FAQS ABOUT MENTAL HEALTH AND SUBSTANCE USE DISORDER PARITY IMPLEMENTATION AND THE CONSOLIDATED APPROPRIATIONS ACT, 2021 PART 45

April 2, 2021

The Consolidated Appropriations Act, 2021 (the Appropriations Act) amended the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) to provide important new protections. The Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury (collectively, "the Departments") have jointly prepared this document to help stakeholders understand these amendments. Previously issued Frequently Asked Questions (FAQs) related to MHPAEA are available at https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/mental-health-and-substance-use-disorder-parity and https://www.cms.gov/cciio/resources/fact-sheets-and-faqs#Mental_Health_Parity.

Mental Health Parity and Addiction Equity Act of 2008

MHPAEA generally provides that 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] In addition, MHPAEA prohibits separate treatment limitations that apply only to MH/SUD benefits. MHPAEA also imposes several important disclosure requirements on group health plans and health insurance issuers.

The MHPAEA final regulations require that a group health plan or health insurance issuer may not impose a non-quantitative treatment limitation (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.[2] Under this analysis, the focus is not on whether the final result is the same for MH/SUD benefits as for medical/surgical benefits, but rather on whether the underlying processes, strategies, evidentiary

[1] The six classifications of benefits defined in final regulations 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).

[2] 26 CFR 54.9812-1(c)(4)(i); 29 CFR 2590.712(c)(4)(i); and 45 CFR 146.136(c)(4)(i) and 147.160.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.

standards, and other factors are in parity. These processes, strategies, evidentiary standards, and other factors must be comparable and applied no more stringently for MH/SUD benefits than for medical/surgical benefits.

Since the enactment of MHPAEA, the Departments have issued guidance and compliance assistance materials to help stakeholders understand the law and its implementing regulations, including the requirements for NQTLs. Most recently, in September 2019, the Departments issued Final FAQs part 39.[3] In an effort to promote compliance, the FAQs provided additional examples regarding how the NQTL requirements in the MHPAEA final regulations apply to different fact patterns.

The DOL also maintains on its website a MHPAEA Self-Compliance Tool that is intended to help group health plan sponsors and administrators, health insurance issuers, State regulators, and other stakeholders determine whether a group health plan or health insurance issuer complies with MHPAEA.[4] The MHPAEA Self-Compliance Tool includes a section on NQTLs that outlines a process for conducting comparative analyses of NQTLs. The MHPAEA Self-Compliance Tool is updated every two years and was most recently updated in 2020 by the DOL (in coordination with the Department of the Treasury and HHS).

The Consolidated Appropriations Act, 2021

The Consolidated Appropriations Act, 2021 was enacted on December 27, 2020.[5] Section 203 of Title II of Division BB of the Appropriations Act amended MHPAEA, in part, by expressly requiring group health plans and health insurance issuers offering group or individual health insurance coverage that offer both medical/surgical benefits and MH/SUD benefits and that impose NQTLs on MH/SUD benefits to perform and document their comparative analyses of the design and application of NQTLs. Further, beginning 45 days after the date of enactment of the Appropriations Act, these plans and issuers must make their comparative analyses available to the Departments or applicable State authorities, upon request, including the following information:

1. The specific plan or coverage terms or other relevant terms regarding the NQTLs and a description of all MH/SUD and medical or surgical benefits to which each such term applies in each respective benefits classification;

2. The factors used to determine that the NQTLs will apply to MH/SUD benefits and medical or surgical benefits;

[3] FAQs about Mental Health and Substance Use Disorder Parity Implementation and the 21st Century Cures Act Part 39 (Sept. 5, 2019), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-39-final.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-39.pdf.

[4] 2020 MHPAEA Self-Compliance Tool, available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/self-compliance-tool.pdf.

[5] Pub. L. 116-260 (Dec. 27, 2020).

