FAQS ABOUT MENTAL HEALTH AND SUBSTANCE USE DISORDER PARITY IMPLEMENTATION AND THE 21ST CENTURY CURES ACT PART 39

August XX, 2019

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 responses to FAQs also address implementation of the 21st Century Cures Act (Cures Act), the SUPPORT for Patient and Communities Act (Support 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 the law and benefit from it as intended through examples that illustrate the requirements of MHPAEA and its implementing regulations. While some of the fact patterns used as examples may be relatively uncomplicated, they should enable the public to identify and address important MHPAEA issues. These FAQs do not contain any new interpretations of MHPAEA, but instead provide additional examples of how the MHPAEA final regulations apply to different fact patterns to promote compliance.

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.[1]

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

[1] The six classifications of benefits defined in final rules implementing the requirements of MHPAEA 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. 26 CFR 54.9812-1(c)(2)(ii); 29 CFR 2590.712(c)(2)(ii); and 45 CFR 146.136(c)(2)(ii).

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 offering group or individual health insurance coverage.

The Cures Act requires the Departments to solicit feedback and issue guidance regarding the disclosure and NQTL requirements of MHPAEA. Section 13001(b) of the Cures Act specifically 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.

As part of the Departments' implementation of the Cures Act, on June 16, 2017, the Departments issued MHPAEA compliance assistance guidance regarding benefits for eating disorder treatment.[2]

The Departments issued several additional documents related to MHPAEA on April 23, 2018, including an MHPAEA self-compliance tool to aid plans, issuers, and other stakeholders in understanding the requirements of MHPAEA, an action plan developed by HHS, DOL's biannual report to Congress regarding MHPAEA implementation and enforcement efforts, and DOL's fiscal year 2017 MHPAEA enforcement fact sheet.[3] At the same time, the Departments

[2] 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.
[3] 2018 MHPAEA Self-Compliance Tool, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/publications/compliance-assistance-guide-appendix-a-mhpaea.pdf; 21st Century Cures Act: Section 13002 Action Plan For Enhanced Enforcement of Mental Health and Substance use Disorder Coverage,

also proposed two guidance documents with requests for comment. The first document was a model disclosure request form that could be used to request information from group health plans and health insurance issuers offering group or individual health insurance coverage.[4] The second was, "Proposed FAQs about Mental Health and Substance Use Disorder Parity Implementation and The 21st Century Cures Act Part 39."

In addition, on January 10, 2019, the DOL, in coordination with the Departments of HHS and the Treasury, hosted a roundtable discussion with stakeholders to discuss issues regarding MHPAEA implementation, including the proposed FAQs and model disclosure request form.

Commenters on the FAQs generally supported the Departments' efforts to give additional guidance and compliance assistance. Stakeholders also shared important insights into certain compliance issues faced by plans and issuers, as well as issues faced by plan participants and their authorized representatives when they are seeking information about MH/SUD benefits. After considering these comments and making edits to clarify the guidance (including, where necessary, deleting language that commenters have identified as confusing or unclear), the Departments are issuing a final model disclosure request form and final FAQs Part 39 with clarifications.

The Departments intend to continue to provide additional MHPAEA implementation information on a rolling basis, including revised compliance program documents and updated enforcement data. For the most current information on MHPAEA, Cures Act, and Support Act implementation, see https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/mental-health-and-substance-use-disorder-parity and https://www.cms.gov/cciio.

Nonquantitative Treatment Limitations

An NQTL is generally a limitation, often non-numeric, on the scope or duration of benefits for treatment. In developing and applying an NQTL, the regulations provide that a plan or issuer may consider a wide array of factors.[5] For example, a plan can consider economic factors, such as high cost growth, or other factors such as the incidence of fraud with respect to services in a particular classification. In applying those factors, the NQTL analysis does not focus on whether the final result (for example, coverage denial rates) is the same for MH/SUD benefits and medical/surgical benefits; instead, compliance depends on parity in development and application of the underlying processes and strategies. There should not be arbitrary or discriminatory

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available at https://www.hhs.gov/sites/default/files/parity-action-plan-b.pdf; DOL 2018 Report to Congress: Pathway to Full Parity, available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/dol-report-to-congress-2018-pathway-to-full-parity.pdf and FY 2017 MHPAEA Enforcement Fact Sheet, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/fact-sheets/mhpaea-enforcement-2017.pdf.

