



Alert: Sweeping mental health parity rules add new requirements

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<u>Final rules</u> implementing the Mental Health Parity and Addiction Equity Act (MHPAEA) may require employer action before Jan. 1, 2025. The final rules amend certain provisions of existing MHPAEA regulations and add new requirements for the comparative analyses of nonquantitative treatment limitations (NQTLs) required by the <u>Consolidated Appropriations Act, 2021</u> (Pub. L. No. 116-260). Released by the departments of Health and Human Services (HHS), Labor, and Treasury, the final rules are generally effective for plan years beginning on or after Jan. 1, 2025, with select provisions taking effect one year later. Changes to existing parity standards that strive to reduce barriers to mental health and substance use disorder (MH/SUD) services by focusing on benefit coverage and network adequacy take effect for plan years beginning on or after Jan. 1, 2026. Most content requirements for NQTL comparative analyses — including certification by a plan fiduciary — apply for plan years beginning on or after Jan. 1, 2025. Although litigation challenging these rules is expected, employers sponsoring self-funded plans should consider acting before the 2025 plan year to review and revise their NQTL comparative analyses and identify the appropriate fiduciary to complete the certification.

Background

Since 2009, MHPAEA has required self-funded and fully insured group health plans that cover MH/SUD benefits to do so in parity with covered medical and surgical (M/S) benefits. MHPAEA generally prohibits financial and other quantitative limits as well as NQTLs like preauthorization on MH/SUD benefits that are more restrictive than what are imposed on M/S benefits.

The initial <u>2010 interim final rules</u> identify six benefit classifications and require separately measuring parity within each classification. The six benefit classifications are:

- · Inpatient, in-network benefits
- Inpatient, out-of-network benefits
- Outpatient, in-network benefits
- Outpatient, out-of-network benefits
- Emergency benefits
- · Prescription drug benefits

Retiree-only plans, excepted benefits and self-funded plans sponsored by small employers — generally 50 or fewer employees, although a few states have <u>expanded</u> the definition to include employers with 100 or fewer employees — are exempt from MHPAEA's requirements.

Financial and other quantitative limits. Financial and other quantitative limits (e.g., deductibles, copays, coinsurance, out-of-pocket limits, and annual or lifetime limits on treatment days or visits) for MH/SUD benefits are subject to mathematical testing using plan-level data. First outlined in the 2010 interim final rules, this testing must confirm these limits on MH/SUD benefits are no more restrictive than the predominant requirements that apply to substantially all M/S benefits in a classification.

NQTLs. No NQTL (e.g., medical-management standards, formulary or network tiers, and provider reimbursement criteria) can be imposed on MH/SUD benefits in a classification, unless the processes, strategies, evidentiary standards, or other factors used to design and apply the NQTL under the plan's written terms and actual operations are comparable to and applied no more stringently than those used for M/S benefits in the same classification. The <u>2010 interim final rules</u> and <u>2013 final rules</u> provided an illustrative, nonexhaustive list of NQTLs and examples of noncompliance, but the rules did not outline what was necessary to demonstrate compliance. Subregulatory FAQ guidance (<u>Part 31</u>, <u>Part 34</u>, <u>Part 38</u> and <u>Part 39</u>) indicated group health plans must conduct, document and disclose on request an analysis of NQTL compliance with MHPAEA, but the guidance lacked specifics.

Written comparative analysis. The Consolidated Appropriations Act, 2021 (2021 CAA, <u>Pub. L. No. 116-260</u>) formalized the requirement for health plans to complete and document a comparative analysis of the design and application of NQTLs to demonstrate parity between MH/SUD and M/S benefits in each of the six classifications (<u>Section 203 of Title II of Division BB</u>). Since Feb. 10, 2021, plans have had to make the written analysis available to the departments on request. Although <u>FAQs Part 45</u> provided insight into the departments' expectations for health plan compliance, plans struggled to understand how to meet the 2021 CAA's written analysis requirement.

