Final Rules under the Mental Health Parity and Addiction Equity Act (MHPAEA)
Fact Sheet

On September 9, 2024, the U.S. Departments of Health and Human Services (HHS), Labor, and the Treasury (collectively, the Departments) released new final rules implementing MHPAEA. The final rules amend certain provisions of the existing MHPAEA regulations and add new regulations to set forth content requirements and timeframes for responding to requests for nonquantitative treatment limitation (NQTL) comparative analyses required under MHPAEA, as amended by the Consolidated Appropriations Act, 2021 (CAA, 2021). The final rules reflect and address the thousands of comments received from the public during the comment period on the proposed rules that were published on August 3, 2023. The Departments appreciate the feedback and insight received through this process on this critically important issue.

The United States of America continues to experience a mental health and substance use disorder crisis. In the almost 16 years since the enactment of MHPAEA, disparities in coverage between mental health and substance use disorder (MH/SUD) benefits and medical/surgical (M/S) benefits have persisted and grown. These final rules aim to further MHPAEA's fundamental purpose – to ensure that individuals in group health plans or group or individual health insurance coverage who seek treatment for covered MH conditions or SUDs do not face greater burdens on access to benefits for those conditions or disorders than they would face when seeking coverage for the treatment of a medical condition or a surgical procedure. These final rules are critical to addressing barriers to access to MH/SUD benefits.

Among other things, these final rules:

- Make clear that MHPAEA protects plan participants, beneficiaries, and enrollees from facing greater restrictions on access to MH/SUD benefits as compared to M/S benefits.
- Reinforce that health plans and issuers cannot use NQTLs that are more restrictive than the predominant NQTLs applied to substantially all M/S benefits in the same classification. Examples of NQTLs include prior authorization requirements and other medical management techniques, standards related to network composition, and methodologies to determine out-of-network reimbursement rates.
- Require plans and issuers to collect and evaluate data and take reasonable action, as necessary, to address material differences in access to MH/SUD benefits as compared to M/S benefits that result from application of NQTLs, where the relevant data suggest that the NQTL contributes to material differences in access.
- Codify the requirement in MHPAEA, as amended by the Consolidated Appropriations Act, 2021, that health plans and issuers conduct comparative analyses to measure the impact of NQTLs. This includes evaluating standards related to network composition, out-of-network reimbursement rates, and medical management and prior authorization NQTLs.
- Prohibit plans and issuers from using discriminatory information, evidence, sources, or standards that systematically disfavor or are specifically designed to disfavor access to MH/SUD benefits as compared to medical/surgical benefits when designing NQTLs.

- Implement the sunset provision for self-funded non-Federal governmental plan elections to opt out of compliance with MHPAEA.

The Departments anticipate that these final rules will improve network composition by making mental health and substance use disorder provider networks more robust, and making it easier for individuals seeking mental health and substance use disorder care to actually receive it by cutting red tape, with fewer and less restrictive prior authorization requirements and other medical management techniques to navigate. The final rules will also provide additional clarity and information needed for plans and issuers to meet their obligations under MHPAEA and for the Departments and States to enforce those obligations. The Departments intend to continue to provide guidance and compliance assistance materials in the coming months to assist plans and issuers in complying with MHPAEA and its implementing regulations, as well as informing participants, beneficiaries, and enrollees regarding their rights under MHPAEA.

Purpose and Meaning of Terms

The final rules add a purpose section to the regulations, consistent with the statute, which emphasizes that plans must not design or apply financial requirements and treatment limitations that impose a greater burden on access (that is, are more restrictive) to MH/SUD benefits under the plan than they impose on access to medical/surgical benefits in the same classification of benefits and note that the MHPAEA regulations should be interpreted in a manner consistent with the purpose section.

The final rules amend the definitions of the terms "medical/surgical benefits," "mental health benefits," and "substance use disorder benefits" by removing a reference to state guidelines.

The final rules continue to provide that any condition, disorder, or procedure defined by the plan or coverage as being or as not being a mental health (MH) condition, substance use disorder (SUD), medical condition, or surgical procedure must be defined consistent with generally recognized independent standards of current medical practice. For this purpose, a plan's or issuer's definition of whether a condition or disorder is a MH condition or SUD must follow the most current version of the International Classification of Diseases (ICD) or the Diagnostic and Statistical Manual of Mental Disorders (DSM). If generally recognized independent standards of current medical practice do not address how to treat a condition, disorder, or procedure, plans and issuers may define it in accordance with applicable Federal and State law.

