

AMA summary of MHPAEA final rule

Introduction

On September 9, 2024, the U.S. Departments of Labor (DOL), Health and Human Services (HHS), and Treasury (collectively, the Departments) released a <u>final rule</u> implementing the Mental Health Parity and Addiction Equity Act (MHPAEA). The 513-page rule includes numerous provisions strongly supported by the AMA and represents an opportunity for state legislatures and departments of insurance to strengthen their own parity laws. This summary highlights key provisions where the AMA encouraged action by the Departments. AMA <u>comments</u> on the proposed rule emphasized that "enhanced enforcement of all of the MHPAEA's provisions, including those existing and proposed in this rule, is essential to realize the promise of MHPAEA."

On the final rule, the AMA worked closely with key Federation partners, including the American Psychiatric Association, American Society of Addiction Medicine (ASAM) and the American Academy of Child and Adolescent Psychiatry to urge the Biden Administration to finalize the proposed rule—keeping the strongest components while amending provisions that the AMA believed health plans would exploit to patients' detriment—just as health plans have done for more than 15 years. The AMA also worked closely with consumer advocates, including the Legal-Action Center, Mental Health America, The Kennedy Forum, Inseparable and others.

In applauding the final rule, AMA President Bruce A. Scott, MD, <u>said</u> that it is essential "to ensuring that MHPAEA has the teeth to protect patients from health insurance company actions that unfairly and too often discriminatorily restrict access to mental health and substance use disorder care." Dr. Scott highlighted the AMA's support for "provisions that will help increase transparency, oversight and enforcement of MHPAEA in areas such as prior authorization and network adequacy. Health plans have violated MHPAEA for more than 15 years, and this final rule is a step in the right direction to protect patients and hold health plans accountable for those failures."

General overview of the final rule

The final rule provides extensive detail about how the oversight and enforcement actions undertaken by federal agencies flow directly from statute. These include the Mental Health Parity Act of 1996; MHPAEA in 2008; the Affordable Care Act in 2010; and the Consolidated Appropriations Act (CAA) in 2021. The Departments also take an optimistic tone to help individuals with a mental illness or substance use disorder in saying that "the Departments anticipate that these final rules will result in changes in network composition and medical management techniques related to mental health and substance use disorder care, more robust mental health and substance use disorder provider networks, and fewer and less restrictive prior authorization requirements for individuals seeking mental health and substance use disorder care, as well as 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."

In addition, the final rule emphasizes that "These final rules aim to strengthen consumer protections consistent with MHPAEA's fundamental purpose – to ensure that individuals in group health plans or with group or individual health insurance coverage who seek treatment for covered mental health conditions or substance use disorders 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." The final rule also includes broad recognition of racial and ethnic disparities for individuals with mental health and substance use disorder (MH/SUD) needs. In addition, the final rule recognizes the broad, adverse impacts being felt by younger people.

Key provisions of the final rule

Please note that the summary below highlights multiple, major provisions of the final rule. The AMA encourages states to consider adopting these provisions into state law to build consistency with federal oversight as well as strengthen state-level protections.