3. The evidentiary standards used for the factors identified, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTLs to MH/SUD benefits and medical or surgical benefits;

4. The comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to MH/SUD benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical/surgical benefits in the benefits classification; and

5. The specific findings and conclusions reached by the plan or issuer, including any results of the analyses that indicate that the plan or coverage is or is not in compliance with the MHPAEA requirements.[6]

The Appropriations Act also provides that the Departments shall request that a group health plan or issuer submit the comparative analyses for plans that involve potential MHPAEA violations or complaints regarding noncompliance with MHPAEA that concern NQTLs, and any other instances in which the Departments determine appropriate.[7]

The Appropriations Act further requires the Departments, after review of the comparative analyses, to share information on findings of compliance and noncompliance with the State where the plan is located or the State where the issuer is licensed to do business. Additionally, not later than one year after enactment of the Appropriations Act and annually by October 1 thereafter, the Departments must submit to Congress and make publicly available a report that sets forth:

1. A summary of the comparative analyses requested, including the identity of each plan or issuer that is determined not to be in compliance after a final determination;

2. The Departments' conclusions as to whether each plan or issuer submitted sufficient information for the Departments to review the comparative analyses requested;

3. For each plan or issuer that submitted sufficient information for the Departments to review the comparative analyses requested, the Departments' conclusion as to whether and why the plan or issuer is in compliance with the disclosure requirements of MHPAEA;

[6] Internal Revenue Code (Code) section 9812(a)(8)(A)(i)-(iv), ERISA Section 712(a)(8)(A)(i)-(iv) and Public Health Service (PHS) Act section 2726(a)(8)(A)(i)-(iv).
[7] Code section 9812(a)(8)(B)(i), ERISA section 712(a)(8)(B)(i), and PHS Act section 2726(a)(8)(B)(i).

4. The Departments' specifications for each plan or issuer that did not submit sufficient information for the Departments to review the comparative analyses for compliance; and

5. The Departments' specifications of the actions each plan or issuer that the Departments determined is not in compliance must take to be in compliance with MHPAEA, including the reason the Departments determined the plan or issuer was not in compliance.

Q1: When must plans and issuers make available their NQTL comparative analyses, as required by the Appropriations Act?

Plans and issuers that offer both medical/surgical benefits and MH/SUD benefits and impose NQTLs must make their comparative analyses of the design and application of NQTLs available to the Departments or applicable State authorities upon request, beginning 45 days after the date of enactment of the Appropriations Act. Because the Appropriations Act was enacted on December 27, 2020, the requirement applies beginning February 10, 2021. Accordingly, plans and issuers should now be prepared to make their comparative analyses available upon request.

Q2: What information must plans and issuers make available in response to the Departments' requests for documentation of their comparative analyses?

Plans and issuers should ensure that comparative analyses are sufficiently specific, detailed, and reasoned to demonstrate whether the processes, strategies, evidentiary standards, or other factors used in developing and applying an NQTL are comparable and applied no more stringently to MH/SUD benefits than to medical/surgical benefits, as described further below. To that end, a general statement of compliance, coupled with a conclusory reference to broadly stated processes, strategies, evidentiary standards, or other factors is insufficient to meet this statutory requirement.

As explained above, the DOL's MHPAEA Self-Compliance Tool includes robust guidance related to requirements for NQTLs and outlines a process for analyzing whether a particular NQTL meets those requirements. It also includes numerous examples and compliance tips that may be helpful to plans and issuers regarding how to conduct comparative analyses of NQTLs, along with potential warning signs that may be indicative of noncompliance and warrant further review. In particular, the Self-Compliance Tool outlines four steps that plans and issuers should take to assess their compliance with MHPAEA for NQTLs. For each step, the Self-Compliance Tool also identifies certain information to support the analysis and the conclusions reached about whether the plan or coverage complies with MHPAEA. This information closely aligns with the information, outlined in the next paragraph, that plans and issuers must include as part of their comparative analyses. Therefore, plans and issuers that have carefully applied the guidance in the Self-Compliance Tool should be in a strong position to comply with the Appropriation Act's requirement to submit comparative analyses upon request. The MHPAEA Self-Compliance Tool was last updated in 2020, before the enactment of the Appropriations Act, and it recommends

that plans and issuers analyze NQTLs and document those analyses as a best practice. However, the Appropriations Act expressly requires that plans and issuers now conduct and document comparative analyses of the design and application of NQTLs. Therefore, this process is no longer a "best practice;" it is required.