[4] A previous version of the model disclosure request form was issued by the Departments on June 16, 2017 with a request for public comment.

[5] See 26 CFR 54.9812(c)(4)(iii),29 CFR 2590.712(c)(4)(iii), 45 CFR 146.136(c)(4)(iii), example 8, outlining an illustrative list of factors that a plan uses to develop and apply a compliant NQTL.

differences in how a plan or issuer is applying those processes and strategies to medical/surgical benefits and MH/SUD benefits. Moreover, in the preamble to the MHPAEA final regulations (which reiterates guidance issued by the Departments in 2011), the Departments stated that it is unlikely that a reasonable application of the NQTL requirement would result in all MH/SUD benefits being subject to an NQTL in the same classification in which less than all medical/surgical benefits are subject to the NQTL.[6] While similar or dissimilar outcomes between MH/SUD benefits and medical/surgical benefits with respect to, for example, benefit denial rates are NOT determinative of compliance, higher rates of denials for MH/SUD benefits may be viewed as a warning sign, or indicator of potential operational parity noncompliance. Vast differences in such rates can serve as a strong indicator of potential noncompliance. The following examples illustrate how to evaluate the factors used to develop and apply an NQTL in a variety of fact patterns.

Q1. My health plan document states that it excludes coverage for treatment that is experimental or investigative for both medical/surgical benefits and for MH/SUD benefits. For both medical/surgical benefits and MH/SUD benefits, the plan generally follows current medical evidence and professionally recognized guidelines on the efficacy of treatment. With respect to both medical/surgical benefits and MH/SUD benefits, the plan's documents state that the plan excludes coverage for 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 Behavior Analysis (ABA) therapy to treat certain children with Autism Spectrum Disorder. The plan, in practice, excludes coverage 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 covers treatment when supported by one or more professionally recognized treatment guidelines and two or more controlled randomized trials. Is this permissible under MHPAEA?

No. The plan's application of the NQTL to MH/SUD benefits is not permissible because, in operation, the plan applies the NQTL more stringently to certain MH/SUD benefits than to medical/surgical benefits. A medical management standard limiting or excluding benefits based on whether a treatment is experimental or investigative is an NQTL under MHPAEA.[7] A group

[6] See 78 FR 68240, 68245 (Nov. 13, 2013). See also FAQs About Affordable Care Act Implementation (Part VII) and Mental Health Parity Implementation (November 17, 2011) at Q&A-5 https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-vii.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs7.html.

[7] 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 or medical appropriateness, or based on whether the treatment is

health plan or group or individual health insurance issuer 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 used by the plan in applying the NQTL to MH/SUD benefits 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 certain MH/SUD benefits, as the plan excludes 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, the plan's exclusion of certain MH/SUD benefits—in this case, for ABA therapy—does not comply with MHPAEA because the plan applies the NQTL more stringently to these MH/SUD benefits than to medical/surgical benefits.

To comply with MHPAEA, the plan must ensure that any processes, strategies, evidentiary standards, and other factors used to impose the exclusion are applied comparably to all medical/surgical and MH/SUD benefits in the relevant classification. This could be accomplished, in practice, by not excluding as experimental or investigative any treatment that has professionally recognized treatment guidelines defining clinically appropriate standards of care for the condition and for which at least two randomized controlled trials are available to support the treatment's use with respect to the condition. To the extent the plan determines any treatment should be excluded after properly applying this standard, the plan should also document the factors relied upon to exclude the treatment on this basis.

Q2: My health plan documents state that the plan excludes coverage for treatment that is experimental or investigative for both medical/surgical benefits and for MH/SUD benefits. The plan defines experimental or investigative treatments as those with a rating below "B" in the Hayes Medical Technology Directory, with exceptions for certain treatments that have a rating of "C" only where an exception is determined to be medically appropriate. However, in operation, the plan reviews and covers certain treatments for medical/surgical conditions that have a rating of "C" only when an exception is determined to be medically appropriate, 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 medically appropriate. Is this permissible under MHPAEA?

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experimental or investigative; formulary design for prescription drugs; network tier design; and plan methods for determining usual, customary, and reasonable charges.

