Mental Health and Substance Use Disorder Parity Compliance: Navigating New Proactive Documentation Requirements and Shifting Federal Enforcement Priorities

David Shillcutt is an Associate in the Health Care and Life Sciences practice, in the Washington, DC, office of Epstein Becker Green. He can be reached at dshillcutt@ebglaw.com.

Kevin Malone is a Senior Counsel in the Health Care and Life Sciences practice in the Washington, DC, office of Epstein Becker Green and a Strategic Advisor in the firm's affiliated consulting practice EBG Advisors. He can be reached at kmalone@ebglaw.com.

Helaine Fingold is a Member of the Firm in the Health Care and Life Sciences practice, in the Baltimore office of Epstein Becker Green. She can be reached at hfingold@ebglaw.com.

Lesley Yeung is a Member of the Firm in the Health Care and Life Sciences practice in Epstein Becker Green's Washington, DC, office. She can be reached at lyeung@ebglaw.com.

David Shillcutt / Kevin Malone / Helaine Fingold / Lesley Yeung

In the absence of needed guidance with respect to the implementation of recent Congressional amendments to the federal Mental Health Parity and Addiction Equity Act (MHPAEA), stakeholders can gain key insights into the federal enforcement approach on parity from a new set of Frequently Asked Questions (FAQs) issued by the federal Departments of Labor (DOL), Health and Human Services (HHS), and Treasury (collectively, "the Departments").[1] The new parity documentation requirements, enacted through the Consolidated Appropriations Act, 2021 (CAA) on December 27, 2020, are already in effect as of February 10, 2021. Accordingly, plans and issuers must ensure that they understand and are prepared to provide regulators with documentation of their compliance with parity requirements on at least a small group of specific non-quantitative treatment limits (NQTLs), as the Departments have declined to explicitly exercise their enforcement discretion to provide affected entities with an extended timeline for compliance with the new requirements.

Proactive Documentation Requirements Added by Congress under The Consolidated Appropriations Act

Within the CAA, Congress added new requirements for group health plans and health insurance issuers to proactively document their compliance with MHPAEA requirements regarding NQTLs using a mandatory five-step framework for analysis. Plans and issuers also must

make such analyses available to DOL, HHS, or applicable state authorities upon request, along with any other information or documentation that the regulator determines is necessary to determine compliance. If, upon review of the analysis, the Departments find that a plan or coverage is not in compliance, the plan is afforded 45 days to implement a corrective action plan. If the regulator determines that the plan or coverage is still not in compliance after the 45-day corrective period, the plan, or issuer must notify all enrollees or members within seven days that the coverage has been determined to be noncompliant with MHPAEA.

The CAA also grants DOL new authority to exercise enforcement directly against issuers of individual and small group health plans, in contrast to the general rule that only the plan administrator is subject to direct oversight by DOL. Third-party administrators (TPAs) for self-insured health plans, pharmacy benefit managers (PBMs), and related health plan service vendors are not subject to direct federal oversight and enforcement but may be contractually obligated to assist a health plan with developing parity compliance documentation.

The Need for Guidance

The new documentation requirements of the CAA shift the essential question that health plans and issuers must ask from "does this policy or procedure violate parity?" to "how can we objectively demonstrate that this policy or procedure does not violate parity?" This shift in enforcement of parity requirements had already occurred in a number of states that have passed comparable state-level requirements over the course of the past two to three years, so plans and issuers operating in these states already have some experience with this new federal approach to enforcement. Nonetheless, significant questions remain about how these documentation requirements should be fulfilled in practice, including:

- ***Which NQTL analyses must be documented?*** MHPAEA regulations broadly define the concept of an NQTL, and the list of NQTLs provided in the regulations is explicitly stated to be illustrative only and non-exhaustive.
- ***How should the five-step framework be applied to each specific NQTL type?*** Required elements of the parity analysis such as "factors" and "evidentiary standards" can have vastly different meanings in the context of NQTLs related to utilization management, provider networks and contracting, prescription drug formularies, and other disparate aspects of health plan designs and operations, and some of the required steps of the analysis, as framed in the statute, do not have intuitive relevance to all NQTL types.
- ***What is the proper scope and depth of detail that must be provided for each step of the analysis framework?*** Current analyses vary dramatically in length and granularity. We have seen analyses as short as two pages and as long as 60 pages for the same NQTL type.