Additionally, the final rules add new definitions for the following terms:

- "Evidentiary standards" are any evidence, sources, or standards that a plan or issuer considered or relied upon in designing or applying a factor with respect to an NQTL.
- "Factors" are all information, including processes and strategies (but not evidentiary standards), that a plan or issuer considered or relied upon to design an NQTL or to determine whether or how the NQTL applies to benefits under the plan or coverage.
- "Processes" are actions, steps, or procedures that a plan or issuer uses to *apply* an NQTL.

- "Strategies" are practices, methods, or internal metrics that a plan or issuer considers, reviews, or uses to *design* an NQTL.

The definition of each of these terms includes several examples in the final rules.

Requirements for NQTLs

Under the final rules, a plan or issuer may not impose any NQTL with respect to MH/SUD benefits in any classification that is more restrictive, as written or in operation, than the predominant NQTL that applies to substantially all medical/surgical (M/S) benefits in the same classification. For this purpose, a plan or issuer must satisfy two sets of requirements:

1) the design and application requirements and
2) the relevant data evaluation requirements.

The final rules do not require application of the mathematical tests to determine "substantially all" and "predominant" as had been set forth in the proposed rules.

Design and Application Requirements

The general rule of the design and application requirements requires an examination of the processes, strategies, evidentiary standards, and other factors used in designing and applying an NQTL to MH/SUD benefits in the classification to ensure they are comparable to, and are applied no more stringently than, those used in designing and applying the limitation with respect to M/S benefits in the same classification.

The final rules also prohibit the use of discriminatory factors and evidentiary standards to design an NQTL to be imposed on MH/SUD benefits. A factor or evidentiary standard is discriminatory if the information, evidence, sources, or standards on which it is based are biased or not objective in a manner that discriminates against MH/SUD benefits as compared to M/S benefits.

Biased or not objective

Whether information, evidence, sources, or standards are considered to be biased or not objective is based on all the relevant facts and circumstances and whether they systematically disfavor or are specifically designed to disfavor access to MH/SUD benefits as compared to M/S benefits. However, plans and issuers may take the steps necessary to correct, cure, or supplement anything that is biased or not objective.

Historical plan data or other historical information from a time when the plan or coverage was not subject to or was not in compliance with MHPAEA is generally biased or not objective, if the historical plan data or other historical information systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits, and the plan has not taken the steps necessary to correct, cure, or supplement the data or information.

Not biased and objective

Generally recognized independent professional medical or clinical standards and carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate MH/SUD benefits are not biased and are objective.

Relevant Data Evaluation Requirements

Plans and issuers must ensure, in operation, that an NQTL applicable to MH/SUD benefits in a classification is no more restrictive than the predominant NQTL applied to substantially all M/S benefits in the same classification. To do so, plans and issuers must collect and evaluate relevant data in a manner reasonably designed to assess the impact of the NQTL on relevant outcomes related to access to MH/SUD benefits and M/S benefits. Then, they must carefully consider the impact. For NQTLs related to network composition standards, a plan or issuer must collect and evaluate relevant data in a manner reasonably designed to assess the NQTLs' aggregate impact on relevant outcomes related to access to MH/SUD benefits and M/S benefits.

As the relevant data for any given NQTL will depend on the facts and circumstances, the final rules provide flexibility for plans and issuers to determine what should be collected and evaluated, as appropriate. The final rules list examples of relevant data for all NQTLs and additional relevant data for NQTLs related to network composition standards.

The Departments or applicable State authorities may also request other data in addition to what a plan or issuer determines to be relevant data for any particular NQTL included in their comparative analyses.

The final rules also provide guidance for how a plan or issuer should comply with the relevant data evaluation requirements when it newly imposes an NQTL for which relevant data is initially temporarily unavailable or when no data exist that can reasonably assess any relevant impact on access. However, the Departments expect there will be data available in almost all circumstances and that this guidance will be used only in very limited circumstances.

Material Differences and Reasonable Action

If the evaluated relevant data suggest that the NQTL contributes to material differences in access to MH/SUD benefits as compared to M/S benefits, that will be considered a strong indicator of a MHPAEA violation. Differences in access are material if, based on all relevant facts and circumstances, the difference in the data suggests that the NQTL is likely to have a negative impact on access to MH/SUD benefits as compared to M/S benefits.

