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Mental Health Parity: Federal Departments of Labor, Treasury, and Health Release Landmark Regulations

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On September 9, 2024, the three federal departments responsible for regulating the health care benefits for more than 175 million Americans with private health insurance issued a final rule (the "Final Rule") implementing amendments made by the Consolidated Appropriations Act, 2021 (CAA), to the 2008 Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act (MHPAEA).[1]

These federal departments—the U.S. Department of Labor (DOL), the U.S. Department of the Treasury, and the U.S. Department of Health and Human Services (collectively, the "Departments")—have been working on the regulations since 2021 and have spent more than a year processing thousands of comments they received in response to their Notice of Proposed Rulemaking released on July 23, 2023 (NPRM).[2]

The Final Rule applies to nearly all forms of commercial health benefits and insurance in the United States, including employers and other entities that offer self-funded group health plans; commercial insurance in the individual, small, and large-group markets; and, now through the Final Rule, all non-federal government-sponsored plans as well (collectively, "Health Plans"). Starting upon the key enforcement date of January 1, 2026,[3] Health Plans will need to have a significant body of new documentation ready to provide to regulators, beneficiaries, and their authorized representatives upon request. The MHPAEA compliance documentation under the Final Rule builds upon the requirements being imposed under existing law and guidance. The documentation will need to prove, to the satisfaction of the applicable regulator, that the Health Plan covers benefits in a manner that does not discriminate against beneficiaries with mental health or substance use disorders (MH/SUDs).

Background to the Final Rule

Enacted in 2008, MHPAEA built upon the earlier Mental Health Parity Act of 1995 (MHPA)[4] by expanding the scope of MHPA's anti-discrimination framework to include SUDs. MHPAEA is

enforced across insurance markets by the applicable primary regulatory authority, such as:

- the DOL for self-funded group health plans,
- state Departments of Insurance for fully-insured commercial group policies (and the DOL to the extent such groups are also covered by the Employee Retirement Income Security Act (ERISA)),
- the Center for Consumer Information and Insurance Oversight for individual policies on federally-facilitated marketplaces and federal enforcement states, and
- the Centers for Medicare & Medicaid Services (CMS) and state Medicaid agencies for Medicaid managed care and the Children's Health Insurance Program (under a different set of regulations from the Final Rule at 42 CFR 438, which were not changed through the current rulemaking process).

The Departments issued the first commercial market final regulations for MHPAEA in 2013 (the "2013 Final Regulations"), which specified that the parity requirements apply to financial requirements, quantitative treatment limitations, and non-quantitative treatment limits (NQTLs), which are generally non-numerical requirements that limit the scope or duration of benefits, such as benefit exclusions, prior authorization requirements, step therapy requirements, and standards for provider admission to participate in a network. Since 2013, the Departments have steadily issued interpretive guidance[5] and increased audit and enforcement activity related to MHPAEA.[6]

Congress made material amendments to MHPAEA through the CAA, adding a provision that formalized and expanded upon the NQTL requirements from the 2013 Final Regulations and earlier sub-regulatory guidance and required Health Plans to perform and document NQTL comparative analyses and provide them to the Departments or to an applicable state authority upon request.[7] Since the passage of the CAA amendments, federal and state insurance regulators have continued to expand their oversight and enforcement of MHPAEA.[8]

The Final Rule

The NPRM was expected to align closely with the CAA and formalize in regulatory text much of the sub-regulatory guidance that had been issued since 2013. However, it instead included a number of highly intricate and completely new requirements for MHPAEA's anti-discrimination tests, which garnered an enormous number of substantive comments from stakeholders. The Departments elected **not** to include many of the most complicated and controversial proposals in the Final Rule. Key proposals that were not adopted in the Final Rule include:

- a requirement to apply a version of the quantitative parity test (also known as the "substantially-all and predominant test") that is used under existing regulations only for cost sharing and quantitative treatment limits (like day/hour/visit benefit caps) to NQTLs, such as medical necessity criteria development, utilization management, provider network contracting, and other medical and network management activities;
- a complex set of exceptions to the quantitative NQTL test that only applied to managed care functions pursued for the purpose of clinical standards or fraud, waste, and abuse; and
- a "special rule" for provider network contracting NQTL-types that would deem NQTLs to be presumptively non-compliant if outcomes data for the NQTL demonstrated a "material difference" in the data for MH/SUD services compared to medical/surgical (M/S) services.

However, the Final Rule did finalize a number of significant changes to MHPAEA requirements compared to current policy, including:

- requiring Health Plans to:
    - collect and evaluate relevant data on the outcomes of each NQTL that is applied to MH/SUD benefits, including major managed care operations like utilization management, network contracting, and provider reimbursement;
    - undertake continuous comparative monitoring of outcomes for MH/SUD and M/S services; and
    - take "reasonable actions" whenever the data demonstrates a "material difference" between MH/SUD and M/S outcomes;
- defining intellectual and neurodevelopmental disorders, including dementia and autism spectrum disorder, as MH conditions for the purposes of MHPAEA, even if applicable state laws define these conditions as M/S conditions;
- requiring Health Plans to provide "meaningful benefits" for all covered MH/SUD conditions in each of MHPAEA's benefit classifications (inpatient (in and out-of-network), outpatient (in and out-of-network), emergency, and prescription drugs);[9] and
- authorizing federal and state regulators to prohibit the Health Plan from applying an NQTL if the plan's comparative analysis does not adequately demonstrate compliance.

