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Employee Benefit Plan Review

Tri-Agencies Finalize NQTL Comparative Analysis Standards in Final Rule

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The U.S. Department of the Treasury, Department of Labor, and Department of Health and Human Services (collectively, the Tri-Agencies) have issued a final rule (the Final Rule) implementing new regulations applicable to nonquantitative treatment limitations (NQTLs) under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act (MHPAEA). The Final Rule codifies many of the requirements set forth in the Proposed Rule, while pulling back on some of the Tri-Agencies' more controversial proposals.

Overall, the Final Rule provides additional detail and clarification on the Tri-Agencies' expectations for NQTL comparative analyses, including on the content of comparative analyses, the importance of outcomes data, a prohibition on discriminatory factors and evidentiary standards, and the effects of non-compliance. This article lays out key items plans and issuers need to know.

Rejection of the Mathematical "Predominant" and "Substantially All" Tests to Determine NQTL Compliance

The Proposed Rule would have required plans and issuers to assess NQTL compliance under the mathematical "predominant" and "substantially all" test currently used to assess compliance for quantitative treatment limitations (QTLs) and financial requirements.[1] The Tri-Agencies received significant comments that the application of this test to NQTLs would be unworkable and confusing, and ultimately did not adopt the mathematical test for NQTLs. This addressed a significant concern voiced by payors, many of whom had expressed that the test was difficult to operationalize.

The Final Rule instead reinforces MHPAEA's statutory language, which requires, without articulating a mathematical test, that NQTLs applicable to mental health and substance use disorder (MH/SUD) benefits be no more restrictive than the predominant requirements and limitations applicable to substantially all medical/surgical benefits. The Tri-Agencies stated that "to demonstrate compliance with the no more restrictive requirement, which is now the general rule for NQTLs, a plan or issuer is required under these final rules to satisfy (1) the design and application requirements and (2) the relevant data evaluation requirements. . . ."[2] Thus, plans and issuers must ensure, as further discussed below, that they meet both the comparative analysis content requirements and

the data requirements under the Final Rule, but there is no required mathematical formula for how to do so.

Content of Comparative Analysis – Focus on the Design of the NQTL

The Final Rule provides formal guidance, mostly in line with the Proposed Rule, on the content required in NQTL comparative analyses, laying out in detail the specific information that plans and issuers must provide in each of the six steps of a comparative analysis.[3] The Final Rule is clear: it is not enough that the comparative analysis focus on the application of the treatment limitation. Plans and issuers must also analyze the design of the NQTL in the comparative analysis.[4] This means that plans and issuers' comparative analyses will need to explain how the processes used to develop the NQTL were comparable, not just that the application is comparable.

The Final Rule reinforced and codified prior guidance that each NQTL comparative analysis should address, at a minimum, six elements:

1. *A Description of the NQTL*: This includes the specific terms of the plan or coverage or other relevant terms relating to the NQTL and the policies or guidelines in which the NQTL appears; identification of all MH/SUD and medical/surgical benefits to which the NQTL applies; and a description of which benefits are included in each classification. Notably, the entire policy, guideline, or document that is referenced is not required to be included in a comparative analysis, although it could later be requested.
2. *Identification and Definition of the Factors Used to Design or Apply the NQTL*: The plan or issuer must include a detailed description of each factor; or relied upon to design and apply each factor; and the source from which each evidentiary standard was derived.
3. *Description of How Factors Are Used in the Design or Application of the NQTL*: If one or more factors is used, the plan must explain how the factors relate to each other; the order in which the factors are applied; if any factors are given more weight; and any deviations or variations from factors.
4. *Demonstration of Comparability, as Written*: The Final Rule requires plans and issuers to submit documentation for the design and application of the NQTL, including quantitative data, calculations, or other analyses and records maintained by the plan or issuer showing whether an NQTL met or did not meet any applicable thresholds identified in the relevant evidentiary sources.
5. *Demonstration of Comparability, in Operation*: The comparative analysis must include identification of the relevant data collected and evaluated, as well as documentation of the outcomes that resulted from the application of the NQTL.
6. *Findings and Conclusions*: The comparative analysis must include a reasoned and detailed discussion as to the comparability of the processes, strategies, evidentiary standards, and other factors used in the design and application of the NQTL.

