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Agencies Issue Extensive MHPAEA Guidance: Plan and Issuer Action Required

On July 25 the Departments of Labor, Treasury, and Health and Human Services issued a proposed rule on requirements related to the Mental Health Parity and Addiction Equity Act (MHPAEA). The Proposed Rule, if finalized in its current form, will impose significant new compliance obligations on group health plans and health insurance issuers and would be effective for plan years beginning on or after January 1, 2025.

The focus on the Proposed Rule is on nonquantitative treatment limitations (NQTLs) under MHPAEA. Along with the Proposed Rule, the departments issued a technical release (TR) related to the Proposed Rule's data collection requirements, a report to Congress, an enforcement fact sheet, and an MHPAEA guidance compendium.

EXECUTIVE SUMMARY

This advisory contains background regarding MHPAEA; a detailed analysis of the Proposed Rule, the TR, and the report to Congress; and Practice Pointers, but the following is a summary of the key provisions. We will refer to just "group health plans" or "plans" in this advisory with the understanding that the MHPAEA requirements also apply to health insurance issuers.

NQTLs Must Meet Three Requirements

Of most significance, the Proposed Rule provides that a plan must satisfy three newly stated requirements to impose NQTLs on mental health and substance use disorder (MH/SUD) benefits.

First, an NQTL that applies to MH/SUD benefits can be no more restrictive than the predominant NQTL that applies to substantially all medical/surgical (Med/Surg) benefits within the same MHPAEA benefit classification. This "no more restrictive" requirement borrows the mathematical "substantially all/predominant test" that currently exists for financial requirements and quantitative treatment limitations (collectively QTLs) under the 2013 MHPAEA final rule.

Second, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH/SUD benefits must be comparable to, and applied no more stringently than, those used in designing and applying the NQTL to Med/Surg benefits within the same MHPAEA benefit classification. This requirement codifies the departments' current view of what must be established in an NQTL comparative analysis.

Third, the Proposed Rule would require the use of outcomes data in analyzing NQTLs. The Proposed Rule would require extensive collection of data, such as claims denials, for an NQTL and then compare data outcomes for both MH/SUD and Med/Surg benefits. A "material difference" in outcomes represents a "strong indicator" of an NQTL violation, and certain action would need to be taken and documented. While this data collection requirement applies to all NQTLs, there are additional unique data collection requirements for the "network composition" NQTL. For this NQTL, material differences in the data would go beyond a strong indicator of an MHPAEA violation but would establish that there *was* an actual violation. The TR goes into detail regarding the extensive data that plans would need to collect to establish parity/comparability for the network composition NQTL. Based on this outcomes data, the TR notes the possibility of creating a safe harbor for this specific NQTL. The TR asks for comments on that data collection and safe harbor.

The Proposed Rule does contain important exceptions for "independent professional medical or clinical standards" as well as standards to prevent "fraud, waste, and abuse." Those exceptions apply to each of these three NQTL requirements.

Meaningful Benefits in Each MHPAEA Benefit Classification

The 2013 MHPAEA final rule provides that if a plan provides MH/SUD benefits in one of the MHPAEA benefit classifications, it must provide MH/SUD benefits in all MHPAEA benefit classifications. The Proposed Rule would amend and expand this requirement to require that a plan provide "meaningful benefits" in each classification compared to Med/Surg benefits. The Proposed Rule contains two examples providing clarification of this "meaningful benefits" requirement.

Content of an NQTL Comparative Analysis

The Consolidated Appropriations Act, 2021 (CAA 2021) required each plan to have a written NQTL comparative analysis with five elements: (1) the identification of NQTLs and the MH/SUD and Med/Surg benefits the NQTLs apply to; (2) the factors used to determine application of the NQTLs; (3) the evidentiary standards used to develop the factors; (4) an analysis of processes, strategies, evidentiary standards, and factors demonstrating comparability; and (5) specific findings and conclusions. The Proposed Rule reorganizes and expands on these elements, incorporating a demonstration of the three requirements for NQTLs as part of the comparative analysis.

Other Provisions

The Proposed Rule provides further detail on actions the departments may take if they find an NQTL comparative analysis lacking. The departments, for example, can require that the plan eliminate the NQTL as it applies to MH/SUD benefits. Specific time periods are provided for responding to a department's initial request for an NQTL comparative analysis and follow-up requests.

For ERISA-covered plans, the Proposed Rule provides that the NQTL comparative analysis is an instrument under which a plan is established or operated under Section 104(b)(4) of ERISA and must be provided to participants and beneficiaries within 30 days of a written request. If not provided, the plan administrator could face up to a $110 per day penalty for not providing that comparative analysis.

Previously, state and local governmental plans could opt out of MHPAEA. The Consolidated Appropriations Act, 2023 ended that opt-out and provided a sunset timetable. The Proposed Rule would implement those sunset provisions.

Report to Congress

In many respects, the departments' 2023 MHPAEA Comparative Analysis Report to Congress is like the 2022 MHPAEA Report to Congress. Both reports noted that even though plans were required to have a written NQTL comparative

analysis by February 10, 2021, many plans were still unprepared to submit their comparative analyses upon request. And when the comparative analyses were provided, they failed to contain what the departments viewed as required information. The DOL states that it has "not seen a marked improvement in the sufficiency of the initial comparative analyses received" since 2022.

