condition, if, under the terms of the plan or coverage (and in accordance with applicable Federal and State law, the particular acute condition affecting an individual's physical health is defined as a medical condition, then benefits for emergency room care provided for the diagnosis, cure, mitigation, treatment, or prevention of the acute condition are medical/surgical benefits for purposes of MHPAEA. For example, assuming that a plan treats all lacerations as a medical condition, if a participant with a mental health condition or substance use disorder seeks emergency treatment for lacerations, the emergency treatment for the lacerations would be medical/surgical benefits for purposes of MHPAEA.

If, however, under the terms of the plan or health insurance coverage (and in accordance with applicable Federal and State law, if an insured plan), the particular acute condition affecting an individual's physical health is defined as a mental health or substance use disorder condition then benefits for emergency room care provided for the diagnosis, cure, mitigation, treatment, or prevention of the acute condition are MH/SUD benefits for the purposes of MHPAEA.

**ERISA Disclosure for MH/SUD Benefits**

The MHPAEA final regulations provide express disclosure requirements. Specifically, the criteria for medical necessity determinations with respect to MH/SUD benefits must be made available by the plan administrator or the health insurance issuer to any current or potential participant, beneficiary, or contracting provider upon request.[11] In addition, under MHPAEA, the reason for any denial of reimbursement or payment for services with respect to MH/SUD benefits must be made available to participants and beneficiaries.[12] The Departments also explained in the preamble to the final regulations that, in addition to these specific disclosure obligations under MHPAEA, ERISA's general disclosure obligation in section 104(b) and the accompanying disclosure regulation at 29 CFR 2520.104b-1 provide that, for plans subject to ERISA, instruments under which the plan is established or operated must generally be furnished to plan participants within 30 days of request. Instruments under which the plan is established or operated include documents with information on medical necessity criteria for both medical/surgical benefits and MH/SUD benefits, as well as the processes, strategies, evidentiary

[11] 26 CFR 54.9812-1(d)(1), 29 CFR 2590.712(d)(1), 45 CFR 146.136(d)(1) and 147.160.
[12] 26 CFR 54.9812-1(d)(2), 29 CFR 2590.712(d)(2), 45 CFR 146.136(d)(2) and 147.160.

standards, and other factors used to apply an NQTL with respect to medical/surgical benefits and MH/SUD benefits under the plan. In addition, 29 CFR 2560.503-1, 29 CFR 2590.715-2719 and 45 CFR 147.136 set forth rules regarding claims and appeals, including the right of claimants (or their authorized representative) upon appeal of an adverse benefit determination (or a final internal adverse benefit determination) to be provided upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the claimant's claim for benefits. This includes documents with information on medical necessity criteria for both medical/surgical benefits and MH/SUD benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply an NQTL with respect to medical/surgical benefits and MH/SUD benefits under the plan.

Contemporaneous with the issuance of the MHPAEA final regulations, the Departments published FAQs about Affordable Care Act Implementation Part XVII and Mental Health Parity Implementation[13] addressing a group health plan's disclosure obligations under MHPAEA and ERISA generally, as well as the specific information a participant is entitled to receive when a claim for MH/SUD benefits has been denied. In addition to reiterating that "instruments under which the plan is established or operated" under ERISA section 104 includes documents with information on medical necessity criteria for both medical/surgical and MH/SUD benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply an NQTL, this guidance noted that other provisions of Federal law require such disclosures. The following FAQs provide examples of how other provisions of Federal law may require disclosures relevant to MH/SUD benefits.

**Q11: My ERISA-covered group health plan utilizes a provider network and provides a provider directory with its summary plan description (SPD). My former psychiatrist retired three years ago and is therefore no longer participating in the network. However, the provider directory furnished by the plan lists her as still participating in the network. When I began making calls to find a replacement provider, it became clear that the entire directory is out of date and inaccurate. Is this permissible?**

No. Under 26 CFR 2520.102-3 of the Department of Labor's regulations, if an ERISA-covered plan utilizes a network, its SPD must provide a general description of the provider network. The list of providers in that SPD must be up-to-date, accurate, and complete (using reasonable efforts). The list may be provided as a separate document that accompanies the plan's SPD if it is furnished automatically and without charge and the SPD contains a statement to that effect. Moreover, an ERISA-covered plan must disclose a summary of material modifications or changes in the information required to be included in the summary plan description not later than

[13] See FAQs about Affordable Care Act Implementation (Part XVII) and Mental Health Parity Implementation, available at http://www.dol.gov/ebsa/faqs/faq aca17.html and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs17.html.

