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EMPLOYEE BENEFITS

DOL, Treasury and HHS Release Proposed Regulations on Requirements Related to the Mental Health Parity and Addiction Equity Act

On July 25, 2023, the DOL, Treasury and HHS (hereinafter referred to as "the Departments") released proposed regulations titled "Requirements Related to the Mental Health Parity and Addiction Equity Act." These proposed rules seek to amend current rules related to the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) by introducing new requirements surrounding Non-Quantitative Treatment Limitations (NQTLs). Through these proposed regulations, the Departments seek to provide more clearly defined standards to ensure that health plan sponsors, insurance carriers and other stakeholders do not apply more stringent limits on access to mental health (MH) and substance use disorder (SUD) benefits as compared to medical/surgical (M/S) benefits within a health plan or policy. More information regarding these proposed regulations is contained below. Currently, the Departments are open to receiving comments from the public/ stakeholders on the below topics.

Background and Enforcement

History of the MHPAEA

On October 3, 2008, as part of the Emergency Economic Stabilization Act of 2008, the MHPAEA became law. This law was intended to create parity/equality between MH/SUD benefits and M/S benefits. Later, final regulations were issued on November 13, 2013, implementing the MHPAEA. These final regulations created six classifications of benefits when comparing parity between MH/SUD benefits and M/S benefits. These categories include (1) inpatient, in-network; (2) inpatient, out-of-network; (3) outpatient, in-network; (4) outpatient, out-of-network; (5) emergency care; and (6) prescription drugs.

The 2013 final regulations also provided that the parity in benefits requirements apply not only to the financial requirements within a health plan (e.g., copayments, deductibles, numerically expressed quantitative treatment limitations) but also to the non-quantitative treatment limitations (NQTLs) (e.g., non-numerical requirements such as prior authorization requirements, step therapy, provider admission requirements, etc). On December 27, 2020, the Consolidated Appropriations Act of 2021 amended the MHPAEA, expressly requiring group health plans and insurers to document and perform an NQTL analysis to determine whether a plan's design and application of NQTLs are more stringent on MH/SUD benefits as compared to M/S benefits. The Departments have released multiple sets of Frequently Asked Questions (FAQs), fact sheets, compliance assistance tools, templates, reports and publications since the inception of the MHPAEA.

DOL and CMS Enforcement Priorities

The federal Department of Labor (DOL) and the Centers for Medicare & Medicaid Services (CMS) are the enforcement agencies responsible for ensuring compliance under private employer-sponsored group health plans, non-federal governmental health plans and even some insurance carriers. The DOL and CMS listed certain priority areas on which they plan to focus in a July 2023 Congressional Report.

DOL Enforcement Priorities

The DOL provided the following as their six enforcement priority areas, which include both past priorities contained in a previous Congressional Report and new priorities contained in the current July 2023 Congressional Report:

1. Plan requirements for prior authorizations related to in-network and out-of-network inpatient services;
2. Concurrent care review for in-network and out-of-network inpatient and outpatient services;
3. Provider admission standards to participate in a network, including reimbursement rates;
4. Reimbursement rates for out-of-network services (i.e., methods for determining the reasonableness and what is usual and customary within the industry);
5. Prohibited exclusions for key treatments for mental health conditions and substance use disorders (updated since the previous January 2022 Congressional Report); and
6. Standards for network adequacy for MH/SUD provider networks (updated since the previous January 2022 Congressional Report).

Since January 2022, the DOL has focused on reviewing plan reimbursement rates and whether plans systematically and regularly review the network adequacy of provider networks offered under the plan.

CMS Enforcement Priorities

CMS also included its three enforcement priorities within the July 2023 Congressional Report:

1. Prior authorizations as a treatment limitation that apply in the context of inpatient/in-network, inpatient/out-of-network, outpatient/in-network and outpatient/out-of-network benefit classifications.
2. Concurrent review treatment limitations for outpatient/in-network and outpatient/out-of-network benefit classifications.
3. Specific treatment exclusions for certain health conditions as they relate to certain prescription drug classifications, which is an updated priority since the January 2022 Congressional Report.