- Requires that comparative analyses must be performed and documented to show that the processes, strategies, evidentiary standards, and other factors used in designing or applying a Non-Quantitative Treatment Limitations (NQTL) to MH/SUD benefits is comparable to, and are applied no more stringently, than an NQTL for medical/surgical (M/S) benefits.
- Establishes specific timelines for payer compliance to provide information to the Departments for review of a comparative analysis of an NQTL.
- Adds new definitions for NQTL terms such as *evidentiary standards*, *factors*, *processes*, and *strategies*, to remove plans' and issuers' complaints about confusing terms.
- Requires use of a standard definition for what is a MH condition or SUD. The final rule provides that plans
 and issuers must follow the most current version of the International Classification of Diseases (ICD) or the
 Diagnostic and Statistical Manual of Mental Disorders (DSM).
- Connects the "meaningful benefits" standard to "core treatments" for MH/SUD conditions, which are defined as a standard treatment or course of treatment, therapy, service, or intervention indicated by generally recognized independent standards of current medical practice.
- Provides an "illustrative, non-exhaustive list" of NQTLs, rather than an exhaustive list of "treatment limitations," as requested by plans and issuers.
- Reinforces the fact that health plans and issuers cannot use NQTLs, such as prior authorization and other
 medical management techniques, standards related to network composition, or methodologies to determine
 out-of-network reimbursement rates, for MH/SUD benefits, that are more restrictive than the predominant
 NQTLs applied to substantially all M/S benefits in the same classification.
- Requires plans to provide their comparative analysis. If a beneficiary or enrollee receives an adverse benefit determination for a MH/SUD treatment or coverage decision, the individual can request—and the plans must comply—a copy of the plan's comparative analysis.
- Gives regulators the authority to prohibit plans from continuing use of an NQTL if the plan cannot
 demonstrate it complies with the law. If a plan fails to demonstrate that an NQTL is no more restrictive as
 written or in operation when compared to M/S benefits, regulators now have the authority to prohibit the plan
 from continuing use of the NQTL until the violation is cured. This includes a plan who does not submit
 sufficient information for regulators to evaluate an NQTL's parity compliance.
- Adopts AMA-supported language that "To ensure that [standards] are not biased and are objective, independent professional medical or clinical standards should reflect the standards of care and clinical practice that are generally recognized in relevant clinical specialties across a range of settings of care and should be transparent."
- Addresses "network composition," and many access-related issues, including a current lack of transparency surrounding MH/SUD networks as well as when plans and issuers create, implement, and evaluate SUD networks.
- Prohibits the use of discriminatory factors and evidentiary standards to design an NQTL imposed on MH/SUD benefits.
- Requires plans and issuers to incorporate fraud, waste, and abuse as a factor—not a standalone exception
 as plans wanted—for relevant NQTLs, which are subject to MHPAEA's comparability and stringency tests
 for MH/SUD and M/S benefits.

The final rule's provisions apply to group health plans (and health insurance coverage offered by an issuer in connection with a group health plan) on the first day of the first plan year beginning on or after January 1, 2025, except for 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, which apply on the first day of the first plan year beginning on or after January 1, 2026.

Detailed analysis of specific provisions in the final rule

Increased clarity for how non-quantitative treatment limitations (NQTLs) must be evaluated

The final rule effectively clarifies that plans may not impose greater barriers and burdens for MH/SUD benefits than for M/S benefits. Plans and issuers must perform and document their comparative analyses to show that the processes, strategies, evidentiary standards, and other factors used in designing or applying an NQTL to MH/SUD benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing or applying the NQTL to M/S benefits in the relevant classification. This includes ensuring that the information, evidence, sources, or standards on which factors and evidentiary standards are based are not biased and are objective in a manner that does not discriminate against MH/SUD benefits as compared to medical/surgical benefits.

Anything used by a plan or issuer to design or apply an NQTL should be considered a process, strategy, evidentiary standard, or factor (or information, evidence, sources, or standards on which a factor or evidentiary standard is based), consistent with the Departments' broad interpretation of these terms. The six benefit classifications subject to MHPAEA parity analysis are as follows:

- *Inpatient, in-network.* Benefits furnished on an inpatient basis and within a network of providers established or recognized under a plan or health insurance coverage.
- Inpatient, out-of-network. Benefits furnished on an inpatient basis and outside any network of providers established or recognized under a plan or health insurance coverage. This classification includes inpatient benefits under a plan (or health insurance coverage) that has no network of providers.
- Outpatient, in-network. Benefits furnished on an outpatient basis and within a network of providers established or recognized under a plan or health insurance coverage.
- Outpatient, out-of-network. Benefits furnished on an outpatient basis and outside any network of providers established or recognized under a plan or health insurance coverage. This classification includes outpatient benefits under a plan (or health insurance coverage) that has no network of providers.
- Emergency care. Benefits for emergency care.
- Prescription drugs. Benefits for prescription drugs.

Specific timelines for payer compliance to provide information

The final rules set forth the steps the DOL, HHS, and Treasury 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 seven 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.

