Federal Agencies Release Final MHPAEA Regulations: Navigating the Key Changes

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The U.S. Departments of Health and Human Services, Labor, and the Treasury (collectively, the Departments) released their much-anticipated final rules implementing the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), including a fact sheet summarizing key takeaways, on September 9, 2024. The final rules amend existing provisions and introduce new requirements for nonquantitative treatment limitation (NQTL) comparative analyses as mandated by the Consolidated Appropriations Act, 2021.

We previously covered how the proposed rules sought to enhance mental health coverage by expanding enforcement efforts and analyzed the impact the proposed rules would have on group health plan sponsors and fiduciaries.

Final Rules

After evaluating the more than 9,500 comments received, the Departments have largely finalized the rules as proposed, with some modifications based on the feedback provided. U.S. Department of Labor, Fact Sheet: Final Rules under the Mental Health Parity and Addiction Equity Act (MHPAEA). The Departments indicated that these changes aim to ensure that group health plan participants can access mental health and substance use disorder (MH/SUD) benefits without encountering more restrictions than those applied to medical and surgical (M/S) benefits, in line with the core objective of MHPAEA. Below we highlight the key changes:

Defined Terms

The final rules generally retain the newly defined terms that were proposed with the following clarifications:

- The proposed rules included definitions of "ICD" and "DSM" to ensure group health plans define MH/SUD benefits consistent with generally recognized independent standards of current medical practice. The proposed definitions also specified, for purposes of the definition, which version of the ICD or DSM is the most current as of a particular date. The final rules clarified that the current version is the version in effect 60 days after the date the final rules are published in the *Federal Register*, and any subsequent version will be considered the "most current" beginning on the first day of the plan year that is one year after the date that version is adopted or published (as applicable).

- The proposed rules introduced new definitions for terms related to NQTLs (i.e., "processes," "strategies," "evidentiary standards," and "factors"), addressing outcomes related to access for the first time. The final rules adjust the definition of "processes" slightly to better illustrate the operational application of an NQTL. For example, the Departments clarify that a group health plan's prior authorization and concurrent review "processes" include the procedures established by the plan to evaluate such requests.

Meaningful Benefits

Under the final rules, if a plan covers MH conditions or SUDs in any of the established six benefit classifications, it must also provide meaningful benefits for those conditions or disorders in all classifications where it offers meaningful benefits for M/S conditions. 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 that the plan cover a "core treatment" for the MH or SUD condition in each classification where core treatments are provided for medical or surgical conditions. Group health plans must offer benefits for a core treatment for each MH condition or SUD in each classification where the plan also covers core treatments for M/S conditions.

A "core treatment" is defined as a standard, widely recognized treatment or intervention based on current medical practice. If there is no core treatment for a MH condition or SUD in a given classification, the plan is not required to provide benefits for a core treatment for such condition or disorder in that classification, but the plan must still provide benefits for such conditions or disorders in those classifications where M/S benefits are provided.

Consistent with earlier MHPAEA FAQ guidance issued under the 21st Century Cures Act, the final rules include the following examples of core treatments:

- ABA therapy to treat autism spectrum disorder
- Nutritional counseling to treat eating disorders
- Counseling and behavioral therapies and medications to treat opioid use disorder

Nonquantitative Treatment Limitations

Group health plans cannot impose NQTLs on MH/SUD benefits that are more restrictive, as written and in operation, than the predominant NQTL applied to most M/S benefits in the same classification. The proposed rules outlined a three-prong test to assess whether NQTLs are more restrictive and specified two exceptions for NQTLs based on independent medical standards or fraud prevention measures. The final rules eliminate the mathematical "predominant/substantially all" test for NQTLs that the proposed rules included as part of the "no more restrictive" prong. Instead, an NQTL is considered more restrictive if it fails to meet specific requirements related to its design and application and/or does not meet the relevant data evaluation requirements. If a plan does not comply with these requirements, it is deemed to violate MHPAEA and the NQTL cannot be applied to MH/SUD benefits.

Design and Application Requirements

Group health plans must ensure that their processes, strategies, evidentiary standards, and factors for MH/SUD NQTLs are comparable to, and not more stringent than, those NQTLs used for M/S benefits. Under the final rules, plans are prohibited from using discriminatory factors or evidentiary standards in designing their NQTLs. "Factors" and "evidentiary standards" are considered discriminatory if, based on the relevant facts and circumstances, they are based on biased or nonobjective information that systematically disfavor MH/SUD as compared to M/S benefits.

Relevant facts and circumstances include the reliability of its source, the independence of the data, the methods used to select and apply the information, and any safeguards against biased data. Historical plan data from periods when the plan was not subject to MHPAEA or was noncompliant are considered biased against MH/SUD benefits if they systematically disadvantage these benefits compared to M/S benefits unless and until corrective measures have been taken. However, generally accepted medical standards and fraud prevention measures are exempt from being considered biased if they comply with other requirements.