EBSA and CMS NQTL Plan Reviews and Investigations

Some statistics related to the enforcement actions of EBSA and CMS include:

- Between February 2021 and July 2022, EBSA issued 182 letters requesting comparative analyses for over 450 NQTLs across 102 investigations, which resulted in the issuance of three final determination letters finding that three plans violated ERISA section 712 for three NQTLs, and 104 plans (and their service providers) and issuers taking prospective corrective action with respect to their plans addressing 135 NQTLs.
- Between February 2021 and September 2022, CMS issued 26 letters requesting comparative analyses for 44 NQTLS from 24 plans and issuers, finding seven NQTLs on MH/SUD benefits were not in parity with the NQTLs as applied to M/S benefits and sending corrective action plans to two plans and seven issuers covering 15 NQTLs in response to CMS' initial determination letters.
- The overall changes made to plans from these corrective action plans include:
  - A health plan that covers over 22,000 participants removed an exclusion for opioid treatment programs (OTPs) for opioid use disorder.
  - A health plan added direct access to MH/SUD benefits (rather than having an EAP act as the gatekeeper to MH/SUD benefits) for over 4,000 participants in a health plan.
  - A service provider removed a non-compliant exclusion of applied behavior analysis (ABA) therapy for treating autism spectrum disorder (ASD), affecting approximately 1,000 plans covering over 1 million participants.
  - A continued stay and discharge requirement that only applied to MH/SUD benefits for inpatient, out-of-network services was removed from an issuer's policy.
  - Two issuers chose to adopt an annual comparative analysis of NQTLs to help ensure their NQTL policies are updated and reviewed yearly.

Proposed Regulations

Purpose of the MHPAEA and MHPAEA Definitions

Much of the proposed regulations focus on defining and providing substantive requirements for NQTLs under the MHPAEA so that both group health plans and insurance carriers have more clearly defined standards and parameters when applying NQTLs to MH/SUD benefits within their health plans. These newly proposed definitions and substantive requirements seek to promote adherence to the ultimate goal of the MHPAEA, which is to require that MH/SUD benefits have parity with M/S benefits offered under a health plan.

1) The proposed regulations further define and create rules surrounding how plans must analyze NQTLs for "mental health benefits," "surgical/medical benefits," and "substance use disorder benefits" to further delineate what benefits a health plan is comparing within it. The proposed regulations indicate that these terms, as they relate to NQTLs, must generally be congruent with "generally recognized independent standards of current medical practice" (i.e., International Classification of Diseases (ICD) or Diagnostic and Statistical Manual of Mental Disorders (DSM)). States will no longer be used as a main source for defining these terms due to the federal and state definitions not aligning in the past. References to the ICD or DSM would be the version in effect within one (1) year of the applicable plan year. Specifically, the proposed rules clarify that eating disorders and Autism Spectrum Disorder (ASD) fall into the "mental health" condition category and not as a medical/surgical condition.

2) The proposed regulations provide a new substantive requirement for analyzing whether a benefit plan can include an NQTL. A benefit plan cannot include an NQTL unless the NQTL:

   - Is no more restrictive as to MH/SUD benefits as compared to M/S benefits (i.e., no more restrictive requirement)
   - Satisfies the "design and application" requirements; and
   - Is found to be justified after a plan/issuer collects, evaluates and considers the impact of any and all relevant data on access to MH/SUD benefits in comparison to M/S benefits, and reasonable action is taken by the plan/issuer to address any material differences between the two. Plans would be prohibited, however, from using historical data from a time during which the plan was not subject to or violated the MHPAEA.

   However, regardless of any analysis completed for the justification of an NQTL, if the NQTL discriminates against MH/SUD in comparison to M/S benefits, it would automatically be considered non-compliant under the rules, which also apply to NQTLs related to network composition.

3) The terms "substantially all," "predominant" and "restrictive" when comparing whether the treatment limitations for MH/SUD benefits are "no more restrictive than the predominant treatment limitations applied to substantially all M/S benefits covered by the plan" would contain a financial component. Specifically, plans/issuers would be required to calculate the portion of plan payments for M/S benefits subject to an NQTL as compared to the total dollar amount of all plan payments for M/S in the classification reasonably expected to be paid under the plan or coverage for the plan year. In this instance, an NQTL would meet the "substantially all" test for M/S benefits in a classification if it applies to at least two-thirds of all M/S benefits in that classification without regard to a particular factor/evidentiary standard[1].

   For purposes of defining "predominant," the proposed regulations indicate the concept means the "most common or most frequent variation[2]...such as prior authorization in a manner that differs based on the manner of review (auto adjudication vs. manual review) and the number of levels of review (first-level review vs. first-level review and peer-to-peer review), the plan would regard each unique combination as a separate variation."