Particularly relevant to Steps 2 and 3, the Final Rule added a new prohibition on the use of "discriminatory factors and evidentiary standards."[5] Under this new prohibition, a plan or issuer may not rely on a factor or evidentiary standard to design or apply an NQTL if the information, evidence, sources, or standards on which the factor or evidentiary standard is based discriminates against MH/SUD benefits as compared to medical/surgical benefits.[6] Information is considered biased or not objective in a manner that discriminates against MH/SUD benefits if, based on all the relevant facts and circumstances, the information systematically disfavors access or is specifically designed to disfavor access to MH/SUD benefits.[7] For example, the Tri-Agencies explain that a step therapy third-party methodology source could be improperly biased if the methodology addresses instances in which a delay in treatment with a drug prescribed for a medical/surgical service could result in either severe or irreversible consequences, but only addresses instances in which a delay in a treatment for an MH/SUD services could result in both severe and irreversible consequences.[8]

Importance of Data Outcomes

Although regulators have long expected and requested plans to submit data supporting parity compliance, the Final Rule codified the requirement that plans and issuers "collect and evaluate relevant data" to assess the impact of an NQTL on "relevant outcomes related to access" to MH/SUD and medical/surgical benefits.[9] Data showing "material differences in access" between MH/SUD and medical/surgical benefits will be seen as a "strong indicator" of a MHPAEA violation.[10] The Final Rule vaguely defines a "material difference in access" as data that suggests the NQTL "is likely to have a negative impact on access" to MH/SUD benefits.[11] In such cases, plans must "take reasonable action, as necessary, to address the differences" and document those actions.[12]

The Final Rule generally preserves a plan's flexibility to select which data metrics to collect and evaluate. The Tri-Agencies note that, in general, relevant data could include "the number and percentage of claims denials" and data relevant to the NQTL required by state law or "private accreditation standards,"[13] while the preamble to the Final Rule provides additional guidance

for specific data metrics for certain NQTLs. For example, for prior authorization, the Final Rule suggests data metrics could include rates of approvals and denials for prior authorization requests, rates of denials of post-service claims, application of penalties for failure to obtain prior authorization, and turnaround times for prior authorization requests.[14]

Unlike the Proposed Rule, the Final Rule does not contain any "safe harbors" in the event a plan or issuer meets certain data metrics. But it does state that differences in data attributable to "generally recognized independent professional medical or clinical standards" or "carefully circumscribed measures" to detect or prevent fraud and abuse are not considered "material."[15]

The Tri-Agencies noted their intention to issue further guidance on "type, form, and manner of collection and evaluation" of data metrics, and to provide "lists of examples of data that are relevant across the majority of NQTLs."[16] They also stated they plan to update the MHPAEA Self-Compliance Tool to provide additional guidance on specific data plans should collect and evaluate.[17] Plans and issuers should be on the lookout for this additional guidance.

Focus on Network Composition

The Final Rule places a particular focus on network composition because, according to the Tri-Agencies, "NQTLs related to network composition inherently impact a participant's or beneficiary's access" to MH/SUD benefits.[18] NQTLs "related to network composition" are defined as including standards for provider admission to the network, reimbursement rates, credentialing, and procedures for ensuring the network includes an adequate number of providers.[19]

The Final Rule provides some examples of data metrics relevant to network composition, including:

(1) In-network and out-of-network utilization rates (including data related to provider claim submissions);
(2) Network adequacy metrics (including time and distance data, and data on providers accepting new patients); and
(3) Provider reimbursement rates (for comparable services and as benchmarked to a reference standard).[20]

The preamble also provides additional metrics, including metrics specific to credentialing and network admission, such as response times and denial rates for provider applications.[21] Plans should consider establishing known processes and systems to collect and evaluate the metrics identified in the Final Rule and preamble.