However, differences in access to MH/SUD benefits are not treated as material if they are attributable to generally recognized independent professional medical or clinical standards or carefully circumscribed measures reasonably and appropriately designed to detect, prevent, or prove fraud and abuse. If material differences in access exist, the plan or issuer must take

reasonable action, as necessary, to address them to ensure compliance with MHPAEA in operation.

The final rules provide examples of possible reasonable actions that a plan or issuer could take to address any material differences in access for NQTLs related to network composition standards.

Effect of a Final Determination of Noncompliance

If a plan or issuer receives a final determination that an NQTL is not in compliance with the comparative analysis requirements, including because the plan or issuer has not submitted a sufficient comparative analysis to demonstrate compliance, the relevant Department may direct the plan or issuer to not impose the NQTL with respect to MH/SUD benefits unless and until the plan or issuer demonstrates compliance or takes appropriate action to remedy the violation.

Meaningful Benefits

If a plan or coverage provides any benefits for a MH condition or SUD in any benefits classification, the final rules state that it must provide meaningful benefits for that condition or disorder in every classification in which meaningful M/S benefits are provided. Whether the benefits provided are meaningful is determined in comparison to the benefits provided for M/S conditions in the same classification. Meaningful benefits require coverage of a core treatment for that condition or disorder in each classification in which the plan or coverage provides benefits for a core treatment for one or more medical conditions or surgical procedures.

Comparative Analysis Content Requirements

Plans and issuers that cover both M/S benefits and MH/SUD benefits and impose NQTLs on MH/SUD benefits must perform and document a comparative analysis of the design and application of each applicable NQTL. The final rules require the comparative analysis to contain, at a minimum, six content elements:

1. a description of the NQTL, including identification of benefits subject to the NQTL;
2. identification and definition of the factors and evidentiary standards used to design or apply the NQTL;
3. a description of how factors are used in the design or application of the NQTL;
4. a demonstration of comparability and stringency, as written;
5. a demonstration of comparability and stringency, in operation, including the required data, evaluation of that data, explanation of any material differences in access, and description of reasonable actions taken to address such differences; and
6. findings and conclusions.

Comparative Analysis Request and Review Process

The final rules set forth the steps the Departments will follow to request and review a plan's or issuer's comparative analysis of an NQTL.

1. After an initial request for a comparative analysis, the plan or issuer must submit it to the relevant Secretary within 10 business days (or an additional period of time specified by the relevant Secretary).
2. If the Secretary determines the comparative analysis is insufficient, the Secretary will specify the additional information necessary, which must be provided by the plan or issuer within 10 business days (or an additional period of time specified by the relevant Secretary).
3. If the Secretary makes an initial determination of noncompliance, the plan or issuer has 45 calendar days to specify the actions it will take to comply and provide additional comparative analyses.
4. If the Secretary makes a final determination of noncompliance, the plan or issuer must notify all participants, beneficiaries, and enrollees enrolled in the plan or coverage not later than 7 business days after the Secretary's determination. The final rules set forth specific content for this notice and require that a copy of the notice be provided to the Secretary and relevant service providers and fiduciaries.

Plans and issuers must make a copy of the comparative analysis available when requested by any applicable State authority, a participant, beneficiary, or enrollee who has received an adverse benefit determination related to MH/SUD benefits, and participants and beneficiaries in ERISA plans at any time.

Sunset of MHPAEA Opt-Out

In these final rules, HHS finalizes regulatory amendments to implement the sunset provision for self-funded non-Federal governmental plan elections to opt out of compliance with MHPAEA, as adopted in the Consolidated Appropriations Act, 2023.

Applicability Dates

The final rules generally apply to group health plans and group health insurance coverage on the first day of the first plan year beginning on or after January 1, 2025. However, the meaningful benefits standard, the prohibition on discriminatory factors and evidentiary standards, the relevant data evaluation requirements, and the related requirements in the provisions for comparative analyses apply on the first day of the first plan year beginning on or after January 1, 2026.

The final rules apply to health insurance issuers offering individual health insurance coverage for policy years beginning on or after January 1, 2026.

Until the applicability date, plans and issuers are required to continue to comply with the existing requirements, including the CAA, 2021 amendments to MHPAEA.