The 2023 report reiterated four NQTLs the DOL is concentrating its enforcement efforts on, as announced in 2021 FAQs. The 2023 report also added two new NQTLs. Those that were identified in 2022 were (1) prior authorization requirements for in-network and out-of-network inpatient services; (2) concurrent care review for in-network and out-of-network inpatient and outpatient services; (3) standards for provider admission to participate in a network, including reimbursement rates; and (4) out-of-network reimbursement rates (methods for determining usual, customary, and reasonable charges). Added to this list in the 2023 report are (5) impermissible exclusions of key treatments for mental health conditions and substance use disorders; and (6) adequacy standards for MH/SUD provider networks.

The DOL noted its continuing focus on service providers and seeking any plan correction through those service providers. The DOL stated it was expanding its approach by "sending request letters or subpoenas to three more service providers, including some of the largest in the country."

BACKGROUND

The Legislation

MHPAEA was enacted on October 3, 2008 and broadly requires that group health plans and health insurance issuers ensure that the financial requirements and treatment limitations that apply to MH/SUD benefits are no more restrictive than those that apply to Med/Surg benefits. MHPAEA applies to plans sponsored by private and public sector employers with more than 50 employees, including self-funded and fully insured arrangements. The Affordable Care Act, through the requirement to offer "essential health benefits," also made MHPAEA apply to small non-grandfathered fully insured plans.

The 2013 Final Rule

A final rule was issued in 2013 that contained separate provisions for QTLs and NQTLs.

QTLs are "quantitative" or numeric aspects of group health plans such as deductibles, copays, co-insurance, maximum out-of-pocket, and visit limits. The QTLs that apply to MH/SUD benefits are required to be no more restrictive than the predominant QTLs that apply to substantially all Med/Surg benefits in a classification. This is referred to as the "substantially all/predominant test."

The final rule established six benefit classifications. The QTL substantially all/predominant test must be applied to each classification:

- Inpatient, in-network.
- Inpatient, out-of-network.
- Outpatient, in-network.
- Outpatient, out-of-network.
- Emergency care.
- Prescription drugs.

The final rule allowed certain limited subclassifications for drug tiering, in-network tiering, and an outpatient subclassification for office visits.

The Proposed Rule confirms that these classifications and subclassifications apply equally to NQTLs.

> ***Practice Pointer:*** A group health plan cannot expand this list of classifications and subclassifications. For example, there is no separate classification for telehealth. The Proposed Rule emphasizes this point: "The departments expect plans and issuers to treat telehealth benefits the same way they treat those benefits when provided in person in determining the classification or sub-classification in which a particular benefit belongs." There are often different QTLs (copays and co-insurance) that apply to telehealth, raising QTL issues, and often the MH/SUD benefits offered through telehealth might be more limited than those offered for Med/Surg benefits, raising NQTL issues.

For QTLs, the final rule defined "substantially all" as two-thirds and "predominant" as more than one-half. If a QTL does not apply to substantially all Med/Surg benefits in a classification, it cannot apply to any MH/SUD benefits in that classification. For example, if in-network, outpatient Med/Surg services were equally divided between copays and co-insurance (i.e., 50/50), based on claims, then there is no cost-sharing that applied to substantially all (i.e., 2/3) Med/Surg benefits and no cost sharing could then apply to MH/SUD benefits. If, however, copays applied to substantially all Med/Surg benefits in that classification, then an analysis would look to the predominant copay. If, for example, the Med/Surg in-network primary physician office visit copay was $20 and the specialist copay was $40, then based on plan payments, a determination would need to be made on the predominant copay. If the predominant copay was $20, then only a $20 copay could be charged for an MH/SUD in-network office visit and the specialist copay could not be charged. The substantially all/predominant test now takes on added meaning since the Proposed Rule adopts this test for NQTLs in a slightly modified fashion.

The final rule set forth parity protections for NQTLs as well. NQTLs are any limitations on the scope or duration of treatment that are not expressed numerically. The final rule and subsequent guidance provided the following illustrative (nonexclusive) list of NQTLs. This list would be slightly modified under the Proposed Rule.

- Medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative.
- Prior authorization or ongoing authorization requirements.
- Concurrent review standards.
- Formulary design for prescription drugs.
- For plans with multiple network tiers (such as preferred providers and participating providers), network tier design.
- Standards for provider admission to participate in a network, including reimbursement rates.
- Plan methods for determining usual, customary, and reasonable charges.
- 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 of specific treatments for certain conditions.
- Restrictions on applicable provider billing codes.
- Standards for providing access to out-of-network providers.

- 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.

The final rule provided that a plan may not impose an NQTL on MH/SUD benefits in any classification unless, under the terms of the plan as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation to Med/Surg benefits.

CAA 2021

CAA 2021 was enacted on December 27, 2020 and expressly required group health plans to perform and document a comparative analysis of the design and application of NQTLs. Beginning 45 days after CAA 2021's enactment (February10, 2021), a group health plan was required make its comparative analysis available upon request from any department. The comparative analysis must have five different pieces of information as described in the Executive Summary. FAQs issued in April 2021 clarified these requirements and stated that at a minimum a comparative analysis must have a "robust discussion" of nine different elements.