Under the Appropriations Act, plans and issuers must now be prepared to submit their comparative analysis with respect to each NQTL imposed when requested by any of the Departments or by an applicable State authority. For an analysis to be treated as sufficient under the Appropriations Act, it must contain a detailed, written, and reasoned explanation of the specific plan terms and practices at issue, and include the bases for the plan's or issuer's conclusion that the NQTLs comply with MHPAEA. At a minimum, sufficient analyses must include a robust discussion of all of the elements listed below.

1. A clear description of the specific NQTL, plan terms, and policies at issue.

2. Identification of the specific MH/SUD and medical/surgical benefits to which the NQTL applies within each benefit classification, and a clear statement as to which benefits identified are treated as MH/SUD and which are treated as medical/surgical.

3. Identification of any factors, evidentiary standards or sources, or strategies or processes considered in the design or application of the NQTL and in determining which benefits, including both MH/SUD benefits and medical/surgical benefits, are subject to the NQTL. Analyses should explain whether any factors were given more weight than others and the reason(s) for doing so, including an evaluation of any specific data used in the determination.

4. To the extent the plan or issuer defines any of the factors, evidentiary standards, strategies, or processes in a quantitative manner, it must include the precise definitions used and any supporting sources.

5. The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between MH/SUD and medical/surgical benefits and, if so, describe the process and factors used for establishing that variation.

6. If the application of the NQTL turns on specific decisions in administration of the benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s).

7. If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the

plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both MH/SUD and medical/surgical benefits.

8. A reasoned discussion of the plan's or issuer's findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, factors, and sources identified above within each affected classification, and their relative stringency, both as applied and as written. This discussion should include citations to any specific evidence considered and any results of analyses indicating that the plan or coverage is or is not in compliance with MHPAEA.

9. The date of the analyses and the name, title, and position of the person or persons who performed or participated in the comparative analyses.[8]

Q3: What are examples of reasons why the Departments might conclude that documentation of comparative analyses of NQTLs is insufficiently specific and detailed?

As noted above, a general statement of compliance, coupled with a conclusory reference to broadly stated processes, strategies, standards, or other factors is not sufficient. Accordingly, comparative analyses that consist of conclusory or generalized statements without specific supporting evidence and detailed explanations or a mere production of a large volume of documents without a clear explanation of how and why each document is relevant to the comparative analyses are insufficient. Analyses that are sufficient include all the elements set forth in the response to Q2.

In past investigations relating to NQTLs, the Departments have observed the following practices and procedures, which plans and issuers should *avoid* in responding to requests for comparative analyses because they are insufficient:

1. Production of a large volume of documents without a clear explanation of how and why each document is relevant to the comparative analysis;

2. Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations;

3. Identification of processes, strategies, sources, and factors without the required or clear and detailed comparative analysis;

4. Identification of factors, evidentiary standards, and strategies without a clear explanation of how they were defined and applied in practice;

[8] Code section 9812(a)(8)(B)(ii), ERISA section 712(a)(8)(B)(ii), and PHS Act section 2726(a)(8)(B)(ii); see also the 2020 MHPAEA Self-Compliance Tool, available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/self-compliance-tool.pdf, at pg. 34 (discussing the types of information a group health plan might be asked to provide if audited by DOL investigators for MHPAEA compliance).