Standard definitions

The final rule adds new definitions for the following terms to resolve plans' and issuers' complaints about confusing 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 final rule also provides that a plan's or issuer's definition of whether a condition or disorder is an 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). This is another important provision that will help ensure consistency in oversight of plans' and issuers' NQTLs. **The AMA encourages states to adopt this provision directly into state law.**

Over the objections of plans and issuers, the final rule does not provide an exhaustive list of all of the different types of "treatment limitations" a plan might use given that once such a list is created, plans could then argue that a newly created NQTL was not on the list. The final rule explains that treatment limitations "include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations (such as standards related to network composition), which otherwise limit the scope or duration of benefits for treatment under a plan." The departments do provide an "illustrative, non-exhaustive list of nonquantitative treatment limitations," which include:

- Medical management standards (such as prior authorization) limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative
- Formulary design for prescription drugs
- For plans with multiple network tiers (such as preferred providers and participating providers), network tier design
- Standards related to network composition, including but not limited to, standards for provider admission to
 participate in a network or for continued network participation, including methods for determining
 reimbursement rates, credentialing standards, and procedures for ensuring the network includes an
 adequate number of each category of provider and facility to provide services under the plan
- Plan methods for determining out-of-network rates, such as allowed amounts; usual, customary, and reasonable charges; or application of other external benchmarks for out-of-network rates
- Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols)
- Exclusions based on failure to complete a course of treatment
- Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the plan or coverage

Increased transparency for providing comparative analyses

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 rule requires 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
- 6. Findings and conclusions

This provision also requires that 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 Employee Retirement Income Security Act of 1974 (ERISA) plans at any time. Plans may not withhold information in these analyses from consumers by claiming they are proprietary or are commercially protected. These are important provisions that states can adopt to strengthen existing laws. **The AMA encourages states to adopt these provisions directly into state law.**

Focus on prior authorization and other harmful utilization management tactics

The final rule reinforces that health plans and issuers cannot use NQTLs, such as prior authorization and other medical management techniques, standards related to network composition, or methodologies to determine out-of-network reimbursement rates, for MH/SUD benefits, that are more restrictive than the predominant NQTLs applied to substantially all M/S benefits in the same classification.

The Departments also proposed to add a specific reference to prior authorization requirements as an example of a medical management standard limiting or excluding benefits based on medical necessity or medical appropriateness. The final rule also provides that plans may be required to provide outcomes data—meaning that for NQTLs such as prior authorization, relevant data could include rates of approvals and denials of prior authorization requests, rates of denials of post-service claims, application of penalties for a failure to obtain prior authorization, and turnaround times for prior authorization requests. This increased scrutiny should allow regulators to better understand and prevent the use of prior authorization to delay and deny medically necessary care.

The final rule correctly states that the ASAM national practice guideline is the recognized professional medical standard, and that it "does not support prior authorization every 30 days" for the opioid use disorder (OUD) medication, despite it being a common feature of many plans. If a plan has an NQTL that is written, applied or operates to require prior authorization for buprenorphine every 30 days for OUD, that would be an MHPAEA violation.

NQTLs that violate the law can be stopped

The AMA urged that the DOL, HHS, and IRS use existing authorities to prohibit plans and issuers from imposing NQTLs for MH/SUD services if they cannot affirmatively demonstrate that they are no more restrictive as written or in operation when compared to M/S benefits. The final rule made clear that if a plan or issuer is found to be using an NQTL in operation that is more restrictive than as applied to an M/S service, the plan/issuer can be prohibited from using that NQTL until the violation is cured. The final rule makes clear that "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."

The AMA urges states to adopt these provisions in state law so that when a plan fails to meet the existing requirement to evaluate coverage of MH/SUD services relative to M/S services, the plan can be held accountable

through the imposition of fines and prohibition against using the NQTL until the plan can demonstrate compliance with the law. This is particularly important given that a key tactic of plans and issuers has traditionally been to provide insufficient information and force regulators into timely, costly back-and-forth exercises for plans to provide the information required under the law. Under this provision, if plans do not provide sufficient information and otherwise fail to demonstrate that they have performed the required comparative analyses, regulators now have additional authority to protect consumers.