- A clear description of the specific NQTL, plan terms, and policies at issue.
- Identification of the specific MH/SUD and Med/Surg benefits the NQTL applies to within each benefit classification and a clear statement of which benefits identified are treated as MH/SUD and which are treated as Med/Surg.
- Identification of any factors, evidentiary standards or sources, or strategies or processes considered in the design or application of the NQTL and in determining which benefits are subject to the NQTL, including any weighting of factors.
- To the extent the plan defines any of the factors, evidentiary standards, strategies, or processes in a quantitative manner, it must include the precise definitions used and any supporting sources.
- An explanation of any variation in the application of a guideline or standard used by the plan between MH/SUD and Med/Surg benefits and a description of the process and factors used for establishing that variation.
- If the application of the NQTL turns on specific decisions in the administration of the benefits, the plan should identify the nature of the decisions, the decision-makers, the timing of the decisions, and the qualifications of the decision-makers.
- If the plan relies on any experts, the analysis should include an assessment of each expert's qualifications and the extent to which the plan ultimately relied on each expert's evaluations.
- A reasoned discussion of the plan's findings and conclusions on the comparability of the processes, strategies, evidentiary standards, factors, and sources identified within each affected classification, and their relative stringency, both as applied and as written. The discussion should include citations to any specific evidence considered and any results of analyses indicating that the plan or coverage is or is not in compliance with MHPAEA.
- The date of the analysis and the name, title, and position of the person or persons who performed or participated in the comparative analysis.

As noted in the 2022 and 2023 reports to Congress, the departments found that every initial comparative analysis reviewed was insufficient.

THE PROPOSED RULE AND TECHNICAL RELEASE

Purpose of the Rule

The Proposed Rule begins with a new statement of purpose to ensure that:

- MH/SUD "benefits are not subject to more restrictive lifetime or annual dollar limits, financial requirements, or treatment limitations with respect to those benefits than the predominant dollar limits, financial requirements, or treatment limitations that are applied to substantially all medical/surgical benefits covered by the plan."
- Plans "must not design or apply financial requirements and treatment limitations that impose a greater burden on access" to MH/SUD benefits under the plan than they impose on access to generally comparable Med/Surg benefits.
- All statutory and regulatory provisions affecting MHPAEA should be interpreted in a manner consistent with the stated purpose.

> ***Practice Pointer:*** Although the statement of purpose for the Proposed Rule may appear broad and generic, it evidences the departments' intent to take a holistic approach to enforcement to make sure that there is actual parity in operation—requiring a plan to establish that it provides participants and beneficiaries appropriate access to MH/SUD benefits.

New and Revised Definitions

The Proposed Rule would remove perceived flexibility in defining mental health benefits, medical surgical benefits, and substance use disorder benefits by limiting the effect of any reference to state law and specifically requiring the definition to align with "generally recognized independent standards of current medical practice." While plans could still reference state law, they could only do so to the extent state law is consistent with those standards—specifically the most current versions of the Diagnostic and Statistical Manual of Mental Disorders (DSM) or the International Classification of Diseases (ICD).

> ***Practice Pointer:*** In the past, some plans have tried to classify autism spectrum disorders and eating disorders as a Med/Surg condition rather than an MH/SUD condition. The preamble to the Proposed Rule notes that since autism and eating disorder are in the DSM as MH/SUD conditions, they must be covered as MH/SUD conditions and cannot be treated as Med/Surg even if state law might provide otherwise.

There are new definitions for "factors," "processes," "strategies," and "evidentiary standards," which are all currently used in the NQTL comparative analysis. These terms were also used in the 2013 final rule but not defined.

Factors include all information that a group health plan relied on to design an NQTL. The preamble emphasized that "factors" should be read broadly and include all information, including processes and strategies, that were relied on in developing the NQTL. Processes and strategies are then treated as subsets of factors. Factors would also include information that was considered but rejected. This definition has a nonexhaustive list of factors such as provider discretion in determining a diagnosis or type or length of treatment, clinical efficacy of any proposed treatment or service, licensing and accreditation of providers, claim types with a high percentage of fraud, quality measures, treatment outcomes, severity or chronicity of condition, variability in the cost of an episode of treatment, high cost growth, variability in cost and quality, elasticity of demand, and geographic location.

Processes are actions, steps, or procedures that a group health plan uses to apply an NQTL. Processes can include actions, steps, or procedures established by the plan for a participant or beneficiary to access benefits. For example, processes can include things such as the actual written and operational steps of a preauthorization process or a

concurrent review process. They could also include the development and approval of a treatment plan. This definition provides other nonexclusive examples of processes.

Strategies are practices, methods, or internal metrics that a plan considers, reviews, or uses to design an NQTL. Some examples of strategies provided in this definition include the development of the clinical rationale used in approving or denying benefits, deviation from generally accepted standards of care, the selection of information deemed reasonably necessary to make a medical necessity determination, and rationales used in selecting and adopting certain threshold amounts, professional protocols, and fee schedules.