   Finally, for purposes of the term "restrictive," a health plan cannot impose conditions, terms or requirements that limit access to benefits. This includes, but is not limited to, "those that compel an action by or on behalf of a participant or beneficiary (including by their authorized representative or a provider or facility) to access benefits and those that limit access to the full range of treatment options available for a condition or disorder under the plan or coverage." Further comments were requested from the public and stakeholders on defining what "restrictive" means. The Departments propose a balance to this standard that if the NQTL is found to be more restrictive on MH/SUD benefits than M/S benefits, the NQTL could still be considered valid if it "impartially applies independent professional medical or clinical standards or applies standards related to fraud, waste, and abuse, that meet specific requirements..."

The Departments stated that the updates to these terms and substantive requirements under the MHPAEA will provide stakeholders with much more clarity regarding compliance under the MHPAEA rules.

[1] "For example, if a plan or issuer applies a general exclusion for all benefits in a classification that are for experimental or investigative treatment, and defines experimental or investigative treatment to be treatments with less than a certain number of peer reviewed studies demonstrating efficacy, the exclusion would be treated as applying to all of the benefits in the classification – not just those that may be subject to the general exclusion for experimental or investigative treatment because they lack the requisite number of peer-reviewed studies (that is, those that actually triggered the NQTL based on the evidentiary standard). These proposed rules further provide that if an NQTL does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that NQTL would not be permitted to be applied to mental health or substance use disorder benefits in that classification."

[2] "If a plan applies inpatient concurrent review commencing 1 day, 3 days, or 7 days after admission, depending on the reason for a stay in a hospital or other inpatient facility, or the procedure performed during such a stay, the plan imposes three different variations of the NQTL within the benefit classification. Under this example, to determine which variation is predominant, the plan would determine the portion of inpatient benefits subject to each of the three different variations of the NQTL based on the dollar amount of all plan payments expected to be paid under the plan or coverage for the plan year (or the portion of the plan year after a change in benefits that affects the applicability of the NQTL). The most common or frequent variation would be the variation that applies to the highest portion of all medical/surgical benefits within a classification that are subject to the NQTL based on expected plan payments."

Illustrative, Non-Exhaustive List of NQTLs

The proposed rules make minor changes to the list of NQTLs, including providing additional examples not previously included in prior regulations and making clear that the list of examples is non-exhaustive. In other words, there may be NQTLs that should be evaluated that are not included in the list within the proposed rules. An NQTL is "any provision that limits the scope or duration of benefits for treatment under a plan or coverage that is not a quantitative treatment limitation."

Due to the broad scope of this definition, the Departments plan to include additional examples as they are encountered. The preamble to these proposed rules provides the following examples of additional NQTLs: "concurrent care review; billing restrictions, such as a requirement for a licensed provider to bill through or under the supervision of another type of licensed provider; retrospective review; treatment plan requirements; refusal to cover treatment until completion of a comprehensive assessment by specific providers; outlier management; and limitations based on expectation of improvement, likelihood of progress, or demonstration of progress."

The proposed rules would add the following examples to the non-exhaustive list of NQTLs:

- Standards related to network composition "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 covered services under the plan or coverage."
- The application of "other external benchmarks for out-of-network rates[3]."
- "Prior authorization requirements as an example of a medical management standard limiting or excluding benefits based on medical necessity or medical appropriateness."

[3] *One common external benchmark is using a percentage of Medicare rates.*

Required Use of Outcomes Data and Special Rule for NQTLs Related to Network Composition

In addition to expanding the non-exhaustive list of NQTLs and clarifying that additional NQTLs not included in the list are subject to the same standards, the proposed regulations also clarify that the plan must evaluate the outcomes of these standards to ensure there is not a disparate impact between M/S benefits and MH/SUD benefits. Further, if a disparate impact is uncovered, the plan should take reasonable action to remedy this issue and document the actions taken. The proposed rules require plans to collect data that outlines "the number and percentage of relevant claims denials, as well as any other data relevant to the NQTLs as required by State law or private accreditation standards" to measure the impact of the NQTLs.

Of particular concern to the Departments are the outcomes related to network composition. Therefore, plan sponsors would be required to collect "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 (including as compared to billed charges)" along with any other data that may assist the plan sponsor in assessing the plan's network composition.

Further, the Departments have introduced a special rule stating that "if the relevant data show material differences in access to in-network MH/SUD benefits as compared to in-network M/S benefits in a classification," the plan sponsor will have failed to meet the requirements of the MHPAEA. In this case, the plan sponsor would be required to act to address the material differences or discontinue the application of the NQTL that caused the material differences.