2024 final rules. The latest <u>final rules</u> amend existing parity regulations to:

Establish a meaningful benefit standard for MH/SUD coverage

- Prohibit group health plans from using NQTLs that place greater restrictions on access to MH/SUD benefits as compared to M/S benefits
- Formally adopt content requirements for NQTL comparative analyses
- Specify comparative analysis disclosure requirements the departments, plan participants and beneficiaries
- Clarify a number of important terms related to MH/SUD benefits and establishing parity with respect to NQTLs

Lastly, the final rules reflect the sunset provision for the self-funded nonfederal government plan MHPAEA compliance opt-out adopted in the Consolidated Appropriations Act, 2023 (Section 1321 of Pub. L. No. 117-328) No opt-outs were allowed for self-funded state and local government employer plans after Dec. 29, 2022, and any opt-out elections that expired on or after June 27, 2023, couldn't be renewed. As a result, all state and local government plans (other than retiree and small-employer plans) should be in compliance with MHPAEA. For more information on this topic, see MHPAEA opt-out ends for nonfederal government plans (June 29, 2023).

Meaningful benefits standard

The existing MHPAEA regulations require a group health plan that offers MH/SUD benefits in any one of the six benefit classifications to provide MH/SUD benefits in all classifications. Effective for plan years starting on or after Jan. 1, 2026, the final rules take this one step further and require a group health plan that offers any benefits for a MH/SUD in any classification to provide meaningful benefits for that MH/SUD in every classification in which M/S benefits are provided.

Whether benefits are meaningful is determined by comparing the benefits provided for M/S conditions in the same classification. At a minimum, the plan must cover benefits for the MH/SUD condition in each classification in which the plan covers M/S benefits. This requires covering a core treatment for a MH/SUD condition (if one exists) in each classification in which the plan covers a core treatment for one or more M/S conditions or procedures. Under the final rules, a core treatment is "a standard treatment or course of treatment, therapy, service or intervention indicated by generally recognized independent standards of current medical practice."

The final rules provide several examples, such as a group health plan that covers outpatient, in-network treatment for autism spectrum disorder (ASD) and limits ASD services in the outpatient, out-of-network classification to developmental screenings. This plan fails to provide meaningful benefits if the plan covers the full range of outpatient, out-of-network treatments for M/S procedures.

New standards for NQTLs

To impose an NQTL on MH/SUD benefits, a group health plan must satisfy two new standards in the final rules: the design and application requirements and the outcomes data evaluation. The final rules

omit a third test in the <u>proposed rules</u> that would have required mathematical testing of NQTLs similar to the testing conducted on quantitative and financial limits.

Design and application requirements. The final rules prohibit group health plans from imposing an NQTL on MH/SUD benefits unless the processes, strategies, evidentiary standards, or other factors used to design and apply the NQTL are comparable to and applied no more stringently than those for designing and applying the limit to M/S benefits in the same classification. While this prohibition is not new, beginning with the plan year starting on or after Jan. 1, 2026, the final rules ban the use of *discriminatory* factors and evidentiary standards. The final rules explain that factors and evidentiary standards are discriminatory if they rely on information, evidence, sources, or standards that are biased or not objective in a manner that discriminates against MH/SUD benefits. Standards are biased or not objective if, based on the facts and circumstances, they disfavor access to MH/SUD benefits as compared to M/S benefits (systematically or by design).

Outcomes data evaluation. For plan years starting on or after Jan. 1, 2026, group health plans must collect and evaluate relevant data to assess an NQTL's impact on outcomes related to MH/SUD benefit access. This assessment should ensure that the NQTL is no more restrictive in operation than the predominant NQTL applied to M/S benefits in the same classification. Outcomes data suggesting that the NQTL contributes to material differences in access — in other words, a difference in the data suggesting the NQTL "is likely to have a negative impact on access" to MH/SUD benefits — is considered "a strong indicator" of a MHPAEA violation and the plan must take reasonable actions to address the differences. The final rules give plans some flexibility to determine what relevant data to collect and provide illustrative examples (for example, the number and percentage of claims denials) rather than a prescriptive list. The departments may specify in future guidance the type, form, and manner of collection and evaluation for the data required.