Evidentiary standards are any evidence, sources, or standards that a group health plan considered or relied on in designing or applying a factor in an NQTL. They include specific benchmarks and thresholds. Evidentiary standards may be empirical, statistical, or clinical in nature. They include items such as recognized medical literature, professional standards and protocols, published research studies, payment rates for items and services (such as publicly available databases of the "usual, customary, and reasonable" rates paid for items and services), clinical treatment guidelines, and internal plan data or criteria for assuring a sufficient mix and number of network providers. The Proposed Rule emphasizes in several places that evidentiary standards are used to develop factors and are not factors themselves.

> ***Practice Pointer:*** Although the definitions are only in the Proposed Rule, factors, processes, strategies, and evidentiary standards are all key aspects of what the departments currently view as central requirements of an NQTL comparative analysis. Using these definitions as part of a comparative analysis should satisfy the departments that correct definitions are being used.

Although not contained in the definitions section of the Proposed Rule, there is a change in wording in the nonexhaustive sample list of NQTLs. What was previously described as "[s]tandards for provider admission to participate in a network, including reimbursement rates" has been replaced and expanded with "standards related to network composition, including but not limited to, standards for provider and facility 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 covered services under the plan or coverage." The preamble notes that, in the departments' view, the standards that govern how a network is constructed and defined is a critical NQTL affecting the delivery and availability of MH/SUD benefits. The Proposed Rule contains specific new provisions for network composition.

The Substantially All/Predominant Test as Applied to NQTLs

As mentioned in the Executive Summary, for NQTLs the Proposed Rule would apply the substantially all/predominant test that currently applies to QTLs. If finalized, this test might dramatically affect plan design. The previous understanding of the 2013 final rule was that a plan could have an NQTL, such as prior authorization, that applies to some but not all MH/SUD benefits and applies to some but not all Med/Surg benefits. Then, if the factors, processes, strategies, and evidentiary standards in developing and applying the NQTL were comparable for MH/SUD and Med/Surg benefits, there was no MHPAEA violation even if the NQTL applied to more MH/SUD than Med/Surg benefits. There is an example of this concept in the final rule. That example is deleted in the Proposed Rule and replaced by one incorporating the substantially all/predominant test and the proposed required analysis of data outcomes.

The first part of this test is that any NQTL that applies to MH/SUD benefits in a classification must apply to substantially all Med/Surg benefits in that classification. "Substantially all" is defined as two-thirds. While the Proposed Rule gives several examples of the "predominant" requirement of this test, it does not provide an example solely dedicated to just the substantially all part of the test. But looking at the actual Proposed Rule itself, it could affect NQTLs such as

preauthorization especially for outpatient benefits (whether in network or out of network). If the preauthorization requirement does not apply to at least two-thirds of the Med/Surg benefits in the applicable classification, then it cannot be imposed on MH/SUD benefits in that classification.

> ***Practice Pointer:*** Intensive outpatient treatment and partial hospitalization are usually treated as outpatient benefits for MH/SUD purposes. Those treatments are often subject to preauthorization. Under the Proposed Rule, preauthorization could not be required for these benefits in an outpatient, in-network classification unless preauthorization was required for two-thirds of Med/Surg benefits in that classification. We believe that many plans will have difficulty meeting this threshold. Under the Proposed Rule, all outpatient NQTLs will need to be examined closely. There are, however, important exceptions for "independent professional medical or clinical standards," as well as standards to prevent "fraud, waste, and abuse."

The substantially all determination is made based on the dollar amounts expected to be paid for Med/Surg benefits in the particular classification for the plan year. Any reasonable method may be used. In the preamble, the departments make several observations on this testing. They refer to the rules on QTL testing and the credibility of data with distinctions made between self-funded, large group market, and small group market plans. They state that in making any projections plans should "document the assumptions used in choosing a data set and making projections." Similar to QTL testing, they indicated that testing is not required each plan year "unless there is a change in plan benefit design or utilization that would affect an NQTL within a classification."

The departments acknowledge that the substantially all/predominant test does not always fit neatly into an NQTL context and ask for further comments, including on whether there are systems in place to perform this testing.

If the substantially all part of the test is met, then a plan may still only apply the predominant Med/Surg form of the NQTL. The Proposed Rule defines "predominant" as "the most common or frequent variation of the NQTL" (this is slightly different than the "more than one-half" standard for "predominant" in QTL testing). There is also no definition of what constitutes a variation of an NQTL. As with the substantially all part of the test, which variation of the NQTL is predominant is also based on projected plan payments.

The Proposed Rule does provide two examples. The first is a preauthorization requirement that applies to all inpatient, in-network benefits—both MH/SUD and Med/Surg. Med/Surg benefits are approved for periods of one, three, and seven days, after which a treatment plan must be submitted. Based on projected plan payments, preauthorizations for seven days is the most common duration. For MH/SUD, preauthorizations are most commonly given for only one day. In this example, the departments find an MHPAEA violation. The plan satisfies the substantially all requirement since preauthorization is required for every benefit in the inpatient, in-network classification. The plan, however, fails the predominant test because the most common approval for MH/SUD is one day instead of the predominant seven days for Med/Surg. This example does assume that the difference in duration is not the result of independent professional medical or clinical standards or standards to detect or prevent and prove fraud, waste, and abuse.