In addition, the Final Rule includes new regulatory sections that represent technical clarifications to elements of the NQTL testing process that are already in use under the CAA and existing sub-regulatory guidance. For instance, the Final Rule includes sections that (i) establish a prohibition on discriminatory or biased "factors and evidentiary standards," which are terms addressing the reasons and justifications the Health Plan staff may rely upon in the design and implementation of an NQTL, and (ii) clarify structure requirements in the provisions for comparative analyses.

Further Guidance Forthcoming on "Relevant Data"

Among the changes adopted in the Final Rule, the requirement that Health Plans collect and monitor a broader range of "relevant data" on the outcomes of the implementation of each NQTL type in each classification and compare it between MH/SUD and M/S benefits may be the most significant. How significant this requirement will be depends on the next steps the Departments take in providing further guidance. The Final Rule does not identify the specific measures Health Plans are required to use for any specific NQTL type, and it similarly does not provide technical specifications for any measure types. However, the Departments are considering certain specific measures and are likely to provide further guidance on them in the near future.

The NPRM was accompanied by Technical Release 2023-01P, which outlined the Departments' thinking on technical measures for MH/SUD provider access, namely that they intend to use them for the purpose of evaluating whether access to MH/SUD providers is lower than for M/S providers. As noted above, the Final Rule did not adopt the "special rule" that would have deemed that any "material difference" between access (as defined by those measures) for MH/SUD and M/S services would be a *per se* parity violation for NQTLs related to network composition (including reimbursement methodologies). However, the Final Rule indicates that the Departments are still reviewing the feedback they received in response to the Technical Release 2023-01P and anticipate issuing further technical guidance on the "relevant data" element of the Final Rule.

Enforcement Dates

The statutory provisions added to MHPAEA by the CAA, 2021, were self-implementing and have been in effect since February 10, 2021. They include the underlying requirements to complete and maintain comparability and stringency analyses for all NQTL types and to make them available upon

request. The new requirements of the Final Rule will go into effect on different dates depending on the requirement. The most complex new components of the Final Rule will apply to Health Plans on the first day of the first plan year beginning on or after January 1, 2026, including the meaningful benefits standard, the prohibition on discriminatory factors and evidentiary standards, the relevant data evaluation requirements, and guidance regarding the design and scope of the comparative analyses. All other requirements, including the change to the definition for MH conditions to include intellectual and cognitive conditions, apply earlier, on the first day of the first plan year, beginning on or after January 1, 2025.

Conclusion

After the CAA was signed into law on December 27, 2020, stakeholders eagerly awaited the adoption of new regulations to clarify and formalize the sub-regulatory guidance issued between 2013 and 2021. Nearly four years later, the Final Rule has now finally arrived and will likely lead to another round of federal sub-regulatory guidance (especially on relevant data requirements) and legislative, regulatory, and enforcement activity from states as they seek to catch up and align with the new federal requirements they are tasked with enforcing in the fully-insured market. The Final Rule adds new requirements to what was already one of the most complex regulatory regimes in managed care and will require Health Plans across the industry to adopt new operational and compliance frameworks in the performance of their most basic managed care functions.

At its heart, MHPAEA, as outlined in the Final Rule, imposes a burden of presumptive discrimination on all managed care functions and requires Health Plans to prepare **and maintain** parity compliance documentation that is ready to rebut that presumption at any time upon request. MHPAEA remains the biggest national-level cross-market lever for MH/SUD financing policy, and the Final Rule is a clear indication that at least federal regulators intend to keep using it until MH/SUD treatments are equally accessible as M/S treatments for all patients.

ENDNOTES

[1] Requirements Related to the Mental Health Parity and Addiction Equity Act [not yet published in the *Federal Regulations]*.

[2] Notice of Proposed Rulemaking CMS-9902-P Requirements Related to the Mental Health Parity and Addiction Equity Act, 88 FR 51552.

[3] Some of the less complex requirements go into effect earlier, on January 1, 2025.

[4] The Mental Health Parity Act of 1996 (MHPA) Pub. L. No. 104-204, Tit. VII, § § 701-702, 100 Stat. 2874, 2944-50 (Sept. 26, 1996) prohibited the imposition of annual or lifetime dollar limits on MH benefits that were more restrictive than the annual or lifetime dollar benefits applied to medical/surgical benefits in large employer-sponsored plans. However, it did not apply to SUDs, other employer types, or insurance issuers, and it did not restrict the use of discriminatory quantitative benefit limits or cost sharing, or to non-quantitative limits like categorical benefit exclusions for MH/SUD services.

[5] The Departments have jointly issued 15 sets of FAQs with 96 questions, eight enforcement fact sheets, six compliance assistance tools and templates, seven reports to Congress, six press releases, and seven consumer publications.

[6] *See* MHPAEA Comparative Analysis Report to Congress, July 2023.

[7] Code section 9812(a)(8)(A), ERISA section 712(a)(8)(A), and PHS Act section 2726(a)(8)(A).

[8] *See* MHPAEA Comparative Analysis Report to Congress, July 2023.

[9] The Final Rule defines “meaningful benefits” as being, at minimum, at least one standard treatment or course of treatment, therapy, service, or intervention indicated by generally recognized independent standards of current medical practice.

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