Network composition. Special provisions apply to NQTLs related to network composition. The final rules specify that relevant data for these NQTLs could include data reflecting utilization rates (in and out of network), provider claim submissions, time and distance, providers accepting new patients, and provider reimbursement rates. The data collected must be analyzed to assess aggregate impact of all network composition NQTLs on access to MH/SUD benefits. The final rules do not include a proposal that would have considered *any* material differences in access to in-network MH/SUD benefits a MHPAEA violation. Instead, the final rules list reasonable actions a plan could take, such as recruiting additional providers, expanding telehealth to mitigate geographic shortages, helping enrollees find in-network providers and updating provider directories.

No categorical exceptions. The proposed rules would have provided limited exceptions to some of the NQTL requirements for NQTLs that are consistent with independent, professional medical or clinical standards, or narrowly tailored and reasonably designed to deter fraud, waste, and abuse, while minimizing impact on access to MH/SUD benefits. The final rules omit these proposed exceptions but explain how group health plans in designing and applying NQTLs should analyze and account for independent, professional medical or clinical standards and measures to deter fraud and abuse. In particular, differences in benefit access due to NQTLs based on these standards or measures are not

considered material. Further, subject to certain conditions, these standards or measures could be considered a nondiscriminatory factor for purposes of the design and application standard.

The final rules have no safe harbor for group health plans meeting specific network composition standards, although the departments had requested comments about this topic.

Comparative analysis

The final rules outline a six-part NQTL comparative analysis framework that formalizes and expands prior subregulatory guidance (<u>FAQs Part 45</u>). A new requirement is to obtain and evaluate operational data to demonstrate that an NQTL doesn't impede access to MH/SUD benefits or otherwise violate MHPAEA. In addition, when material differences in access exist, group health plans now must demonstrate why those differences don't present a parity violation or list the actions taken to mitigate those differences. A plan fiduciary certification must accompany the written comparative analysis.

Effective dates. The final rules for the comparative analysis generally take effect for plan years beginning on or after Jan. 1, 2025 (including the fiduciary certification). However, the requirements related to plan data collection and analysis and any efforts to address material differences in benefit access apply for plan years beginning on or after Jan. 1, 2026. The departments note that the requirement to perform and document an NQTL comparative analysis has applied to group health plans since 2021, irrespective of whether a plan receives a request from the departments, an applicable state authority, or a plan participant or beneficiary.

Framework. Group health plans 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 NQTL, illustrating parity across each classification. The written comparative analysis must contain, at a minimum, the following six content elements:

- 1. Description of each applicable NQTL and benefits subject to it
- 2. Identification and definition of the factors and evidentiary standards used to design and/or apply each NQTL
- 3. Description of how factors are used in the design and/or application of each NQTL
- 4. Demonstration that, as written, the NQTL for the MH/SUD benefits is comparable to and no more stringent than it is for the M/S benefits
- 5. Demonstration that in operation, the NQTL for the MH/SUD benefits is comparable to and no more stringent than it is for the M/S benefits (this includes showing that the required data were collected and evaluated, explaining any material differences in access, and describing reasonable actions taken to address those differences as warranted)
- 6. Findings and conclusions, including a fiduciary certification and specific information about those involved in preparing the comparative analysis

Fiduciary certification. Effective for plan years beginning on or after Jan. 1, 2025, the final rules require the comparative analysis to include a certification that the plan fiduciary engaged in prudent processes to:

- Select one or more qualified service providers to perform and document the comparative analysis
- Monitor those service providers' performance and documentation of the comparative analysis

In a pivot from the proposed rules, plan fiduciaries do not have to certify that the comparative analysis complies with the content requirements.