No. A medical management standard that limits or excludes benefits based on whether a treatment is experimental or investigative is an NQTL under MHPAEA.[8] A plan or issuer 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 used by the plan in applying its NQTL with respect to MH/SUD benefits 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, although the terms of the plan set forth the same evidentiary standard for MH/SUD benefits and medical/surgical benefits (defining experimental as having a Hayes Medical Technology Directory rating below "B," with exceptions for those with a "C" rating where medically appropriate), the plan applies a different evidentiary standard, and the standard is more stringent for MH/SUD benefits than for medical/surgical benefits because claims for medical/surgical treatments with a "C" rating are reviewed to determine whether an exception is medically appropriate while claims for MH/SUD treatments with a "C" rating are denied without review by the plan to determine whether an exception might be medically appropriate. 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's medical management standard does not comply with MHPAEA.

To comply with MHPAEA, the plan must apply the same exception for MH/SUD treatments in the same classification if the plan, in operation, provides an exception based on medical appropriateness for medical/surgical treatments. To ensure that its approach is compliant with MHPAEA and that it will be able to satisfy participants' requests for documents, the plan should document in writing the availability and requirements of its exceptions process, as well as the factors relied upon in determining how the exception process applies to both MH/SUD and medical/surgical benefits.

Q3: 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 for prescription medications 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.[9] Plans and issuers may impose dosage limits as a medical management technique with respect to prescription drug coverage under the

[8] 26 CFR 54.9812-1(c)(4)(ii); 29 CFR 2590.712(c)(4)(ii); 45 CFR 146.136(c)(4)(ii).
[9] 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).

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 a plan or issuer deviates from nationally-recognized treatment guidelines for buprenorphine/naloxone to treat opioid use disorder based on P&T committee recommendations or 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, the plan or issuer should determine (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 (*e.g.*, if a plan ensures that certain members of the P&T committee are board certified in the area of medicine that will prescribe the treatment or drug in question, the plan must impose this requirement comparably for benefits for both medical/surgical and MH/SUD treatments), and (2) whether the committee's evaluation of nationally-recognized treatment guidelines in setting dosage limits for medications for both MH/SUD and medical/surgical conditions is comparable.

Q4: 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 a specific mental health condition, including prescription drugs to treat that condition. Is this permissible under MHPAEA?

Yes. Generally, MHPAEA requires that treatment limitations imposed on MH/SUD benefits cannot be more restrictive than treatment limitations that apply to medical/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" as set forth in the MHPAEA regulations. The MHPAEA regulations also provide that if a plan or issuer provides benefits for

a mental health condition or substance use disorder, benefits for that condition or disorder must be provided in every classification in which medical/surgical benefits are provided. Because the plan or coverage does not provide any MH/SUD benefits for that specific mental health condition in any classification, this exclusion is permissible under MHPAEA.[10]

Q5: My health plan requires step therapy for both medical/surgical and MH/SUD inpatient, 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 requires only 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, as it is unlikely that the plan's analysis will support the application of this NQTL. 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.[11] 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 medical/surgical benefits. 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. If the plan can make that demonstration, the plan should document the factors relied upon to support the different step therapy protocols.

Q6. My health plan documents state that in-network provider reimbursement rates are determined based on a variety of factors, including the providers' required training, licensure, and expertise. For medical/surgical benefits, the difference in reimbursement rates for physicians and non-physician practitioners for the same Current Procedural Technology (CPT) code[12] varies based on a combination of factors such as the nature of the

[10] Note that small group and individual health insurance coverage are generally 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 essential health benefits benchmark plan. State law may also impose certain benefit mandates for large group insured coverage. See PHS Act section Sec. 2707(a); Patient Protection and Affordable Care Act section ACA Sec. 1302(a).

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

[12] The CPT is a uniform numeric coding system maintained by the American Medical Association (AMA) consisting of descriptive terms and identifying codes that are used primarily to identify medical services and procedures furnished by physicians and other health care professionals. See HCPCS - General Information, available at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html.

service, provider type (including demographics), market dynamics, and market need availability (demand). For MH/SUD benefits, the plan states that it varies reimbursement rates for non-physician practitioners for the same CPT code based on a combination of similar factors; however, despite these terms in the plan, the plan reduces the reimbursement rate by the same percentage for every CPT code for an MH/SUD service rendered by a non-physician practitioner. The plan does not do so with respect to medical/surgical providers. Is this permissible under MHPAEA?