In another example, concurrent review is required for every inpatient, in-network facility stay. In each instance there is a first-level concurrent review, and if the first-level reviewer is unable to make a medical necessity determination to allow a continued stay, it is escalated to a second-level review. At this second level, the plan, in operation, conducts a peer-to-peer review for MH/SUD benefits while not requiring a peer-to-peer for Med/Surg. Here again, the concurrent review requirement applies to all benefits in the specific category so the substantially all test is satisfied. The predominant variation of the concurrent review NQTL at the second level of review for Med/Surg is not to apply a peer-to-peer requirement. Accordingly, the departments conclude the peer-to-peer requirement in operation for MH/SUD benefits at the second level would be an MHPAEA violation. Once again, the example assumes that the

application of peer-to-peer for MH/SUD is not the result of any impartially applied independent professional medical or clinical standards or standards to detect or prevent and prove fraud, waste, and abuse.

> ***Practice Pointer:*** Distinctions between NQTLs for purposes of the substantially all part of the test and variations in NQTLs for the predominant part of the test may be difficult. It is unclear when a variation in an NQTL becomes so significant that it is actually a separate NQTL.

The Design and Application Requirement

The Proposed Rule contains a design and application requirement that applies the factors, processes, strategies, and evidentiary standards requirements that plans have been laboring over for the past two and one-half years in documenting an NQTL comparative analysis. This requirement states that an NQTL cannot be imposed "under the terms of the plan as written and in operation" unless "any processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the limitation with respect to medical/surgical benefits in the classification." This language is almost identical to the 2013 final rule, but that rule was limited to "applying" the NQTL, and the word "designing" has been added in the Proposed Rule. The preamble notes that this provision is intended to codify the departments' "consistent interpretation" on the current requirements for NQTLs and to bring it in harmony with the CAA 2021 statutory requirements.

The Proposed Rule adds a provision that a plan cannot rely on a factor or evidentiary standard if the basis of the factor or evidentiary standard "discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits." Impartially applied independent professional medical or clinical standards or standards to detect or prevent fraud, waste, and abuse are specifically listed as *non*discriminatory.

Required Use of Outcomes Data

NQTLs other than network composition

In designing and applying an NQTL, the Proposed Rule would require plans to "collect and evaluate relevant data" to assess the impact an NQTL has on MH/SUD benefits compared to Med/Surg benefits. The manner and form of that data request (except for network composition) is left open to further guidance from the departments, but specifically mentioned are claims denials and data required by state law or private accreditation standards.

> ***Practice Pointer:*** This requirement would codify what the departments are already doing with MHPAEA examinations in practice. In their April 2021 FAQs, the departments noted that a plan should be prepared to provide, as part of an examination, "internal testing" performed as well as "samples of covered and denied MH/SUD and medical/surgical benefit claims." The DOL, in its investigations, insists that data analysis is part of the required stringency testing. The 2023 report emphasized that the DOL currently requests this sort of data in any examination. In fact, the DOL noted that "Data showing the effect of an NQTL's application were particularly important and sometimes operated as a 'green flag' signaling that an NQTL in question did not appear to apply more stringently to MH/SUD benefits relative to medical/surgical benefits."

If the analysis of the outcomes data reveals "material differences" in access to MH/SUD benefits compared to Med/Surg benefits, then the Proposed Rule states that this is a "strong indicator" that the NQTL violates MHPAEA. The Proposed Rule then requires the plan to take "reasonable action" to address the material differences and then document the action taken to mitigate those material differences. Neither the Proposed Rule nor the TR defines "material differences," but the departments have requested comments on how to define the term.

The preamble to the Proposed Rule states that, except for network composition, material differences alone would not be dispositive of a violation but reasonable action would need to be taken. The preamble further provides:

> Whether any particular action would be considered reasonable in response to any given material differences in access resulting from an evaluation of outcomes data would be determined based on the relevant facts and circumstances, including the NQTL itself, the relevant data, the extent of the material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, and the impact of the material differences in access on participants and beneficiaries.

A discussion of that reasonable action would then be a required element of the plan's NQTL comparative analysis. The preamble notes that this inclusion in the comparative analysis would allow plans "to explain why material differences in access demonstrated by the outcomes data should not result in a violation of the rules for NQTLs."

Required data collection for the network composition NQTL and the TR

The Proposed Rule emphasizes the importance of the network composition NQTL in providing access to MH/SUD benefits. This NQTL is different from other NQTLs in two ways. First, material differences would not just be a strong indicator of an NQTL violation—they *would actually be* an NQTL violation. Second, the Proposed Rule states data collection requirements for this NQTL that are in addition to those required for all NQTLs. This additional data collection includes 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 compared to billed charges).

The TR provides further clarification on the departments' thinking on the data collection for this NQTL and seeks comments. Under the TR there would be four data collection requirements.