Relevant Data Evaluation Requirements

To ensure that NQTLs for MH/SUD benefits are not more restrictive than those for M/S benefits in operation, group health plans must gather and evaluate relevant data to ensure that access to mental MH/SUD benefits is not unduly restricted compared with M/S benefits. Material differences in access indicate potential noncompliance, and plans must document and address these differences to ensure fairness in treatment limitations.

Relevant data may include claims denials and network composition metrics such as provider rates and network adequacy. If data is initially unavailable, plans must provide a detailed explanation of the gap in their comparative analysis (see below) and outline when and how data will be collected and analyzed. Once data becomes available, plans must promptly comply with the data evaluation requirements. If data shows significant differences in access

between MH/SUD and M/S benefits, plans must take action to address these disparities and document their efforts.

For NQTLs related to network composition, plans should assess the overall impact on access and consider actions such as recruiting more providers, expanding telehealth, assisting beneficiaries in finding providers and ensuring accurate provider directories.

Comparative Analysis

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 generally retain the six content elements that were proposed, except that the fifth content element requiring that the comparative analysis demonstrate comparability and stringency in operation has been modified as follows:

- The comparative analysis must assess whether, in operation, NQTLs applied to MH/SUD benefits are comparable to and not more stringent than those applied to M/S benefits, and include explanations of the methodology, data, and criteria used in this evaluation as well as detailed accounts of any data gaps and their resolution.
- The comparative analysis must identify and document the relevant data collected, how it was evaluated, and the outcomes resulting from applying NQTLs to both MH/SUD and M/S benefits.
- The comparative analysis must provide justifications for any observed differences in access, explaining whether they are due to the NQTL itself or other factors beyond the plan's control.

Perhaps one of the more significant changes the final rules made is that the plan fiduciaries are only required to certify that they have carefully selected qualified service providers to conduct and document an NQTL comparative analysis and have satisfied their duty to monitor these service providers to ensure compliance with applicable laws and ERISA regulations. The proposed rules would have required the plan fiduciaries to confirm they found the comparative analysis to be in compliance with all of the content requirements.

Additionally, the rules allow for intervention by the Departments or state authorities if a plan or issuer is found noncompliant based on the comparative analysis review process.

Plan sponsors should ensure that their group health plan comparative analyses are ready in the event of a request from the Departments and/or a participant (participant requests are subject to ERISA disclosure rules). The final rules require that plan sponsors provide their comparative analyses to the Departments within 10 business days upon request. If the comparative analyses are found to be insufficient, the Departments will give the plan sponsor 45 days to make corrections.

The potential consequences of failing to comply or receiving a final determination of noncompliance from the Departments may be significant for plan sponsors, including, for instance, the Departments requiring the group health plan to remove the NQTL with respect to the MH/SUD benefits until such time that the plan demonstrates compliance with MHPAEA or takes the appropriate steps to correct the violation.

What Comes Next?

The final rules generally apply to group health plans beginning on the first day of the plan year beginning on or after January 1, 2025 (i.e., January 1, 2025, for calendar year plans). However, the standards for meaningful benefits, prohibition on discriminatory factors, and data evaluation requirements will take effect on the first day of the plan year beginning on or after January 1, 2026 (i.e., January 1, 2026, for calendar year plans).

The Departments also plan to provide further guidance and compliance assistance to help health plans and issuers meet these requirements and inform participants about their rights under MHPAEA. In the interim, group health plans should continue to follow the existing requirements, including those the comparative analysis requirements enacted under the Consolidated Appropriations Act.

It should be noted that MHPAEA compliance has always centered around methodologies and strategies, demonstrating that the medical management standards imposed on MH/SUD benefits are no more restrictive than what is imposed on M/S benefits. MHPAEA compliance has never been about coverage mandates, and self-insured group health plans have no obligation to cover any mental health services if they choose not to.

In these final rules, the Departments may have gone a step too far by mandating meaningful benefits and outcome-driven data analyses. These components of the final rules may be vulnerable to challenge particularly considering the US Supreme Court's decision in *Loper Bright*, which overturned the Chevron doctrine deferring to regulatory interpretations of law. As a result, these final regulations will likely not be the final chapter in MHPAEA compliance.

We will continue to monitor the developments in this area, particularly any new or pending litigation. If you wish to receive the upcoming analysis, subscribe to our ML BeneBits mailing list.

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- Mental Health Parity and Addiction Equity Act Compliance for Employer Health Plans

State Law Surveys & Regulatory Trackers

- Employee Benefits & Executive Compensation Key Legal Developments Tracker (Current)

Statutes & Regulations

- 89 Fed. Reg. __ (unpublished version)
- US Department of Labor, Fact Sheet: Final Rules under the Mental Health Parity and Addiction Equity Act (MHPAEA)

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