No. While MHPAEA does not require a plan or issuer to pay identical provider reimbursement rates for medical/surgical and MH/SUD providers, a plan's or issuer's standards for admitting a provider to participate in a network (including the plan's reimbursement rates for providers) is an NQTL. A plan or issuer may impose an NQTL if under the terms of the plan as written and in operation, the processes, strategies, evidentiary standards, and other factors used by the plan in applying its NQTL with respect to MH/SUD benefits 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. In other words, the plan or issuer must demonstrate that the methodology for developing and applying reimbursement rates under the plan is comparable and applied no more stringently for MH/SUD benefits when compared to the methodology for developing and applying reimbursement rates for medical/surgical benefits under the plan.

Here, the plan's methodology for developing and applying reimbursement rates, in operation, is to reduce reimbursement rates by the same percentage for all non-physician practitioners providing MH/SUD services, while varying the reimbursement rate for non-physician practitioners providing medical/surgical services only when certain factors (*e.g.* the nature of the service, provider type, market dynamics, and demand) support such variance. The plan does not use a comparable process with respect to reimbursement of non-physician providers of medical/surgical and MH/SUD services. Accordingly, the plan's use of this NQTL does not comply with MHPAEA.

To comply with MHPAEA, the plan must be able to demonstrate that it follows a comparable process in determining payment rates for non-physician providers for both medical/surgical and MH/SUD benefits.

Q7: In setting standards for provider admission to its network, my health plan considers the composition of current in-network providers to help ensure the plan has an adequate number of providers. With respect to its network of medical/surgical providers, the plan sets standards for provider admission in a manner that is calculated to ensure that participants and beneficiaries can schedule an appointment with a network provider within 15 days for non-urgent care, including, where appropriate, by increasing reimbursement rates and developing a process for accelerating participation in the network. The plan does not take comparable measures, where appropriate, to attempt to ensure an adequate network of MH/SUD providers. Is this permissible under MHPAEA?

No. Standards for provider admission to participate in a network, including reimbursement rates, are an NQTL.[13] 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 medical/surgical benefits.

Here, in setting standards for provider admission to the network, the plan's process to ensure the plan considers network adequacy with respect to providers of medical/surgical services is not comparable to its process with respect to providers of MH/SUD services.

The Departments note that greatly disparate results—for example, a network that includes far fewer MH/SUD providers than medical/surgical providers—are a red flag that a plan or issuer may be imposing an impermissible NQTL. Accordingly, further review of the NQTL may be required to determine parity compliance.[14] MHPAEA does not require a plan or issuer to ensure that the numbers of MH/SUD and medical/surgical providers in the plan's network are comparable, but the plan or issuer must undertake a comparable *process* and apply comparable strategies and evidentiary standards when developing and ensuring an adequate network. In this example, because the plan's *process* for setting standards for MH/SUD provider admission to its network is not comparable to the *process* employed with respect to medical/surgical providers, the plan does not comply with MHPAEA.

To comply with MHPAEA, if the plan takes steps to ensure the plan has an adequate number of in-network medical/surgical providers, the plan must take comparable steps to ensure an adequate number of in-network MH/SUD providers, even if, following those steps, ultimately there are a disparate numbers of MH/SUD and medical/surgical providers in the plan's network.

Q8: 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 prior authorization from the plan, the facility meets the licensing and certification requirements set by 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 a hospital setting for eating disorders, including non-hospital residential treatment (which it regards as an inpatient benefit). Is this permissible under MHPAEA?

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

[14] For additional red flags, see Warning Signs - Plan or Policy Non-Quantitative Treatment Limitations (NQTLs) that Require Additional Analysis to Determine Mental Health Parity Compliance (June 1, 2016), available at: https://www.dol.gov/sites/default/files/ebsa/laws-and-regulations/laws/mental-health-parity/warning-signs-plan-or-policy-nqtls-that-require-additional-analysis-to-determine-mhpaea-compliance.pdf and https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/MHAPEAChecklistWarningSigns.pdf.

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. Section 13007 of the Cures Act clarified that if a group health plan or health insurance issuer offering group or individual health insurance coverage provides coverage for eating disorder benefits, including non-hospital 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.[15]

Plan or coverage restrictions based on facility type are NQTLs under the MHPAEA final regulations.[16] A plan or issuer may impose an NQTL if, under the terms of the plan as written and in operation, the processes, strategies, evidentiary standards, and other factors used by the plan or issuer in applying 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 whether an exclusion of an intermediate level of care, including non-hospital residential treatment complies with MHPAEA, it must be 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.[17] If so, then the basis for the exclusion (in this case, non-hospital residential treatment) in the classification must be reviewed to determine if the processes, strategies, evidentiary standards, and other factors used to apply 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.