The departments note that the fiduciary certifying the comparative analysis should (at a minimum):

- Review the comparative analysis prepared by or on behalf of the plan
- Ask questions about the analysis. and discuss it with service providers to understand its findings and conclusions
- Ensure that any service provider responsible (in whole or in part) for performing and documenting the comparative analysis provides assurance that to the best of the provider's ability, the NQTLs and associated comparative analyses comply with MHPAEA requirements and regulations.

Disclosures. The final rules formalize the processes and timing for disclosure of the comparative analysis to the departments on request. Notably, group health plans have only 10 business days to produce the comparative analysis to the requesting agency. Additionally, plans must provide the comparative analysis to an applicable state authority following the state's timeline. The comparative analysis must be included with other plan documents disclosed to plan participants within 30 days of a written request for plan documents in general or related to an adverse MH/SUD benefit determination.

Key terms clarified

The final rules include new and revised meanings of select MHPAEA terms, often with corresponding examples. The new and revised terms take effect for plan years beginning on or after Jan. 1, 2025.

Medical/surgical, mental health and substance use disorder definitions. Group health plans have some discretion in defining which benefits are medical/surgical benefits, mental health benefits, or substance use disorder benefits. However, the departments emphasize that "the discretion must be exercised in a manner that comports with generally recognized independent standards of current medical practice." The final rules revise the meaning of these terms in two significant ways:

- First, reference to state guidelines is removed to avoid any conflict that could improperly limit MHPAEA's protections.
- Second, for a plan's defined term to be consistent with generally recognized independent standards of current medical practice, the definition must be consistent with the most current version of the

World Health Organization's International Classification of Diseases (ICD) adopted by HHS or the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM).

For example, a condition defined by a plan as a mental health condition must include all conditions that fall under any of the diagnostic categories listed in the mental, behavioral, and neurodevelopmental disorders chapter of the most recent version of the ICD or DSM. The departments stated that these revisions are intended to "protect against defining a benefit in a manner that could result in limitations on access to [MH/SUD] benefits that are more restrictive than those applicable to [M/S] benefits."

Specific mental health conditions identified. In response to requests from stakeholders and consistent with the 2013 final MHPAEA rules and the <u>21st Century Cures Act</u> (Pub. L. No. 114-255), the departments confirm that eating disorders (e.g., anorexia nervosa, bulimia nervosa, and binge-eating disorder) and ASD are mental health conditions. As a result, benefits for those disorders are subject to MHPAEA's protections and regulations, including the final rules. In addition, the departments note that because gender dysphoria is a mental health condition in both the current ICD and DSM, related benefits are entitled to protection under MHPAEA and the rules.

Comparative analysis. Other terms are new and specifically related to the required NQTL comparative analysis, including evidentiary standards, factors, processes, and strategies. These new definitions are intended to improve clarity and add specificity regarding the different elements that need to be documented in the written comparative analysis.

Treatment limitations. Treatment limitations include both quantitative limitations and NQTLs that limit the scope or duration of benefits. The revised definition clarifies that the illustrative list of NQTLs referenced is not exhaustive. The definition also clarifies that a plan can exclude a particular condition or service without creating an NQTL, as long as the exclusion is "complete." The revision reinforces the departments' <u>earlier position</u> that if a plan provides any benefits for a MH/SUD condition and excludes benefits for that condition in a classification in which it provides M/S benefits, the exclusion is a treatment limitation because it limits the scope or duration of treatment offered.

Enforcement

The Cures Act, passed in 2016, required the departments to issue MHPAEA guidance and step up parity enforcement for NQTLs. Since then, enforcement fact sheets and reports to Congress demonstrate investigation efforts and correction plans for specific parity violations. The 2021 CAA reinforced this obligation to produce guidance with examples — focusing on NQTLs — and an annual report to Congress identifying plans and issuers out of compliance.