The CAA requires the Departments to issue guidance under this section of MHPAEA, as amended, and to "finalize any such draft or interim guidance" within 18 months of enactment. The legislation specifically adds a new requirement for guidance regarding the process and timelines for consumers to file parity compliance complaints, though to date, our understanding is that few consumer complaints have been filed and the vast majority of enforcement has been regulator-driven. It is unclear, however, whether the new guidance will address topics beyond the consumer complaint process.[2]

New FAQs Add Insight on Federal Enforcement Strategy but Little Guidance on How to Comply

The newly issued Part 45 FAQs do not provide substantive new guidance with regard to the application of MHPAEA

requirements to specific NQTLs or the necessary elements of compliance documentation; however, the Part 45 FAQs do provide insight into the Departments' current strategy for enforcement of the CAA requirements. Key points of the guidance include:

(1) *Starting immediately, plans and issuers should be prepared to make their comparative analyses available.*

Congress provided that the new NQTL documentation requirements take effect on February 10, 2021, just 45 days after the enactment of the CAA. Although the structure of the 5-step framework for analysis is similar to existing guidance, including the DOL Self-Compliance Tool, the requirement to develop and maintain such documentation on a proactive basis took many plans and issuers by surprise. Previously, many plans and issuers had followed a problem-solving approach to compliance, focusing on the identification and resolution of specific compliance concerns.

The development of the five-step analysis for each NQTL is a labor-intensive process that nearly always takes longer than 45 days to complete. However, the statute and Part 45 FAQs do not address the amount of time that may be permitted for a plan or issuer to respond to an initial documentation request or to a follow-up request for further information in the event that the regulator is unable to make a determination of compliance or noncompliance based on the information originally provided. Thus, the short timeline to the effective date may not prove overly detrimental to plans and issuers that already have been working to develop the required analyses.

(2) *Very short list of NQTLs called out for specific enforcement focus*

The Part 45 FAQs do not specify a complete list of NQTLs for which documentation may be requested, but the FAQs do emphasize that the Departments may request comparative analyses for any NQTL for which a potential MHPAEA violation or complaint is identified, or in any other instance deemed appropriate. The Part 45 FAQs state that in the near term, DOL expects to focus on the following NQTLs in its enforcement efforts:

- ***Prior authorization*** requirements for in-network and out-of-network inpatient services;
- ***Concurrent review*** for in-network and out-of-network inpatient and outpatient services;
- ***Standards*** for provider admission to ***participate in a network***, including ***reimbursement rates***; and
- ***Out-of-network reimbursement rates*** (plan methods for determining usual, customary, and reasonable charges).

Our primary takeaway is that this is a very short list, especially in comparison to the set of 20 different NQTLs that have been required for reporting by the Department of Financial Services in New York, and the extensive lists of NQTLs that are suggested for reporting by the Centers for Medicare & Medicaid Services (CMS) and several state departments of insurance.[3] The narrow scope of this list may reflect, in part, the relatively short timeframe plans and issuers had to come into compliance before the CAA's effective date. In that context, we anticipate that additional guidance will be issued before federal regulators broaden the scope of enforcement priorities, potentially building on feedback from behavioral health consumer and provider advocates, state regulators, and regulated health plans and issuers.

The Part 45 FAQs also are silent on whether plans and issuers may combine or subdivide the identified concepts in their NQTL analyses, or what may occur if a regulator or member requests an analysis for an NQTL type that the plan or issuer does not specifically address in their documentation. For example, some plans may wish to create a single NQTL analysis of service authorizations that addresses both prior authorization and concurrent review.

Conversely, some plans may wish to subdivide standards for provider admission to participate in a network into multiple distinct NQTL types, including provider recruitment, credentialing, and reimbursement, and to analyze each of these separately. The current federal statutes and regulations do not provide regulators with the authority to impose specific definitions for NQTLs, so it would appear that plans and issuers have flexibility to create such definitions, with significant implications for the structure of their comparative analyses, but ambiguity remains on this question at present.

Other notable observations about this NQTL list include the following:

- The Part 45 FAQs do not explicitly reference enforcement with regard to prescription drug benefits. Although a variety of states have pursued enforcement of NQTLs applied to prescription drug benefits, including with regard to prior authorization, step therapy, quantity limits, and formulary tiering, the FAQ framing of prior authorization and concurrent review are explicitly limited to the inpatient and outpatient benefit classifications, and to date we have not seen regulators require NQTL compliance analyses for provider networks or reimbursement applied to the prescription drug benefits classification.
- In-network provider reimbursement rates are a focus for enforcement but are identified in the Part 45 FAQs as a component of a broader analysis of standards for provider admission to participate in a network. Regulators may consider analyses that frame this concept in a way that aligns more closely with a plan's or issuer's actual strategies and processes, such as by analyzing reimbursement rates as a component of provider network development and retention.
- Out-of-network reimbursement rates are identified in the Part 45 FAQs as an independent NQTL. We anticipate that, as with in-network reimbursement rates, regulators will focus primarily on the plan's or issuer's rate-setting *methodology* rather than the rates themselves. Nonetheless, because out-of-network reimbursement is set forth as a standalone concept (and not part of a broader strategy such as provider network development and retention), regulators are likely to place significant emphasis on the reimbursement rates themselves.