5. Reference to factors and evidentiary standards that were defined or applied in a quantitative manner, without the precise definitions, data, and information necessary to assess their development or application; or

6. Analysis that is outdated due to the passage of time, a change in plan structure, or for any other reason.

Q4: In addition to documentation of the comparative analyses, what types of documents should plans and issuers be prepared to make available to the Departments to support the analysis and conclusions reached in their comparative analyses of NQTLs?

As specified by the Appropriations Act, plans and issuers should be prepared to make available documents that support the analysis and conclusions of their NQTL comparative analyses, including any documents and other information relevant to the factors used to determine the application of an NQTL and the evidentiary standards used to define the factors identified. In its most recent update of the MHPAEA Self-Compliance Tool, DOL highlighted the following types of documents and relevant information that a plan or issuer should have available to support its NQTL comparative analyses.

1. Records documenting NQTL processes and detailing how the NQTLs are being applied to both medical/surgical and MH/SUD benefits to ensure the plan or issuer can demonstrate compliance with the law, including any materials that may have been prepared for compliance with any applicable reporting requirements under State law.

2. Any documentation, including any guidelines, claims processing policies and procedures, or other standards that the plan or issuer has relied upon to determine that the NQTLs apply no more stringently to MH/SUD benefits than to medical/surgical benefits. Plans and issuers should include any available details as to how the standards were applied, and any internal testing, review, or analysis done by the plan or issuer to support its rationale.

3. Samples of covered and denied MH/SUD and medical/surgical benefit claims.

4. Documents related to MHPAEA compliance with respect to service providers (if a plan delegates management of some or all MH/SUD benefits to another entity).

For example, if comparative analyses reference studies, testing, claims data, reports, or other considerations in defining or applying factors (such as meeting minutes or reports showing how those considerations were applied), then the plan or issuer should be prepared to provide copies of all those items. The precise information needed to support an NQTL analysis will vary depending on the type of NQTL and the processes, strategies, evidentiary standards, and other factors used by the plan or issuer.

Q5: What actions will the Departments take if they determine that a plan or issuer has not submitted sufficient information to review comparative analyses of the design and application of NQTLs, or if the Departments conduct a review and determine that a plan or issuer is not in compliance with MHPAEA?

If the Departments conclude a plan or issuer has not provided sufficient information to review the comparative analyses, the Appropriations Act provides that the Departments shall specify to the plan or issuer the information the plan or issuer must submit to be responsive to the request.

In instances where the Departments have reviewed the comparative analyses and any other materials submitted upon request from a plan or issuer and determined that the plan or issuer is not in compliance with MHPAEA, the Appropriations Act requires the plan or issuer to specify to the Departments the actions the plan or issuer will take to come into compliance. Specifically, the plan or issuer must submit additional comparative analyses that demonstrate compliance not later than 45 days after the initial determination of noncompliance. Following the 45-day corrective action period, if the Departments make a final determination that the plan or issuer is still not in compliance, not later than 7 days after such determination, the plan or issuer must notify all individuals enrolled in the plan or coverage that the coverage is determined to be noncompliant with MHPAEA. The Departments will also share findings of compliance and noncompliance with the State where the group health plan is located or where the issuer is licensed to do business. In addition, the Departments will comply with other laws applicable to their particular review processes.

Q6: May a participant, beneficiary, or enrollee (or their authorized representative), or state regulator request an NQTL analysis?

Yes. Under the Appropriations Act, plans and issuers must make available their respective comparative analyses of NQTLs and other applicable information to the applicable State authority upon request. The term "applicable State authority" means, with respect to a health insurance issuer in a State, the State insurance commissioner or an official or officials designated by the State to enforce the requirements of title XXVII of the Public Health Service (PHS) Act for the State involved with respect to the issuer.