The 2021 CAA also outlines the process for the departments to review a plan's NQTL comparative analysis. That process, which requires plans and issuers to specify corrective action within 45 days of a determination of noncompliance and subsequently notify plan members within seven days, is unchanged by these final rules. However, as emphasized in the 2023 Report to Congress, the departments expect to continue working directly with plans and issuers to achieve voluntary compliance.

Future enforcement. Expect future MHPAEA enforcement to focus on claims data and network adequacy. The departments reaffirm that the final rules' fundamental purpose is to ensure that participants and beneficiaries who seek treatment for covered MH/SUDs don't face greater obstacles than they would for accessing M/S treatments or procedures. The departments note that despite "increased enforcement efforts and ... extensive guidance and compliance assistance materials," barriers to access persist. In support of that purpose and the departments' findings of persistent noncompliance with MHPAEA and deficient comparative analyses, these final rules:

- Require group health plans to collect and evaluate data and take reasonable action to address
 material differences in access to MH/SUD benefits relative to M/S benefits when the relevant data
 suggest that an NQTL contributes to material differences in access.
- Prohibit group health plans from designing NQTLs using discriminatory information, evidence, sources, or standards that systematically disfavor or are specifically designed to disfavor access to MH/SUD benefits.
- Allow the departments to require removal of an NQTL on a final determination of noncompliance.

With respect to network adequacy, the departments' enforcement efforts intend to improve overall network composition and create a more robust MH/SUD provider network. For example, to determine the aggregate impact of NQTLs on network composition, the departments intend to focus on in- and out-of-network utilization rates, including related claims data; network adequacy metrics (e.g., data on time, distance, and providers accepting new patients); and provider reimbursement rates. The comparative analysis must include the plan's evaluation of an NQTL's impact on network adequacy.

Additional guidance/revised tools expected. The departments declined to provide a comprehensive and exhaustive list of NQTLs, instead directing attention to the nonexhaustive list and examples provided in the final rules, and additional examples expected in future reports to Congress. The departments also commit to updating the <u>2020 MHPAEA Self-Compliance Tool</u> and providing "other guidance" but give no target date for completion.

Employer next steps

The final rules represent a major overhaul of the existing parity regulations. Plans and insurers will need to conduct additional analysis to determine the rules' impact in general and for a particular plan. Sponsors of fully insured plans should be able to rely on their insurers to comply since they are directly subject to MHPAEA, but confirmation is advisable. Self-funded plan sponsors have more compliance obligations and will require assistance from one or more service providers to comply. The final rules' numerous examples illustrating how the parity requirements work should be reviewed carefully for insight into plan design, application and outcome red flags. Self-funded plan sponsors may consider consulting with legal counsel about the likelihood of litigation challenging these rules, particularly given the recent Supreme Court decision in *Loper Bright Enterprises v. Raimondo*. For more information on *Loper Bright*, watch <u>SCOTUS</u> weakens agency power (Aug. 1, 2024).

The following are preliminary actions self-insured plan sponsors can take now to start compliance efforts:

- Review the plan's definitions to make sure that they align with the final rule and the most current version of the ICD or DSM.
 - Review any limits on coverage for eating disorders, ASDs, or gender dysphoria to confirm MHPAEA compliance.
- Consider whether the plan must cover additional MH/SUD benefits to satisfy the meaningful benefits standard (for the 2026 plan year).
- Make sure that no NQTL applies to MH/SUD benefits unless the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL are comparable to and applied no more stringently than the processes strategies, evidentiary standards, or other factors used in designing and applying the limit to M/S benefits in the same classification.
 - Review the factors and evidentiary standards used to design and apply new and existing NQTLs to ensure that they are not discriminatory (for the 2026 plan year).
- Prepare to conduct the outcomes data evaluation (for the 2026 plan year).
 - Determine what data will be required and ensure that it is being collected. The departments extended this requirement until the 2026 plan year so plans would have time to make any necessary updates to systems and processes.
 - Document all efforts to increase access to in-network MH/SUD benefits.
- Review the plan's written NQTL comparative analysis, and determine what updates are required to align with the final rules.
 - Prepare to add the required fiduciary certification by identifying the fiduciary and having a certification drafted or reviewed by legal counsel.
 - Confirm the plan's comparative analysis is updated for any change in benefit design, administration or utilization.
 - If a written comparative analysis has not been prepared or is incomplete, prioritize completion as soon as possible.
 - Confirm a process is in place to respond to a request for the comparative analysis from a federal
 or state agency within the prescribed time frame. Also confirm a process is in place to disclose
 the comparative analysis with other plan materials after receiving a participant's written request
 for plan information in general or in relation to an adverse MH/SUD benefit decision.
 - Prepare to add new content related to new NQTL standards (for the 2026 plan year).

