

BLOG



SEPTEMBER 27, 2024

Earlier this month, the U.S. Departments of Labor (the DOL), Health and Human Services (HHS), and Treasury (the Departments) released the long-awaited Mental Health Parity and Addiction Equity Act (MHPAEA) final rule (the Final Rule). The Final Rule walked back a few of the more burdensome and confusing requirements of the <u>Proposed Rule</u>, including the proposed mathematical "substantially all" test, the network composition safe harbor (guidance about which will be forthcoming), and the fiduciary compliance attestation. However, plans will still need to make substantial changes to their nonquantitative treatment limitation (NQTL) analyses going forward. Additionally, the Final Rule indicates that network composition will be a major enforcement priority for the Departments in the coming years.

Under the Final Rule, the following requirements must be met for an NQTL to apply to mental health and substance abuse disorder (MH/SUD) benefits:

Design and Application Requirements: Plans and issuers cannot use information, sources, or standards to design and apply an NQTL if the information, sources, or standards are biased or not objective. Generally recognized independent professional medical or clinical standards and reasonably and appropriately designed measures to detect or prevent fraud and abuse are considered objective. However, historical plan data from before the plan complied with or was subject to the MHPAEA would be considered biased against MH/SUD benefits unless supplemented or corrected.

Relevant Data Evaluation Requirements: Plans and issuers must collect and evaluate relevant data in a manner reasonably designed to assess the impact of an NQTL on access to MH/SUD benefits and medical or surgical (M/S) benefits. While the Departments declined to provide an exhaustive list of the types of data that plans should collect, they listed several examples, such as in-network and out-of-network utilization rates, claims denial rates, network adequacy metrics (such as time and distance data and data on providers accepting new patients), and provider reimbursement rates as compared to a benchmark. The Departments also indicated that the MHPAEA Self-Compliance Tool will be updated in the near future to provide additional information.

Plans and issuers must also take reasonable action, and document such action, to the extent necessary to address any material differences in access revealed by the relevant data. Material differences in outcomes data will be seen as a "strong indicator" of noncompliance. The Final Rule removed language under which a material difference in outcomes data for network composition would have automatically constituted a MHPAEA violation. However, the Departments specified that plans and issuers must be prepared to explain why the material differences exist. If differences in network composition are explained by citing MH/SUD provider shortages, evidence and analysis leading to that conclusion should be provided, and plans and issuers should document steps they have taken to mitigate the effect of those shortages, including increasing provider compensation, streamlining credentialing processes, outreach to out-of-network providers, and expanding access to telehealth. The Final Rule does not define how a plan or issuer should determine whether differences in outcomes data are "material."

NQTL Comparative Analysis Requirements: The Final Rule provides six content elements that must be present in an NQTL comparative analysis, as well as some further detail on what each content element should include. The six elements described in the Final Rule are similar to the content requirements included in previous guidance released by the Departments, and are:

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.

Plans subject to ERISA must provide a copy of their NQTL analyses to any applicable state authority, participant, beneficiary, or enrollee within 30 days upon the individual's request and upon request to any individual who has received an adverse claim decision.

Defining Key Terms: The Final Rule provides clarification on what constitutes an "evidentiary standard," "factor," "process," or "strategy," as well as the differences between these terms. Importantly, the Final Rule requires plans and issuers to define whether a condition is a MH/SUD condition or M/S condition according to the most current version of the *International Classification of Diseases (ICD)* or *Diagnostic and Statistical Manual of Mental Disorders (DSM*).

Meaningful Benefits Standard: Under the Final Rule, if a plan or issuer provides any benefits for a MH/SUD condition in any benefits category, it must provide "meaningful" benefits for that condition or disorder in every classification in which meaningful M/S benefits are provided in that same category. Whether the MH/SUD benefits provided are meaningful is determined in comparison to the benefits provided for M/S conditions in the same classification. Under this standard, plans must cover one or more "core" treatments (as determined by generally accepted standards of care) for a covered MH/SUD condition in every benefits category in which the plan provides benefits for a core treatment for one or more M/S condition. The Final Rule gives several examples of core treatments and compliance with the meaningful benefits standard, including examples in which applied behavior analysis (ABA) therapy is a core treatment for autism spectrum disorder and in which nutrition counseling is a core treatment for eating disorders.

Fiduciary Certification: The Final Rule walked back the requirement in the Proposed Rule that plan fiduciaries certify compliance with the NQTL content requirements. Instead, the Final Rule requires fiduciaries to certify that they have engaged in a prudent process, including the selection and monitoring of any vendor who helped document the NQTL comparative analysis.

Working With Third-Party Administrators: Numerous commenters raised concerns about working with third-party administrators (TPAs) in response to the Proposed Rule, emphasizing that plan sponsors have sometimes struggled to get relevant data from their TPA and that the TPA is the entity responsible for designing and applying NQTLs. The Departments declined to provide specific relief for self-funded plans that use TPAs. Instead, they suggested (but did not require) that plans include provisions in their contracts with TPAs, similar to Business Associate Agreements under the Health Insurance Portability and Accountability Act, that require the TPA to cooperate with the plan

sponsor. They also emphasized that, to the extent a TPA exercises discretionary authority or responsibility in the administration of an ERISA-covered health plan, the DOL generally considers that TPA to be a fiduciary.

The Final Rule helpfully clarified that plans and issuers are not prohibited from performing and documenting a comparative analysis at the issuer or TPA level. However, to the extent that relevant data exists at the plan level and measures access to MH/SUD benefits in a different manner from data at the issuer or TPA level, the comparative analysis must account for that data.

Consequences of Noncompliance: The Final Rule allows the DOL and HHS to prohibit a plan or issuer from imposing an NQTL if the relevant Department has issued a final determination of noncompliance.

Additionally, if a plan receives a final determination of noncompliance, it must provide a stand-alone notice to participants (and, for ERISA plans, relevant service providers and fiduciaries) within seven (7) business days.

Potential Challenges Under New Loper Bright Standard: After the U.S. Supreme Court's decision in *Loper Bright Enterprises v. Raimondo* overturning the *Chevron* doctrine, agency interpretations of ambiguous statutes are no longer accorded the same deference and are more vulnerable to legal challenges. In this new regulatory environment, we can expect legal challenges to the Final Rule. The ERISA Industry Committee has already spoken out criticizing the Final Rule and said it would consider "all possibilities . . . up to and including litigation" to protect plan sponsors who may be negatively affected by the Final Rule.

Effective Date: The Final Rule is generally effective for group health insurance plans and issuers on the first day of the first plan year beginning on or after January 1, 2025. Certain requirements—such as the meaningful benefits standard, the design and application requirement to use unbiased information, the relevant data evaluation-requirements, and the guidance on comparative analysis design and scope—have a delayed effective date of the first day of the first plan year beginning on or after January 1, 2026.

The Department of Labor Fact Sheet is available here.

Please contact your Winston & Strawn attorneys for additional information.

Kristine Lofquist, paralegal, co-authored this blog. 6 Min Read

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