Furthermore, as stated in previous guidance, participants and beneficiaries (or their authorized representatives) in ERISA-covered plans are entitled to comparative 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.[9] The types of

[9] ERISA section 104(b) and 29 CFR §§ 2590.712(d)(3), 2520.104b-1, 2560.503-1, and 2590.715-2719. See also FAQs about Affordable Care Act Implementation Part 31, Mental Health Parity Implementation, and Women's Health and Cancer Rights Act Implementation (Apr. 20, 2016), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-31.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-31_Final-4-20-16.pdf. See also MHPAEA Disclosure Template, available at

documents contemplated in previous guidance would include any analyses performed by the plan as to how the NQTL complies with MHPAEA. Therefore, for plans subject to ERISA, plans and issuers must make the comparative analyses and other applicable information required by the Appropriations Act available to participants, beneficiaries, and enrollees upon request. If a provider or other individual is acting as a patient's authorized representative, the provider or other authorized representative may request these documents.[10]

In addition, as stated in previous guidance, with respect to non-grandfathered group health plans and non-grandfathered group or individual health insurance coverage, claimants (or their authorized representative) have a right 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.[11] This right includes access to 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.[12] These documents would include any analyses performed by the plan or issuer as to how the NQTL complies with MHPAEA.

Q7: Will the Departments issue additional guidance on requirements that were added to MHPAEA by the Appropriations Act?

In light of the expeditious timeframes established under the Appropriations Act regarding comparative analyses of NQTLs, the Departments are issuing these FAQs to address several discrete issues. The Departments will engage with stakeholders to determine what additional guidance might be needed.

Q8: Are there specific NQTLs that the Departments intend to focus on when requesting comparative analyses from plans and issuers for purposes of review in accordance with the requirements of the Appropriations Act?

---

https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/mhpaea-disclosure-template.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/MHPAEA-Disclosure-Template-1.pdf.

[10] See 29 CFR 2560.503-1, which is also incorporated by reference in 26 CFR 54.9815-2719(b)(2)(i), 29 CFR 2590.715-2719(b)(2)(i), and 45 CFR 147.136(b)(2)(i).

[11] A document, 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.

[12] 29 CFR 2560.503-1, 26 CFR 54.9815-2719, 29 CFR 2590.715-2719, and 45 CFR 147.136.

To the extent that the Departments become aware of potential MHPAEA violations or complaints regarding noncompliance with MHPAEA that concern NQTLs, the Departments may request comparative analyses on the NQTLs that are the subject of the complaint or potential violation. For example, in the event that a complaint is received regarding prior authorization requirements for coverage of buprenorphine for the treatment of opioid use disorder, the Departments may request an NQTL comparative analysis for prior authorization requirements placed on prescription drugs. Additionally, the Appropriations Act provides that the Departments may also request NQTL comparative analyses in any other instance deemed appropriate.

In the near term, DOL expects to focus on the following NQTLs in its enforcement efforts:

1. Prior authorization requirements for in-network and out-of-network inpatient services;

2. Concurrent review for in-network and out-of-network inpatient and outpatient services;

3. Standards for provider admission to participate in a network, including reimbursement rates; and

4. Out-of-network reimbursement rates (plan methods for determining usual, customary, and reasonable charges).

Plans and issuers should also be prepared to make available a list of all other NQTLs for which they have prepared a comparative analysis and a general description of any documentation that exists regarding each analysis. In the context of these reviews, plans and issuers may be required to submit analyses for these additional NQTLs. Furthermore, an initial focus on the above four NQTLs by DOL does not in any way limit the Departments' or an applicable State authority's ability to request or review different or additional NQTL analyses for MHPAEA compliance. The Appropriations Act requires plans and issuers to perform and document comparative analyses for all NQTLs imposed.

Q9: Who can I contact if I have additional questions about the MHPAEA amendments included in the Appropriations Act that apply to group health plans and health insurance issuers?

If you have questions about the requirements of the Appropriations Act, or about MHPAEA in general, you may contact DOL for help at www.askebsa.dol.gov or 1-866-444-3272. You may also contact the HHS at marketconduct@cms.hhs.gov.

Paperwork Reduction Act of 1995

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520) and concurrently with this issuance, DOL and HHS are submitting an emergency request to the Office of Management and Budget (OMB) concerning the collections of information in this document.