210 calendar days after the close of the plan year in which the modification or change was adopted. *See* 29 CFR 2520.104b-3(a).

Qualified Health Plan (QHP) issuers are obligated to comply with 45 CFR 156.230(b)(2) that requires the issuer to publish an up-to-date, accurate, and complete provider directory, including information on which providers are accepting new patients, and the provider's location, contact information, specialty, medical group, and any institutional affiliations, in a manner that is easily accessible to plan enrollees, prospective enrollees, the State, the Health Insurance Marketplace, HHS, and the Office of Personnel Management (OPM).

**Q12: Are ERISA-covered plans and issuers that utilize provider networks permitted to provide a hyperlink or URL address in enrollment and plan summary materials for a provider directory where information related to MH/SUD providers can be found?**

Yes. While ERISA-covered plans must provide an SPD that describes provisions governing the use of network providers, the composition of the provider network, and whether, and under what circumstances, coverage is provided for out-of-network services under ERISA section 102 and the Department of Labor's implementing regulations, such information could be provided electronically, for instance in a hyperlink or URL address, provided the Department of Labor's electronic disclosure safe harbor requirements at 29 CFR 2520.104b-1(c) are met.

Furthermore, under PHS Act section 2715 and its implementing regulations, group health plans and health insurance issuers offering group or individual health insurance coverage must provide a Summary of Benefits and Coverage that includes an Internet address (or other contact information) for obtaining a list of in-network network providers.

Finally, QHP issuers currently must make their provider directories available online. For plan years beginning on or after January 1, 2016, a QHP issuer must publish an up-to-date provider directory, including information on which providers are accepting new patients, as well as each provider's contact information, specialty, medical group, and any institutional affiliations, in a manner that is easily accessible to plan enrollees, prospective enrollees, the State, the Exchange, HHS, and OPM.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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# Risk Analyses vs. Gap Analyses – What is the difference?

The Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security and Breach Notification Rules require covered entities and their business associates to safeguard electronic protected health information (ePHI) through reasonable and appropriate security measures. One of these measures required by the Security Rule, is a risk analysis, which directs covered entities and business associates to conduct a thorough and accurate assessment the risks and vulnerabilities to ePHI (*See* 45 CFR § 164.308(a)(1)(ii)(A)). Conducting a risk analysis is the first step in identifying and implementing safeguards that ensure the confidentiality, integrity, and availability of ePHI. A gap analysis, while not required by the HIPAA Rules, is a useful tool to identify whether certain standards and implementation specifications of the Security Rule have been met.

**In Brief:**

- A risk analysis is a comprehensive evaluation of a covered entity or business associate's enterprise to identify the ePHI and the risks and vulnerabilities to the ePHI. The risk analysis is then used to make appropriate modifications to the ePHI system to reduce these risks to a reasonable and appropriate level.
- A gap analysis is typically a narrowed examination of a covered entity or business associate's enterprise to assess whether certain controls or safeguards required by the Security Rule are implemented. A gap analysis can also provide a high-level overview of the controls in place that protect ePHI, without engaging in the comprehensive evaluation required by a risk analysis.

***Risk Analyses:***

The Security Rule does not require a specific methodology to assess the risks to ePHI nor does it require risk analysis documentation to be in a specific format. However, there are certain elements common to a risk analysis that should be incorporated into an entity's risk analysis process. These elements include[1]:

- **Scope**
  The risk analysis should consider the potential risks to all of an entity's ePHI, regardless of the particular electronic medium in which it is created, received, maintained, or transmitted, or the source or location of its ePHI.
- **Data Collection**
  When considering the potential risks to its ePHI, entities should identify all of the locations and information systems where ePHI is created, received, maintained, or transmitted. Such an inventory should consider not only workstations and servers, but also applications, mobile

[1] U.S. Department of Health and Human Services Office for Civil Rights (2010). *Guidance on Risk Analysis Requirements under the HIPAA Security Rule*, 5 – 7. Retrieved from https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/securityrule/rafinalguidancepdf.pdf

devices, electronic media, communications equipment, and networks as well as physical locations.

