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 2, with part 1 in the October issue of The Self-Insurer.

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 nondiscriminatory.

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

INSURANCE SOLUTIONS

DESIGNED FOR YOUR NEEDS

You deserve more than one-size-fits-all insurance. At Companion Life Insurance Company, we provide personalized service and take the time to really listen. Our relationship with you matters, and we offer custom solutions designed for your unique needs.

Choose Companion Life for insurance that works for you:

- Stop Loss Insurance
- Limited-Benefit Health Insurance
- Short Term Medical Insurance
- Group Medical Supplemental Insurance
- Life Insurance
- Dental Insurance
- Short Term Disability Insurance
- Long Term Disability Insurance
- Vision Insurance
- Critical Illness Insurance

Companion Life

Companion Life Insurance Company | 800-753-0404 | CompanionLife.com

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.

Is your payments solution delivering **more** to your bottom line?

Expect **more** with ECHO®

echo
payments simplified

echohealthinc.com

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.

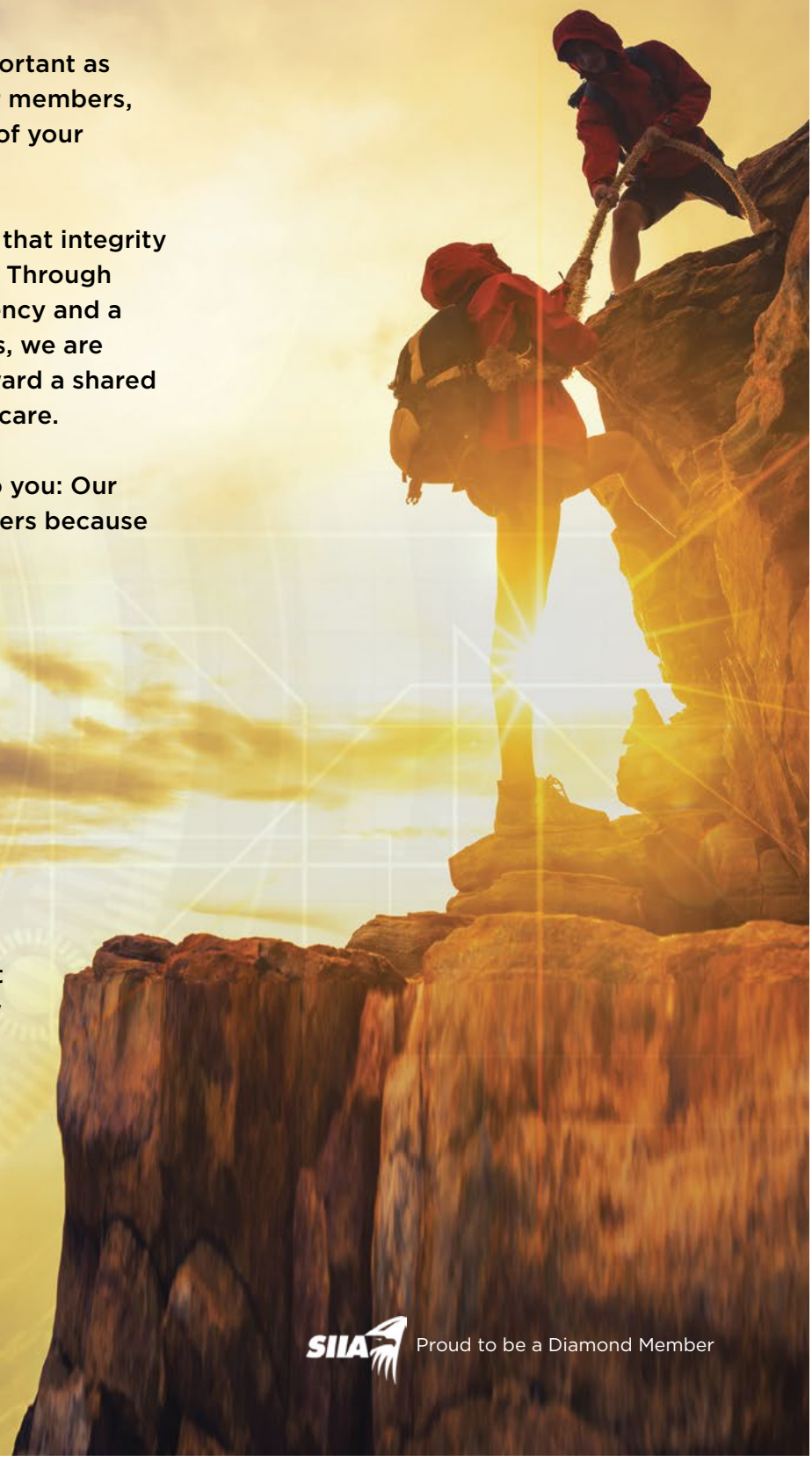
CONNECT AT A HIGHER LEVEL.

When you entrust something as important as the health of your business and your members, you look for integrity as the anchor of your partnership.

We earn your trust by incorporating that integrity into every step of the claim process. Through complete alignment, deep transparency and a platform of fully integrated solutions, we are committed to climbing together toward a shared goal of smarter, better, faster healthcare.

That's the Vālenz® Health promise to you: Our customers stay with us as true partners because no one else does what we do.

Learn more about how to connect at a higher level with Valenz in the new plan year. Visit **valenzhealth.com** or call **(866) 762-4455**.



Vālenz® HEALTH

SIIA Proud to be a Diamond Member

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 should:

- Work with their TPAs/ASOs 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, together with your TPAs/ASOs, 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 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 with your TPA/ ASO that they 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 with the TPA/ASO to have clear provisions on the TPA/ASO's responsibility 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. ■