(3) *Reassertion of existing guidance emphasizing a very broad range of topics and details that must be specifically addressed and analyzed*

The Part 45 FAQs set forth a series of elements that must be provided as a minimum standard for any analysis. These elements largely reassert preexisting guidance from the DOL Self-Compliance Tool; however, the checklist format provides a concise summary that may be helpful, relative to the 39 pages of the Self-Compliance Tool. The elements listed in the checklist appear to have been selected and framed to emphasize both the breadth of topics and the granularity of detail that are expected to be addressed in the comparative analyses. For example:

- In analyzing the factors used to design and apply the NQTL, plans and issuers should explain whether any factors were given more weight than others and the reason(s) for doing so, including an evaluation of any specific data used in the determination.
- To the extent the plan or issuer 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.
- If the application of the NQTL turns on specific decisions in administration of the benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s).
- If the plan's or issuer's analyses rely upon any experts, the analyses, as

documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both mental health/substance use disorder (MH/SUD) and medical/surgical benefits.

- Comparative analyses of the relevant processes, strategies, evidentiary standards, factors, and sources should include citations to any specific evidence considered.

The Part 45 FAQs also reassert existing guidance regarding the need for plans and issuers to be prepared to provide internal records, data, or other evidence to substantiate the analyses upon request. Specifically, the Part 45 FAQs stipulate that plans should be prepared to provide:

- Records documenting NQTL processes and detailing how the NQTLs are being applied to both medical/surgical and MH/SUD benefits;
- Guidelines or other standards the group health plan relied on to determine that NQTLs apply no more stringently to MH/SUD benefits than to medical/surgical benefits;
- Samples of covered and denied MH/SUD and medical/surgical benefit claims; and
- Documents related to MHPAEA compliance by the group health plan's service providers.

The specific application of these and related instructions will vary significantly by NQTL type, but it is clear that the Departments seek to require compliance documentation that is far more voluminous and detailed than most plans and issuers have previously created.

One new element in the Part 45 FAQs that has not been previously required is for plans and issuers to identify the date of the analyses and the name, title, and position of the person or persons who performed or participated in the comparative analyses.

(4) *Announcement of stakeholder engagement to develop additional guidance*

The Part 45 FAQs do not state whether more guidance will be released to explain the Departments' interpretation of the CAA requirements. The FAQs merely state that the Departments will engage with stakeholders to determine what additional guidance might be needed. It is laudable that the Departments worked quickly to issue this brief guidance to provide early insight into their enforcement strategy. Nonetheless, as discussed above, there is a substantial need for additional guidance to address significant gaps that remain with regard to key aspects of the compliance documentation requirements.

What Plans and Issuers Should Do Now

It is clear that plans and issuers should take immediate action to ensure they are prepared to make robust compliance analyses available to regulators and members or beneficiaries upon request. Key steps in that process include:

- Identifying a core set of NQTLs for analysis and documentation. This should include, at minimum, the four NQTLs identified in these FAQs, but consideration also should be given to all 20 NQTLs identified in states like New York and Oklahoma.
- Developing and documenting 5-step analyses, pursuant to the CAA framework, for all core NQTLs.
- Ensuring that policies and procedures adequately address the need to oversee NQTL compliance "in operation."
- Reviewing agreements with relevant vendors, including any TPA, PBM, leased provider networks, publishers of clinical guidelines, and related entities to ensure that compliance documentation and enforcement risks are appropriately addressed.

Plans and issuers also should continue to monitor for additional guidance from the Departments and pursue opportunities

to engage with the Departments on areas where additional guidance is needed.

Endnotes

1. FAQs about Mental Health and Substance Use Disorder Parity Implementation and the Consolidated Appropriations Act, 2021 Part 45, April 2, 2021 (Part 45 FAQs).
2. The CAA also amends the Employee Retirement Income Security Act (ERISA) and the Internal Revenue Code (IRC) to add existing requirements for the issuance of guidance that were previously added to the Public Health Service Act (PHSA) by the CURES Act of 2016. These provisions set forth a long list of substantive details to be explained in guidance, including disclosure requirements and examples of violations for a variety of specific NQTLs. However, oversight and guidance for MHPAEA are shared across the Departments, and the Departments responded to the CURES Act by issuing FAQs Parts 38 and 39 in 2017 and 2019 and updates to the DOL Self-Compliance Tool in 2018 and 2020. In this context, it is unclear whether the CAA's replication and insertion of these guidance requirements into ERISA and the IRC should be interpreted to require new guidance.
3. *See, e.g.*, the NQTL reporting template applied by Oklahoma at *www.oid.ok.gov/regulated-entities/financial/financial-regulation-forms/mentalhealthparity/*, which includes a non-exhaustive list of 20 NQTLs to be reported to the state.

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