- **Identify and Document Potential Threats[2] and Vulnerabilities[3]**
  Be sure to identify technical as well as non-technical vulnerabilities. Technical vulnerabilities can include holes, flaws, or weaknesses in information systems; or incorrectly implemented and/or configured information systems.
- **Assess Current Security Measures**
  Assess and document the effectiveness of current controls, for example the use of encryption and anti-malware solutions, or the implementation of patch management processes.
- **Determine the Likelihood and Potential Impact of Threat Occurrence**
  Determine and document the likelihood that a particular threat will trigger or exploit a particular vulnerability as well as the impact if a vulnerability is triggered or exploited.
- **Determine the Level of Risk**
  Assess and assign risk levels for the threat and vulnerability combinations identified by the risk analysis. Determining risk levels informs entities where the greatest risk is, so entities can appropriately prioritize resources to reduce those risks.
- **Documentation**
  Although the Security Rule does not specify a form or format for risk analysis documentation, such documentation should contain sufficient detail to demonstrate that an entity's risk analysis was conducted in an accurate and thorough manner. If a covered entity or business associate submits a risk analysis lacking sufficient detail in response to an OCR audit or enforcement activity, additional documentation may be required to demonstrate that the risk analysis was in fact conducted in an accurate and thorough manner.
- **Review and Update**
  Conducting a risk analysis is an ongoing process that should be reviewed and updated regularly. Although the Security Rule does not prescribe a frequency for performing risk analyses, risk analysis and risk management processes work most effectively when integrated into an entity's business processes to ensure that risks are identified and addressed in a timely manner.

***Gap Analyses:***

A gap analysis typically provides a partial assessment of an entity's enterprise and is often used to provide a high level overview of what controls are in place to protect ePHI or to identify potential gaps where controls are not in place. Gap analyses may also be used to review an entity's compliance with particular standards and implementation specifications of the Security Rule.

[2] An adapted definition of threat, from NIST SP 800-30, is "[t]he potential for a person or thing to exercise (accidentally trigger or intentionally exploit) a specific vulnerability." *Id.*

[3] Vulnerability is defined in NIST Special Publication (SP) 800-30 as "[a] flaw or weakness in system security procedures, design, implementation, or internal controls that could be exercised (accidentally triggered or intentionally exploited) and result in a security breach or a violation of the system's security policy." Id.

Such a gap analysis may take a form similar to the example below.

| HIPAA Regulation | Regulatory Summary | P&P[4] Documented? | P&P Implemented? | Compliance Rating |
|---|---|---|---|---|
| 45 C.F.R. § 164.308(a)(1)(ii)(A) | **Risk Analysis:** Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to ePHI. | 100% | 0% | Not Compliant |
| 45 C.F.R. § 164.308(a)(1)(ii)(B) | **Risk Management:** Implement security measures to reduce risks and vulnerabilities to a reasonable and appropriate level. | 100% | 50% | Not Compliant |
| 45 C.F.R. § 164.308(a)(1)(ii)(C) | **Sanction Policy:** Apply appropriate sanctions against workforce members who fail to comply with security policies and procedures. | 100% | 100% | Compliant |
| 45 C.F.R. § 164.308(a)(1)(ii)(D) | **Information System Activity Review:** Implement procedures to regularly review records of information system activity. | 50% | 50% | Not Compliant |

An entity's gap analysis generally does not satisfy the risk analysis obligations because it typically does not demonstrate an accurate and thorough assessment of the risks to ***all*** of the ePHI an entity creates, receives, maintains, or transmits (*See* 45 C.F.R. §164.308(a)(1)(ii)(A)).

Resources for conducting a risk analysis are available on OCR's web site at https://www.hhs.gov/hipaa/for-professionals/security/guidance/guidance-risk-analysis/index.html). OCR's HIPAA audit protocol may be helpful to those entities seeking information on their compliance with the HIPAA Rules (See https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/audit/protocol/index.html).

[4] Policies and Procedures.