Clarifications on measuring the impact of NQTL

The AMA agrees with the requirement that plans analyze the impact of an NQTL on access to MH/SUD services as part of a comparative analysis. The AMA also supports the data collection and reporting requirements of the rule, especially with respect to the comparative analyses of NQTLs and including network composition.

The final rule codifies the requirement in MHPAEA, as amended by the CAA, 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. The Departments explained that a plan or issuer with a typical plan or coverage design could look at the ratio of inpatient, in-network and outpatient, in-network mental health and substance use disorder and medical/surgical claims, as compared to inpatient, out-of-network and outpatient, out-of-network mental health and substance use disorder and medical/surgical claims.

Under the final rule, material differences in access related to network composition NQTLs are not automatically treated as a violation of MHPAEA (and instead are treated as a strong indicator of a violation, the same as all other NQTLs). The differences cannot be simply ignored, however. The final rule clarifies that plans and issuers must engage in, and document in their comparative analyses, all reasonable actions, as necessary, to address any material differences in access.

Another important provision in the final rule is that, to the extent the relevant data evaluated suggest that an NQTL contributes to material differences in access to MH/SUD benefits as compared to M/S benefits in a classification, such differences will be considered a strong indicator that the plan or issuer is in violation of MHPAEA.

Clear definitions for "standards"

The final rule makes clear that "a standard that is created or funded by the plan or issuer, or its service provider, would likely lack independence compared to a standard created by an impartial third party or governmental entity. Plan-derived standards, moreover, would require additional justification and "indicators of reliability in order to demonstrate that it is objective and unbiased."

The final rule goes further, including adopting AMA-supported language that "To ensure that [standards] are not biased and are objective, independent professional medical or clinical standards should reflect the standards of care and clinical practice that are generally recognized in relevant clinical specialties across a range of settings of care and should be transparent." The AMA also supports the final rule's clarification that "For example, sources that include such standards could be peer-reviewed scientific studies and medical literature, formal published recommendations of Federal Government agencies, drug labeling approved by the United States Food and Drug Administration (FDA), and recommendations of relevant nonprofit health care provider professional associations and specialty societies, including, but not limited to, patient placement criteria and clinical practice guidelines."

The departments also rejected plans' and issuers' requests to provide a specific list of NQTLs. The departments properly recognized that an "exhaustive list of NQTLs published by the Departments would likely lag behind those actually utilized by plans and issuers due to this information gap, along with the wide variability in NQTLs that exist now and could exist in the future." The departments further understood that plans and issuers already have wide variability in how plans and issuers describe their own utilization management policies and procedures, noting that

"while some commonalities exist, plans and issuers generally do not use uniform nomenclature to refer to their medical management techniques or other NQTLs, making the task of identifying an exhaustive list difficult, if not impossible."

Meaningful benefits and core treatments connected to recognized standards of medical practice

The final rule provides that if a plan or coverage provides any benefits for a MH condition or SUD in any benefits classification, the final rule states that the plan 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. The final rule explains that "A plan does not provide meaningful benefits unless it provides benefits for a core treatment for that condition or disorder in each classification in which the plan provides benefits for a core treatment for one or more medical conditions or surgical procedures. A "core treatment for a condition or disorder is a standard treatment or course of treatment, therapy, service, or intervention indicated by generally recognized independent standards of current medical practice."

The departments provide four illustrative examples:

- Autism Spectrum Disorder (ASD). If a plan covers meaningful benefits, including outpatient, out-of-network
 developmental screenings for ASD, but not core treatments—and does provide core treatments for M/S
 surgical conditions in the outpatient, out-of-network benefits classification, a parity violation is likely present.
- If a plan does not provide meaningful outpatient, out-of-network benefits for M/S conditions, it would likely not violate parity by not providing core treatments for outpatient, out-of-network treatments for MH/SUD conditions.
- Nutrition counseling for eating disorders. If a plan provides meaningful benefits in its outpatient, in-network
 classification, including core treatments such as nutritional counseling for diabetes and obesity, complying
 with parity would likely require the plan to cover nutrition counseling to treat eating disorders in the
 outpatient, in-network classification. This is because nutrition counseling is a core treatment for eating
 disorders, in accordance with generally recognized independent standards of current medical practice.
- Opioid use disorder (OUD). If a plan provides extensive benefits for the core treatments for many medical
 conditions and surgical procedures in the outpatient, in-network and prescription drug classifications,
 determining parity compliance requires determining whether the plan provides coverage for diagnosis and
 treatment for OUD in the outpatient, in-network classification. The comparison would examine whether the
 plan covers counseling and behavioral therapies and, in the prescription drug classification, by covering
 medications to treat opioid use disorder (MOUD). Counseling and behavioral therapies and MOUD, in
 combination, are one of the core treatments for OUD, in accordance with generally recognized independent
 standards of current medical practice.