In addition, the Final Rule is unique to network composition NQTLs because it provides several examples of "reasonable actions" plans can take to address "material differences" in access to benefits.[22] These include recruiting additional providers and facilities by increasing compensation, streamlining credentialing, and contracting with providers and facilities that provided services on an out-of-network basis; expanding telehealth arrangements; providing members with assistance in finding available in-network providers and facilities; and ensuring that provider directories are accurate.

Certification Requirement for Employee Retirement Income Security Act of 1974 (ERISA) Fiduciaries

The Final Rule relaxes a proposed certification requirement for fiduciaries of ERISA group health plans. Under the Proposed Rule, all comparative analyses would have required plan fiduciaries to attest that the analysis complied with the various content requirements of the Proposed Rule.[23] The primary objections to the proposed certification were that it could be unnecessarily costly and burdensome for plan fiduciaries, since it arguably requires a level of nuanced expertise many fiduciaries would not possess.[24]

Under the Final Rule, the named fiduciaries of an ERISA plan (typically the employer) need only to certify that they engaged in a prudent process to select a service provider to perform and document the comparative analysis, and that they have appropriately monitored that service provider.[25] Before making this certification, fiduciaries should carefully review the comparative analysis prepared by the service provider, discuss and ask questions about the analysis with the service provider as necessary to understand all of the findings and conclusions documented in the analysis, and ensure that the selected service provider provides assurance that the analysis complies with the requirements of MHPAEA and its implementing regulations.[26]

In any event, ERISA fiduciaries are always held to a "prudent person" standard when engaging any service provider for the plan. As a result, while specific acknowledgement of a prudent process is now required, the Final Rule's certification requirement should not materially impact a fiduciary's obligations in selecting and monitoring the service provider that conducts the comparative analysis.[27]

Effect of Non-Compliance

The Final Rule formally expands the enforcement authority of the Tri-Agencies in the event of a final determination of non-compliance. The Consolidated Appropriations Act of 2021 (CAA, 2021) limits the remedies available to the government upon a final determination of non-compliance to (i) requiring the plan to notify members of non-compliance, and (ii) including the finding and plan's name in the annual Report to Congress.[28] The Final Rule,

however, now gives federal and state regulators the power to require plans to cease applying any NQTL upon a final determination of non-compliance until the plan or issuer remedies the violation.[29] The Tri-Agencies assert that this expanded authority is authorized under the CAA, 2021, saying that it gives the Tri-Agencies "broad authority to determine the appropriate remedy."[30] In response to comments on the Proposed Rule, the Tri-Agencies added that the determination to require cessation of an NQTL will be based on evaluation of the "relevant facts and circumstances," the "nature" of the NQTL, the "interest" of members, and "feedback" from the plan.[31]

Compliance Takeaways

The Final Rule applies to group health plans effective January 1, 2025, though the meaningful benefits standard, the prohibition on discriminatory factors and evidentiary standards, the relevant data evaluation requirements, and the related requirements in the provisions for comparative analyses apply on the first day of the first plan year beginning on or after January 1, 2026. The Final Rule will apply to individual health insurance coverage on January 1, 2026.

Leading up to these applicability dates, proactive compliance is key, particularly in light of new requirements relating to the provision of comparative analyses to regulators and members. The Final Rule implements the proposed ten-business day timeframe for providing comparative analyses to regulators upon request and responding to supplemental requests for information.[32] Plans or issuers are also now required to make available to the Tri-Agencies, upon request, a written list of all NQTLs under the plan.[33] Even further, the Final Rule mandates that plans provide comparative analyses to members upon request in connection with an adverse benefit determination for MH/SUD benefits, and, with respect to ERISA plans, this requirement extends to any time a member requests a comparative analysis, regardless of whether there has been an adverse benefit determination.[34]