The first requirement would be out-of-network utilization. Data collection and evaluation would be required on the percentage of covered and submitted out-of-network claims for MH/SUD benefits compared to Med/Surg benefits. The TR proposes that the data collection and evaluation would be on the following out-of-network services:

- Inpatient, hospital-based services.
- Inpatient, non-hospital-based services (one focus here is comparing Med/Surg services for rehabilitation facilities and skilled nursing facilities with residential treatment facilities for MH/SUD services).
- Outpatient facility-based items and services (intensive outpatient and partial hospitalization are among those particularly noted here).
- Outpatient office visits.
- Other outpatient items and services.

The second requirement would be the percentage of in-network providers actively submitting claims. Here, the departments believe that plans have provider network directories that include providers not actually providing services and term this a "ghost network." Plans would be required to collect and evaluate the percentage of in-network providers who submitted no in-network claims and the percentage of in-network providers who submitted claims for fewer than five unique participants and beneficiaries during a specified period. The TR designates the types of providers that the departments are considering requiring for this data collection.

The third requirement would be time and distance standards for participants and beneficiaries to obtain MH/SUD services compared to Med/Surg services. Time and distance standards are already required for Medicare Advantage

plans. The data collection and analysis would include data on the percentage of participants and beneficiaries who can access, within a specified time and distance by county-type designation, at least one in-network MH/SUD provider and at least one in-network MH/SUD provider. The TR specifies certain types of MH/SUD and Med/Surg providers the departments are considering for this data collection. For MH/SUD providers, the TR specifically mentions, among others, child and adolescent providers, geriatric providers, eating disorder providers, and autism spectrum disorder providers. The departments envision using the same county-type designations used for Medicare Advantage Plans.

The fourth requirement would be reimbursement rates of in-network MH/SUD providers compared to Med/Surg providers. Plans would be required to collect data on reimbursement rates for yet-to-be-specified types of MH/SUD providers and yet-to-be-specified types of Med/Surg providers. That data collection would be for specified CPT codes (the TR mentions four). The analysis would then determine any material differences between in-network payments (compared to billed charges) for MH/SUD benefits and Med/Surg benefits. There would also be a comparison of allowed amounts and a comparison against a Medicare benchmark.

Practice Pointer: The Proposed Rule's data collection requirement and the substantially all/predominant test would dramatically change the way NQTLs are analyzed. While factors, processes, strategies, and evidentiary standards would still be a part of validating NQTLs, these inherently contain some subjectivity and provide plans some leeway in designing NQTLs. Previously, the departments stated that comparable application of these criteria was the "test" and that outcomes were *not* determinative. Now, at least for the substantially all/predominant test and for the network composition NQTL, outcomes *will be* determinative.

The TR has approximately 75 issues that the departments have asked for specific comments (many with subparts). So it is likely that the data collection requirement for NQTLs will be further refined when the Proposed Rule is finalized.

The TR suggests that this data collection and analysis be performed by a third-party administrator (TPA) or other service provider in the aggregate for all plans that use the same network of providers or reimbursement rate.

If there is a material difference based on any of these four data collections, then the Proposed Rule would find that the plan's network composition NQTL is not valid. That does not mean automatic enforcement of the violation by the departments. The preamble to the Proposed Rule states that the departments will not cite a plan for a violation if there is a shortage of MH/SUD providers in a geographic area and where, despite proper action, and through no fault of the plan itself, that shortage persists—provided that the plan is otherwise compliant with MHPAEA. The preamble goes on to state that plans should document the actions they have taken to resolve the disparity and demonstrate why any disparities are attributable to provider shortages in the geographic area and are due to factors other than NQTLs related to network composition. The departments request comments on this provision, including on whether and how to allow plans to account for external circumstances that impact material differences in access.

A possible safe harbor for the network composition NQTL

The TR raises the possibility of a future safe harbor for the network composition NQTL. If plans meet or exceed future specified standards on the four data elements, they would not be subject to an enforcement action by the departments for the network composition NQTL for a period that would be specified in future guidance. That safe harbor would include a "variety of metrics" on the four data elements. The safe harbor would cover all the following for network composition: standards for provider and facility admission to participate in a network or for continued network participation, 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 departments are proposing that the safe harbor will last two calendar years beginning with the time the comparative analysis is requested. To be able to rely on the proposed safe harbor, however, no changes could be made that would affect the network composition NQTL, and certain other NQTL modifications would be prohibited as well. The departments expect that the safe harbor would set a "high bar" but are considering a phased-in approach in which plans can demonstrate progress toward meeting or exceeding the standards over the course of multiple plan years.

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

All three of the NQTL requirements have exceptions or provisions for independent professional medical or clinical standards or standards to detect fraud, waste, and abuse. For the application and design requirement, this comes in the way of stating that these standards are nondiscriminatory. For the other two NQTL requirements, it is a specific exception.

The Proposed Rule itself is terse on these important exceptions. To fall within the independent professional medical or clinical standards exception, a plan must "impartially apply generally recognized independent professional medical or clinical standards (consistent with generally accepted standards of care) to medical/surgical benefits and mental health or substance use disorder benefits, and may not deviate from those standards in any way, such as by imposing additional or different requirements."

To qualify for the fraud, waste, and abuse exception, an NQTL "must be 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, and also be narrowly designed to minimize the negative impact on access to appropriate mental health and substance use disorder benefits."