- Identify all third parties whose support will be required to comply with the final rules. Besides the third-party administrator, this might include behavioral health vendors, pharmacy benefit managers, point solution vendors, legal counsel, clinical experts and/or data analysts.
- Ensure that vendor contracts provide for the necessary compliance assistance, now and in the future. The departments consider this as a best practice.
- Watch for litigation challenging the final rules.
- Watch for additional guidance. The departments intend to update the self-compliance tool and issue additional guidance about the type, form, and manner of data that plans must collect.

Related resources

Non-Mercer resources

- 29 CFR § 2590.712, Parity in mental health and substance use disorder benefits (Code of Federal Regulations)
- <u>Final rules</u>, Requirements related to the Mental Health Parity and Addiction Equity Act (DOL, HHS and Treasury, Sept. 9, 2024)
- Fact sheet, Final rules under the Mental Health Parity and Addiction Equity Act (DOL Sept. 9, 2024)
- New Mental Health and Substance Use Disorder Parity Rules: What they mean for plans and issuers (DOL, Sept. 9, 2024)
- News release on final rules (DOL, Sept. 9, 2024)
- <u>Proposed rule</u>, Requirements related to the Mental Health Parity and Addiction Equity Act (Federal Register, Aug. 3, 2023)
- 2023 MHPAEA report to Congress (DOL, HHS and Treasury, July 25, 2023)
- <u>Technical release 2023-01P</u> (DOL, July 25, 2023)
- Appendix: MHPAEA guidance compendium (DOL, July 21, 2023)
- Fact sheet: FY 2022 MHPAEA enforcement (DOL, July 21, 2023)
- <u>CMS insurance bulletin</u>, Sunset of MHPAEA opt-out provision for self-funded, nonfederal governmental group health plans (June 7, 2023)
- MH/SUD parity implementation and CAA, 2021 FAQs Part 45 (DOL, HHS and IRS, April 2, 2021)
- Pub. L. No. 116-260, Consolidated Appropriations Act, 2021 (Dec. 27, 2020)

- Mental health parity and substance use disorder resources (DOL)
- Self-funded nonfederal governmental plans, procedures and requirements for HIPAA exemption election (CMS)
- Mental Health Parity and Addiction Equity Act (CMS)

Mercer Law & Policy resources

- Top 10 health, leave benefit compliance and policy issues in 2024, 3 Mental health parity (Oct. 12, 2023)
- MHPAEA opt-out ends for nonfederal government plans (June 29, 2023)
- Mental health parity compliance gets a boost in 2021 spending act (April 13, 2021)
- Mental health parity FAQs address nonquantitative limits, disclosures (Dec. 17, 2019)

Other Mercer resources

- <u>Major mental health parity guidance signals continued enforcement focus for employers</u> (July 27, 2023)
- Regulators' first report on mental health parity analysis finds issues (Feb. 3, 2022)
- Time to check your MAT coverage as overdose deaths reach new high (Dec. 2, 2021)
- ABA therapy coverage exclusions raise a red flag (Oct. 7, 2021)
- The DOL increases mental health parity enforcement (Sept. 2, 2021)

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