If a plan or issuer can articulate comparable and no more stringently applied processes, strategies, evidentiary standards, or other factors to exclude non-hospital residential treatment for MH/SUD benefits in certain circumstances, the plan or issuer may be able to demonstrate that the exclusion is consistent with the regulations under MHPAEA. However, in this example, the plan covers inpatient, out-of-network treatment outside a hospital for medical/surgical conditions so long as a prescribing physician obtains prior authorization from the plan, the treatment is medically appropriate for the individual, and the facility meets the licensing and certification requirements set by the plan, while the plan unequivocally excludes all inpatient, out-of-network

[15] 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-and-FAQs/Downloads/FAQ-Part-38.pdf.

[16] 26 CFR 54.9812-1(c)(4)(ii), 29 CFR 2590.712(c)(4)(ii), and 45 CFR 146.136(c)(4)(ii).

[17] See 26 CFR 54.9812-1(c)(2)(ii)(A), 29 CFR 2590.712(c)(2)(ii)(A), and 45 CFR 146.136(c)(2)(ii)(A). See also the preamble to the Departments' final rules implementing MHPAEA, which states that if a plan or issuer classifies care in skilled nursing facilities or rehabilitation hospitals as inpatient benefits, then the plan or issuer must likewise treat any covered care in residential treatment facilities for MH/SUD services as an inpatient benefit. In addition, if a plan or issuer 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. 78 FR 68240, 68247 (Nov. 13, 2013).

treatment outside a hospital (in this case, non-hospital residential treatment) for eating disorders. This restriction on non-hospital residential treatment for eating disorders is not comparable to the plan's coverage restrictions for inpatient treatment outside a hospital for medical/surgical conditions, which are less stringent. This exclusion does not comply with MHPAEA.

A plan or issuer may rely on one or more factors to develop and apply an NQTL, provided the factors are comparable and no more stringently applied to MH/SUD benefits as compared to medical/surgical benefits \(in this case, both medical appropriateness of the service, as well as the credentials of the facility). Such factors can be a mix of statistical, clinical or other factors, such as high incidence of fraud with respect to services in a particular classification.[18] The plan or issuer should document any factors relied upon in developing and applying this NQTL.

Disclosures with Respect to 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.[19] In addition, under MHPAEA, the reason for any denial of reimbursement or payment for services with respect to MH/SUD benefits in the case of any participant or beneficiary must be made available to the participant or beneficiary.[20]

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. A document that specifies procedures, formulas, methodologies, or schedules that are applied in determining or calculating a participant's benefit under the plan constitutes an instrument under which the plan is established or operated.[21] 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 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, 26 CFR 54.9815-2719, 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,

[18] See 26 CFR 54.9812-1(c)(4)(iii), Example 8; 29 CFR 2590.712(c)(4)(iii), Example 8, and 45 CFR 146.136(c)(4)(iii), Example 8.
[19] 26 CFR 54.9812-1(d)(1), 29 CFR 2590.712(d)(1), 45 CFR 146.136(d)(1) and 147.160.
[20] 26 CFR 54.9812-1(d)(2), 29 CFR 2590.712(d)(2), 45 CFR 146.136(d)(2) and 147.160.
[21] See Advisory Opinion 96-14A, available at https://www.dol.gov/agencies/ebsa/employers-and-advisers/guidance/advisory-opinions.

reasonable access to and copies of all documents, records, and other information relevant to the claimant's claim for benefits.[22] This includes documents with information on medical necessity criteria for both medical/surgical benefits and MH/SUD benefits, as well as documents reflecting 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[23] 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, the FAQs noted that other provisions of Federal law require such disclosures.

On October 27, 2016, the Departments issued Affordable Care Act Implementation FAQs Part 34, which, among other things, solicited feedback regarding disclosures with respect to MH/SUD benefits under MHPAEA and other laws. In the FAQs, the Departments indicated that they had received questions and suggestions regarding disclosures with respect to NQTLs. This feedback included requests for model forms that group health plan participants, beneficiaries, covered individuals in the individual market, or persons acting on their behalf could use to request relevant disclosures. The Departments initially proposed a model form on June 16, 2017 and solicited comments. After reviewing the comments, the Departments proposed a revised model form on April 23, 2018 and again solicited comments. The Departments are finalizing this model disclosure request form, with some clarifications in response to comments. Use of the form by participants, beneficiaries, and enrollees is optional and is meant to facilitate the ability of covered individuals to request information disclosure in certain circumstances. The model form is set forth at the end of this document.