The preamble provides slightly more explanation and emphasizes that these exceptions are not intended as a "loophole" and are "narrowly tailored." The departments do recognize that these exceptions improve health care and outcomes. But the departments warn that if they become aware of the creation of new standards for the purpose of imposing NQTLs that are more restrictive for MH/SUD benefits, they may provide additional guidance consistent with MHPAEA's fundamental purpose. Recognizing that these exceptions could be subject to various interpretations, the departments are soliciting comments on ways to better or more fully frame these exceptions.

> ***Practice Pointer:*** When an NQTL cannot satisfy the substantially all/predominant test or when an analysis of the data collection reveals "material differences," the exceptions or provisions for independent professional medical or clinical standards or standards to detect fraud, waste, and abuse will be critically important if the plan wants to maintain the NQTL.

The Meaningful Benefit Requirement

The final rule provided that if a plan provides MH/SUD benefits in one of the MHPAEA classifications it must provide benefits in all the classifications. The Proposed Rule expands this requirement to provide "meaningful benefits" when compared to Med/Surg benefits in that classification. Two examples in the Proposed Rule demonstrate this requirement. In one, a plan covers outpatient, out-of-network developmental evaluations for autism spectrum disorder (ASD) but excludes all other ASD services in that classification, including applied behavior analysis (ABA). For Med/Surg, the plan provides a "full range" of outpatient treatments for services in this classification. The departments conclude that since the plan only covers one type of benefit for ASD in the classification but provides a full range of Med/Surg benefits in the same classification, it has not met the meaningful benefit requirement.

In another example, a plan covers diagnosis and treatment for outpatient, in-network eating disorders but does not provide nutritional counseling for that disorder. The plan generally provides Med/Surg benefits for primary treatments in that classification. The departments conclude that since nutritional counseling is one of the primary treatments for eating disorders, the plan does not provide meaningful benefits for eating disorders compared to the services provided for Med/Surg benefits in that classification.

Content Requirements for an NQTL Comparative Analysis

The Proposed Rule would reshape the content of the NQTL comparative analysis by incorporating the data collection requirements and the substantially all/predominant test. Other organizational and substantive changes are made as well. There are six separate requirements with multiple subparts under each requirement. Under the Proposed Rule, including subparts, there would be approximately 40 requirements for a comparative analysis (some that might not apply to all plans).

The six broad requirements are:

- Description of the NQTLs: There are four subparts here, including the results of the substantially all/predominant NQTL testing and how the plan identified the variations of the NQTL for the predominant aspect of that testing.
- Identification and definition of the factors used to design or apply the NQTL: Here, with five different subparts, the plan will identify and give a detailed description of the factors relied on to design and apply the NQTL and the evidentiary standards supporting those factors.
- Description of how the factors are used in the design and application of the NQTL: This requirement (with 10 different subparts) codifies much of the prior 2021 FAQs on the content of an NQTL comparative analysis.
- Determination of comparability and stringency as written: There are 10 different subparts for this requirement.
- Determination of comparability and stringency in operation: The "as written" and "in operation" stringency requirements are similar in that they both require discussion of the results of the data collection and analysis. Stringency in operation is more detailed, requiring identification of the data collected, an evaluation of the outcomes of the data, a detailed description of any material differences found that are not attributable to differences in the comparability or stringency of the NQTL, and measures taken to mitigate any material differences.
- Findings and conclusions: There are five different subparts for this requirement.

> ***Practice Pointer:*** If the Proposed Rule is finalized, every NQTL comparative analysis will need to be updated and expanded.

The NQTL Comparative Analysis Process

The Proposed Rule would provide further clarity on the NQTL comparative analysis process. When a department requests an NQTL comparative analysis from an employer, it typically provides a very short timeframe for response. The departments emphasize that under the CAA 2021 that comparative analysis should have been prepared by February 10, 2021. Similarly, the departments typically provide short timeframes for employers to respond to follow-up requests. Under the Proposed Rule, each of those time periods would be codified as 10 business days.

If there is a final finding of noncompliance with the comparative analysis, the CAA 2021 required that the plan notify all participants and beneficiaries of that noncompliance within seven calendar days. The Proposed Rule now contains eight content requirements for that notice, including a statement "prominently displayed" and in no less than 14-point type that the applicable department "has determined that [the group health plan] is not in compliance with the Mental

Health Parity and Addiction Equity Act." The Proposed Rule specifies the delivery method for the notice and allows an internet posting if the participant or beneficiary is notified in paper form (such as a postcard) that the notice is posted on the internet.

Also, if there is a final determination that a group health plan is noncompliant with the comparative analysis requirement, the departments can direct the plan not to apply any NQTL where that analysis was noncompliant until the plan comes into compliance.

For ERISA-covered plans, the Proposed Rule would codify the DOL's position previously expressed in FAQs that the NQTL comparative analysis is an instrument under which the plan is established or operated for purposes of Section 104 of ERISA. Under the Proposed Rule, plan administrators must provide the comparative analysis to participants and beneficiaries within 30 days following a written request or potentially face a $110 per day penalty.

Also, for ERISA-covered plans there must be a certification by one or more named fiduciaries that they have reviewed the comparative analysis and found it to be in compliance with the Proposed Rule's content requirements.