The Departments recognize that due to a shortage of mental health providers, plan sponsors may be unable to correct the material differences in access to in-network MH/SUD benefits compared to in-network M/S benefits in a classification. However, if the plan sponsor takes appropriate action to correct the issue and documents such actions, the material differences in access will not result in the Departments citing the plan sponsor for failure to comply with the MHPAEA.

Independent Professional Medical or Clinical Standards and Standards to Detect or Prevent and Prove Fraud, Waste and Abuse

The proposed regulations provide two exceptions to several of the requirements under the MHPAEA. Specifically, the proposed regulations provide an exception to the no more restrictive requirements, the prohibition on discriminatory factors and evidentiary standards requirements, and the relevant data evaluation requirements "for NQTLs that impartially apply generally recognized independent professional medical or clinical standards (consistent with generally accepted standards of care) to M/S benefits and MH/SUD." In addition, the proposed regulations provide an exception to the no more restrictive requirements "for NQTLs reasonably designed to detect or prevent, and prove fraud, waste, and abuse, based on indicia of fraud, waste, and abuse that have been reliably established through objective and unbiased data."

Effect of Final Determination of Noncompliance

The proposed regulations clarify that a plan could be required to cease the application of an NQTL due to the NQTL not meeting substantive requirements under the MHPAEA and due to the plan failing to comply with the comparative analysis requirements under the MHPAEA. Upon either type of failure, the Departments would evaluate the relevant facts and circumstances before requiring immediate cessation of the NQTL.

NQTL Examples

The proposed regulations provide 13 examples to help illustrate the meaning of the proposed rules, subject to change in the final rules. These examples illustrate areas of concern, such as assisting stakeholders with determining reimbursement rates and adequately maintaining as robust a network of providers for MH/SUD benefits as are offered for M/S benefits of the plan. In addition, the proposed regulations provide examples of how the NQTL requirements apply to specific benefit and plan types, such as ABA therapy, EAP plans and residential treatment facilities.

Prohibition on Treatment Limitations Applicable Only to Mental Health or Substance Use Disorder Benefits

The proposed regulations confirm that plans and issuers may not apply any NQTL to MH/ SUD benefits that is not applicable to any M/S benefits in the same benefit classification. For this purpose, excluding MH/SUD benefits in a classification that is "merely an expression of another NQTL, such as medical necessity requirements or experimental or investigational exclusions that is applied with respect to M/S benefits in the same classification would not be considered a separately applicable treatment limitation. For example, a plan's exclusion of coverage for ABA therapy is not an expression of a broader NQTL if it was not generated through a process or strategy or informed by an evidentiary standard of a broader NQTL like medical necessity."

Meaningful Benefit Requirement

To ensure that the plan covers benefits for a range of services and treatments for MH/SUD conditions in a classification, if any benefits for a MH/SUD condition or disorder in any classification are provided, benefits for that MH/SUD condition or disorder must be provided in every classification in which M/S benefits are provided. To satisfy this requirement, a plan or issuer providing any MH/SUD benefits in any classification must provide "meaningful benefits" for treatment for that condition or disorder in each classification in which M/S benefits are provided. The Departments are requesting comment on whether and how to define "meaningful benefits" for purposes of this rule.

Example: A plan that covers diagnosis and treatment for eating disorders (an MH condition), excludes coverage for nutrition counseling to treat eating disorders, including in the outpatient, in-network classification, and provides benefits for primary treatment for M/S procedures in outpatient, in-network classification would violate the proposed rules due to the exclusion of coverage for nutrition counseling for eating disorders because the plan would not be providing meaningful benefits for the treatment of eating disorders in the outpatient, in-network classification, as determined in comparison to the benefits provided for M/S conditions in the same classification.

Additional Content of NQTL Comparative Analysis

The proposed regulations would implement the statutory requirement that plans and issuers imposing any NQTL on MH/SUD benefits must perform and document comparative analyses of the design and application of all NQTLs and establish additional content requirements, including the requirement that plans and issuers evaluate relevant data to ensure compliance with the MHPAEA.

The proposed rules indicate that, at a minimum, the comparative analysis for each NQTL imposed under a plan or coverage option on MH/SUD benefits includes the following six specific elements:

(1) A description of the NQTL;

(2) The identification and definition of the factors 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; and

(6) Findings and conclusions.