The following FAQs provide examples of how certain provisions of Federal law may require disclosures relevant to MH/SUD benefits.

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[22] A documents, record, or other information is considered "relevant" for a group health plan under 29 CFR 2560.503-1(m)(8) if it (i) was relied upon in making the benefit determination; (ii) was submitted, considered, or generated in the course of making the benefit determination, without regard to whether such document, record, or other information was relied upon in making the benefit determination; (iii) demonstrates compliance with the administrative processes and safeguards required to ensure and verify that claims are decided in accordance with governing plan documents and consistently with similar claims; or (iv) constitutes a statement of plan policy or guidance concerning the denied treatment option or benefit for the claimant's diagnosis, without regard to whether such advice or statement was relied upon in making the benefit determination.

[23] 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.

Q9: I wish to request information from my ERISA-covered group health plan regarding limitations that may affect my access to MH/SUD benefits. Do the Departments have any materials that may assist me?

Under ERISA, plans are required to provide summary plan descriptions (SPDs) that describe, in terms understandable to the average plan participant, the rights, benefits, and responsibilities of participants and beneficiaries. Plans are also required to provide a Summary of Benefits and Coverage (SBC) that includes, among other elements, a description of the coverage; the exceptions, reductions, and limitations of the coverage and the cost-sharing provisions of the coverage. The Departments encourage participants and beneficiaries to first consult their SBC, as well as their SPD, for information on how their plan covers MH/SUD benefits. If you do not have and SPD or SBC, consider requesting them. Generally, the plan is required to give participants and beneficiaries copies of these documents on request.

The Departments also developed a model form that individuals, or their authorized representatives may—but are not required to—use to request information that may affect their MH/SUD benefits. This model form can be used for general requests for information regarding MH/SUD benefits and treatment limitations, such as a request for the relevant portions of the SPD or plan document. This model form can also be used to obtain documentation after an adverse benefit determination involving MH/SUD benefits to support an appeal. Furthermore, plans and issuers may find that making this model disclosure form available to their participants or enrollees may help clarify and streamline requests for information. Use of the form is optional for participants, and plans and issuers may use their own disclosure forms to help facilitate disclosure requests. The model form is set forth at the end of these FAQs.

Q10: My ERISA-covered group health plan utilizes a provider network and provides a provider directory with its SPD. The entire directory is out of date and inaccurate. Is this permissible?

No. Under 29 CFR 2520.102-3(j)(3) of the DOL's regulations, if an ERISA-covered plan utilizes a network, its SPD must provide a general description of the provider network, as well as the composition of the provider network. The list of providers may be distributed 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. The list of providers, whether set forth in the SPD, or separately, must be up-to-date, accurate, and complete (using reasonable efforts).

Qualified Health Plan (QHP) issuers are also obligated to comply with 45 CFR 156.230(b)(2) of HHS's regulations 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).

Q11: 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 network providers, including MH/SUD providers, can be found?

Yes. ERISA-covered plans must provide an SPD that describes provisions related to the use of network providers, and the composition of the provider network, under ERISA section 102 and DOL's implementing regulations. Such information may be provided as a separate document and, in many circumstances, may be provided electronically (for instance in a hyperlink or URL address).[24]

Furthermore, under PHS Act section 2715 and its implementing regulations, for group health plans and health insurance issuers offering group or individual health insurance coverage that maintain one or more networks of providers, the plan or issuer must provide a SBC that includes an Internet address (or similar contact information) for obtaining a list of network providers.[25]

Finally, as stated in Q&A-10, QHP issuers 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, 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 Exchange, HHS, and OPM.[26]

MODEL DISCLOSURE FORM

[INSERT FINAL MODEL DISCLOSURE FORM]

[24] 29 CFR 2520.104b-1(c).
[25] 26 CFR 54.9815-2715(a)(2)(K), 29 CFR 2590.715-2715(a)(2)(K), 45 CFR 147.200(a)(2)(K).
[26] 45 CFR 156.156.230(b)(2).