THE 2023 REPORT TO CONGRESS

The 2023 report covered DOL actions between November 1, 2021 to July 31, 2022 and Centers for Medicare & Medicaid Services (CMS) actions between March 25, 2022 to June 6, 2022, although both departments give statistics from the 2022 report going back to February 2021. Both departments found the same deficiencies stated in the 2022 report.

The DOL has six current NQTL enforcement priorities. Four were previously announced and two are new:

- Prior authorization requirements for in-network and out-of-network inpatient services.
- Concurrent care review for in-network and out-of-network inpatient and outpatient services.
- Standards for provider admission to participate in a network, including reimbursement rates.
- Out-of-network reimbursement rates (methods for determining usual, customary, and reasonable charges).
- New: Impermissible exclusions of key treatments for mental health conditions and substance use disorders.
- New: Adequacy standards for MH/SUD provider networks.

The DOL has placed an increased enforcement emphasis on network composition and participation standards, which also includes how plans set their reimbursement rates. The DOL reports that it is pursuing over 20 network admission standards investigations.

The DOL notes that it is currently devoting 25% of the Employee Benefits Security Administration enforcement program to focus on NQTLs. This is a dramatic shift from years ago when DOL investigations almost always centered on retirement plans and investigations of health and welfare plans were a relative rarity. Also, the DOL states that during the reporting period that it "continued to expand staffing dedicated to MHPAEA enforcement, including an increase of over 30 investigators and technical experts."

The DOL is prioritizing potential violations stemming from actions of service providers since those potential violations may affect hundreds or thousands of plans. During the reporting period, the DOL indicates that it worked with 20 service providers to obtain corrections.

During the reporting period, the DOL took the following actions:

- 25 initial letters requesting comparative analyses for 69 NQTLs.
  - Prior authorization, exclusion of ABA and other therapies, network admission (including reimbursement rates), and concurrent care review were the top four NQTLs for which a comparative analysis was requested.
- 52 insufficiency letters covering over 100 NQTLs.
- 22 initial determination letters finding that plans and issuers had violated MHPAEA's requirements for 26 NQTLs.
- 3 final determination letters finding MHPAEA violations for 3 NQTLs.

The DOL notes that the majority of corrections it obtained were without the need to issue notices of noncompliance.

During the reporting period, the DOL found that none of the comparative analyses initially submitted were sufficient to demonstrate compliance. The DOL also mentions a lack of data to support the comparative analyses that were ultimately submitted. Also, because of NQTL operational compliance issues identified by the DOL, it is "increasingly conducting full investigations" into MHPAEA compliance.

> ***Practice Pointer:*** An insufficient NQTL comparative analysis can lead to a full DOL MHPAEA investigation, which can often span several years and involve numerous data requests, subpoenas, interviews, and depositions.

CMS's reporting was largely similar to the DOL's but was limited to 21 comparative analyses for six state and local governmental plans and five health insurers. CMS's focus was on preauthorization and concurrent review NQTLs.

NEXT STEPS

There is no set timetable for the Proposed Rule to be finalized. Comments on the Proposed Rule and the TR must be submitted to the departments by October 2, 2023, and it is unknown what, if any, aspects of the Proposed Rule may be modified. In the interim, employers, TPAs, and health plans should:

- Work together to make sure there is a compliant NQTL comparative analysis under the CAA 2021 and existing guidance. The 2022 and 2023 Reports to Congress, April 2021 FAQs, and the existing MHPAEA Self-Compliance Tool provide guidance on completing that NQTL comparative analysis.
- Document that a plan fiduciary has actually reviewed the NQTL comparative analysis with the TPA/ASO or other service provider.
- While all NQTLs should be in the analysis, focus on the six NQTLs that the DOL has identified as enforcement priorities.
- Of those six NQTLs, note that network composition including network provider reimbursement rates is an area of increasing scrutiny. Appendix II of the MHPAEA Self-Compliance Tool, "Provider Rate Reimbursement Rate Warning Signs," provides a data framework for analyzing reimbursement rates. We do, however, expect a new version of the MHPAEA Self-Compliance Tool sometime this year.
- In addition to the Appendix II framework, work together to perform additional data stringency analyses on various NQTLs. For example, a comparison of denial/approval rates on requests for preauthorization for Med/Surg and MH/SUD claims in each MHPAEA classification.
- Begin working with your your health plan, insurer, and TPA/ASO on how they will comply with the data collection and analyses requirements contained in the Proposed Rule and the TR even though exact parameters of those requirements are not known.

- As part of the NQTL comparative analysis, isolate "variations" of any NQTL in anticipation of performing the substantially all/predominant testing.
- Confirm that your health plan, insurer, and TPA/ASO will revise (or work with you in revising) any NQTL comparative analysis to conform with the Proposed Rule once finalized.
- Review any service provider agreement to have clear provisions on the respective responsibilities to provide the comparative analysis or information to complete that analysis if another service provider is going to perform this function. Specify any additional fees for this service and indemnification/remedies for failure to comply.

We will discuss the new Proposed Rules and mental health parity in depth at our Health & Welfare Benefits Monthly Update webinar on September 7 at 12:30 pm ET. Please click here to RSVP.

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