The proposed rules would require plans and issuers to prepare and make available, upon request, a written list of all NQTLs imposed under the plan and a general description of any information used in preparing the comparative analysis for each NQTL. Furthermore, the comparative analyses must include the date, title and credentials of all relevant persons who participated in the performance and documentation of the analysis. For plans subject to ERISA, the analysis must include certification by one or more named fiduciaries who have reviewed the analysis, stating whether they found the analysis to comply with the proposed content requirements.

The Departments acknowledge that plan sponsors often rely on issuers, TPAs and other service providers to administer and design their benefits, including coverage limitations and exclusions for MH/SUD and M/S benefits and conduct NQTL comparative analyses. The Departments clarify that although their direct enforcement authority is limited, they are "committed to using all available authority to ensure compliance by plans and issuers with the MHPAEA for all entities that play a role in administering and designing benefits" and solicit feedback on how to ensure all parties involved provide the necessary information to plans/issuers in their effort to maintain compliance with the MHPAEA.

Procedures for Provision of NQTL Comparative Analysis Upon Request from a Department

The proposed regulations would add specific procedures governing the process of providing a plan's NQTL comparative analysis to a Department when requested. They include:

- The comparative analysis must be provided within ten (10) business days of the request from a Department (although the Department has the authority to grant an extension).
- If the Department determines the plan's initial response is inadequate, additional information must be submitted within ten (10) business days of the request for additional information.
- If the Department determines the plan is not complying with the MHPAEA, the plan must respond by specifying the corrective actions it will take and provide an updated comparative analysis demonstrating compliance no later than 45 calendar days after the Department's initial determination of noncompliance.

The proposed regulations also include content and delivery requirements for the notice that must be provided to participants when a Department determines the plan is non-compliant.

Providing NQTL Comparative Analysis to Participants and Beneficiaries

The proposed regulations confirm that a plan's comparative analysis must be provided to participants and beneficiaries upon request as a document under which the plan is maintained. A penalty of up to $110 per day would apply under ERISA if not provided within 30 days of the request.

The proposed regulations also indicate that the analysis must be provided to a participant or beneficiary (or a provider or other person acting as a participant's or beneficiary's authorized representative) who has received an adverse benefit determination related to MH/SUD benefits.

Affirmative Statutory Obligation to Conduct Comparative Analysis

The proposed regulations confirm that plans have an affirmative statutory obligation to conduct the NQTL comparative analysis irrespective of whether they have received a request for the analysis from a Department. They also indicate that a plan's comparative analysis should be updated anytime there is a change in plan design, plan administration or plan utilization that is not reflected in the current analysis.

Sunset of Opt-Out Opportunity for Non-Federal Governmental Plans

The proposed regulations would modify the existing MHPAEA regulations to reflect the sunset provision in the CAA of 2023. Under the law's sunset provision, non-federal governmental plans can no longer make or renew elections to opt out of complying with the MHPAEA on or after 12/29/22. A later date may apply for collectively bargained plans.

Solicitation of Comments

The proposed regulations solicit comments on various other topics related to providing greater access to MH and SUD benefits. Of note, the Departments are seeking comments on ways to further incentivize TPAs to facilitate a plan's comparative analyses and how they could amend the claims and appeal regulations applicable under ERISA and the ACA to further facilitate access to MH and SUD benefits.

Effective Date of Regulations

The Departments have proposed that the amended regulations would apply for plan years beginning on or after January 1, 2025. In the meantime, plans must comply with statutory provisions and existing regulations.

Next Steps

The issuance of these proposed regulations seems to support the general view that the Biden Administration is serious about enforcing the MHPAEA. While plans need not yet comply with the proposed regulations, and there is a definite possibility the final regulations will vary somewhat from the proposed regulations, plan sponsors should consider certain steps in light of the proposed regulations:

1. Confirm the required comparative analysis of NQTLs has been conducted (based on existing guidance from the Departments). This generally involves contacting the plan's insurance carrier or a third-party administrator (TPA).

2. In situations in which the plan's insurance carrier or TPA has not previously agreed to conduct the comparative analysis, take that into account in the course of negotiating new or renewed contacts with the carrier or TPA.

3. Track future developments with the proposed regulations and be prepared to make necessary changes to the plan and/or the plan's NQTL analyses by the date they become effective once they are finalized.

How Brown & Brown Can Help

Connect with your Brown & Brown service team to learn more about how we can help find solutions to fit your unique needs.

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