ACA, HIPAA AND FEDERAL HEALTH BENEFIT MANDATES:

PRACTICAL Q&A

The Affordable Care Act (ACA), the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and other federal health benefit mandates (e.g., the Mental Health Parity Act, the Newborns and Mothers Health Protection Act, and the Women's Health and Cancer Rights Act) dramatically impact the administration of self-insured health plans. This monthly column provides practical answers to administration questions and current guidance on ACA, HIPAA and other federal benefit mandates.

Attorneys John R. Hickman, Ashley Gillihan, Carolyn Smith, Ken Johnson, Amy Heppner, and Laurie Kirkwood provide the answers in this column. Mr. Hickman is partner in charge of the Health Benefits Practice with Alston & Bird, LLP, an Atlanta, New York, Los Angeles, Charlotte, Dallas and Washington, D.C. law firm. Ashley, Carolyn, Ken, Amy, and Laurie are senior members in the Health Benefits Practice. Answers are provided as general guidance on the subjects covered in the question and are not provided as legal advice to the questioner's situation. Any legal issues should be reviewed by your legal counsel to apply the law to the particular facts of your situation. Readers are encouraged to send questions by E-MAIL to Mr. Hickman at john.hickman@alston.com.

AGENCIES ISSUE EXTENSIVE MHPAEA GUIDANCE:

PLAN AND TPA 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 Article contains background regarding MHPAEA, a detailed analysis of the Proposed Rule, the TR, and the Report to Congress as well as Practice Pointers but the following is a summary of the key provisions. We will refer to just "group health plans" or "plans" in this Article with the understanding that the MHPAEA requirements are also applicable to health insurance issuers. This article is part 1, with part 2 continuing in the November issue of *The Self-Insurer*.

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

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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.

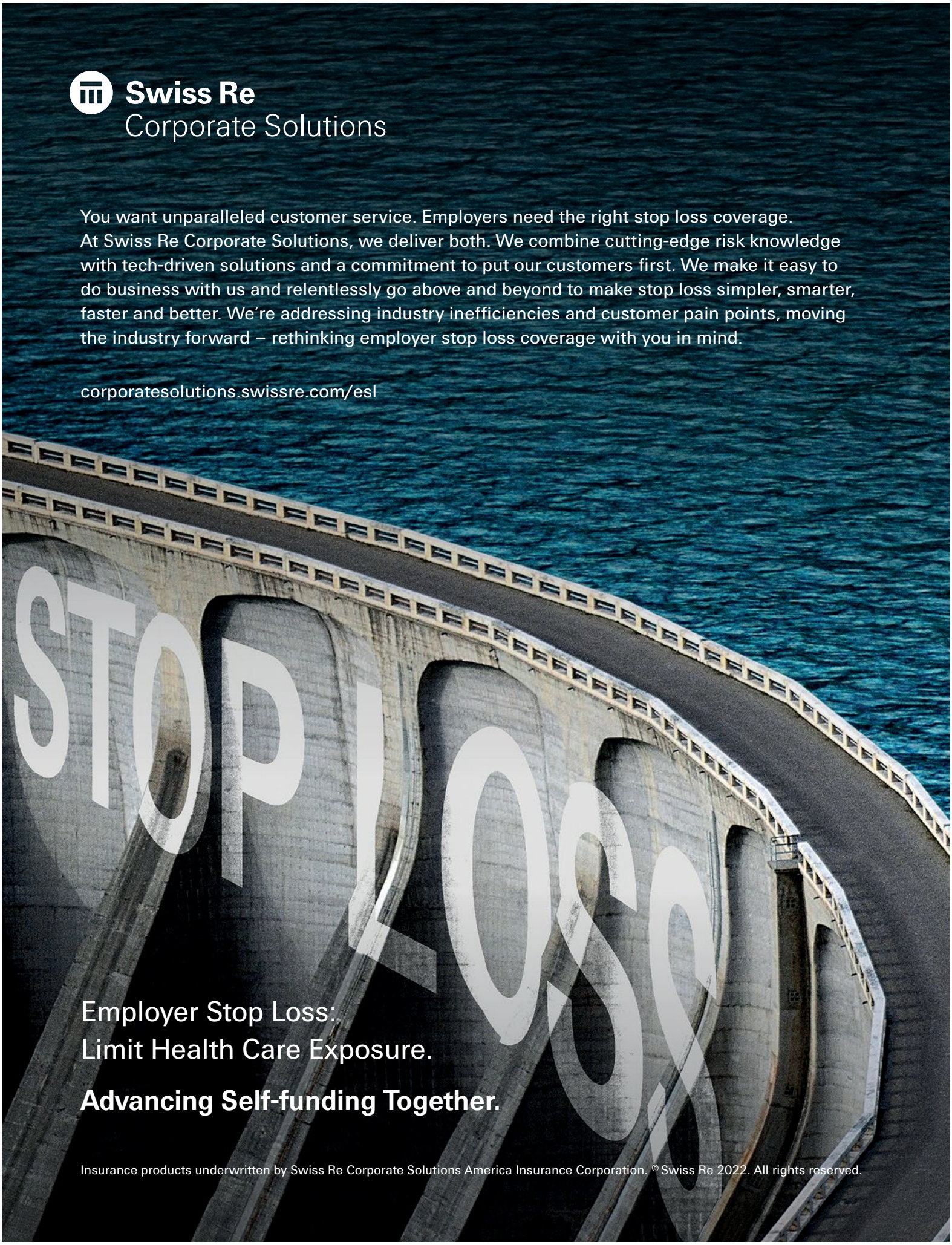
REPORT TO CONGRESS

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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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

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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 above. 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 a 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.

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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, preauthorization for seven days is the most common duration. For MH/SUD, preauthorization is 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.

Part 2 of this article will continue in the November issue of *The Self-Insurer*. ■