Increased clarity and accountability for network composition

The AMA strongly supports the rule's provisions relating to "network composition," which will address many access-related issues, including a current lack of transparency surrounding MH/SUD networks as well as when plans and issuers create, implement, and evaluate MH/SUD networks. The AMA also urged that plans and issuers be required to specifically gather data with respect to whether SUD providers prescribe any of the FDA-approved medications to treat SUDs.

In the final rule, the departments agreed that MHPAEA applies to credentialing standards, as well as the procedures to join a network, and that methods for determining reimbursement rates, credentialing standards, and procedures for ensuring the network includes an adequate number of each category of provider and facility to provide services under the plan or coverage are intended to be interpreted broadly, consistent with the fundamental purpose of MHPAEA.

The departments provided an example that, "under these final rules, to assess the aggregate impact of NQTLs related to network composition, a plan or issuer could evaluate, as appropriate, in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (for comparable services and as benchmarked to a reference standard)."

The final rule also provides that data for NQTLs related to network composition could include median in-network reimbursement rates for services with the same CPT codes, as well as median in-network reimbursement rates for inpatient MH/SUD benefits and M/S benefits, as compared to Medicare rates; and median in-network reimbursement rates for outpatient MH/SUD benefits, and M/S benefits, as compared to Medicare rates.

Prohibition against discriminatory plan design

The final rules prohibit the use of discriminatory factors and evidentiary standards to design an NQTL that is imposed on MH/SUD benefits. A factor or evidentiary standard will be considered 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. Whether information, evidence, sources, or standards are considered to be biased or not objective will be 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. 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 will be considered generally biased or not objective, if the historical plan data or other historical information systematically disfavors access or are specifically designed to disfavor access to MH/SUD benefits as compared to M/S benefits, and the plan has not taken the steps necessary to correct, cure, or supplement the data or information.

Includes "fraud, waste and abuse" as an NQTL factor—not a standalone exception

The AMA did not support the proposed exception relating to fraud, waste, and abuse. To combat fraud, waste, and abuse, plans and issuers should incorporate fraud, waste, and abuse as a factor for relevant NQTLs, which are subject to MHPAEA's comparability and stringency tests for MH/SUD and M/S benefits. The AMA agreed with other commenters that the appropriate vehicle for identifying alleged fraud, waste or abuse in the parity context is through the NQTL design and application analysis, not a standalone exception. Over plans' and issuers' objections, the final rule makes clear that "the proposed exception for standards to detect or prevent and prove fraud, waste, and abuse is not being finalized."

What comes next for parity enforcement

The AMA will continue to support the Departments' efforts to meaningfully enforce MHPAEA. The AMA will also keep urging state policymakers to take similar actions. In addition, state policymakers have the opportunity to adopt key provisions of the final rule directly into state law. As noted in new issue briefs (included below) published by the AMA, state policymakers have multiple options to protect patients' access to MH/SUD care using existing parity laws. The final rule, however, provides states with additional options to improve state laws and targeted enforcement actions. The AMA stands ready to work with all stakeholders to support meaningful oversight and enforcement efforts.

AMA resources

- AMA Issue Brief: State efforts to enforce mental health and substance use disorder parity—This issue brief highlights examples of successful state actions to protect patients and hold health plans accountable.
- <u>AMA Issue Brief: Mental health and substance use disorder parity</u>—This issue brief provides concise background on the law and the problems caused by the lack of parity enforcement.