Further, the expectations for compliance have grown, as evidenced in the Final Rule. In the Report to Congress last year, the Department of Labor indicated that they expect "more complete comparative analyses from the start of the review process" and insufficiencies to be cured more quickly than they did two years ago.[35]

Plans and issuers need to be proactive and, to the extent they have not already, develop a parity compliance process. An effective compliance program must include:

- Working with subject matter experts and counsel to develop comprehensive comparative analyses with the six required elements and demonstrating comparability for each NQTL as set forth in the new Final Rule;
- Updating those comparative analyses as the NQTL's underlying processes and policies change;
- Instituting processes to routinely run and analyze data metrics across NQTLs in a uniform and timely fashion; and
- Evaluating, identifying, and, if needed, addressing material differences in the data metrics related to those NQTLs.

Having these documents and data ready before a request from the government is critical.

Notes

1. Final Rule at p. 47.
2. Final Rule at p. 47.
3. 26 CFR 54.9812-2; 29 CFR 2590.712-1; 45 CFR 146.137.
4. Final Rule at p. 61.
5. 26 CFR 54.9812-1(c)(4)(i)(A); 29 CFR 2590.712(c)(4)(i)(A); 45 CFR 146.136(c)(4)(i)(A).
6. 26 CFR 54.9812-1(c)(4)(i)(A); 29 CFR 2590.712(c)(4)(i)(A); 45 CFR 146.136(c)(4)(i)(A).
7. 26 CFR 54.9812-1(c)(4)(i)(B); 29 CFR 2590.712(c)(4)(i)(B); 45 CFR 146.136(c)(4)(i)(B).
8. 26 CFR 54.9812- 1(c)(4)(vi)(C); 29 CFR 2590.712(c)(4)(vi)(C); 45 CFR 146.136(c)(4)(vi)(C).
9. 26 CFR 54.9812-1(c)(4)(iii)(A); 29 CFR 2590.712(c)(4)(iii)(A); 45 CFR 146.136(c)(4)(iii)(A).
10. 26 CFR 54.9812-1(c)(4)(iii)(B); 29 CFR 2590.712(c)(4)(iii)(B); 45 CFR 146.136(c)(4)(iii)(B).
11. 26 CFR 54.9812-1(c)(4)(iii)(B)(2); 29 CFR 2590.712(c)(4)(iii)(B)(2); 45 CFR 146.136(c)(4)(iii)(B)(2).
12. 26 CFR 54.9812-1(c)(4)(iii)(B)(1); 29 CFR 2590.712(c)(4)(iii)(B)(1); 45 CFR 146.136(c)(4)(iii)(B)(1).
13. 26 CFR 54.9812-1(c)(4)(iii)(A)(1); 29 CFR 2590.712(c)(4)(iii)(A)(1); 45 CFR 146.136(c)(4)(iii)(A)(1).
14. Final Rule at p. 90.
15. 26 CFR 54.9812-1(c)(4)(iii)(B)(2)(ii); 29 CFR 2590.712(c)(4)(iii)(B)(2)(ii); 45 CFR 146.136(c)(4)(iii)(B)(2)(ii).
16. Final Rule at p. 89.
17. Final Rule at p. 89.
18. Final Rule at p. 81.
19. 26 CFR 54.9812-1(c)(4)(ii)(D); 29 CFR 2590.712(c)(4)(ii)(D); 45 CFR 146.136(c)(4)(ii)(D).
20. 26 CFR 54.9812-1(c)(4)(iii)(A)(2); 29 CFR 2590.712(c)(4)(iii)(A)(2); 45 CFR 146.136(c)(4)(iii)(A)(2).
21. Final Rule at pp. 91-92.
22. 26 CFR 54.9812-1(c)(4)(iii)(C); 29 CFR 2590.712(c)(4)(iii)(C); 45 CFR 146.136(c)(4)(iii)(C).
23. Final Rule at p. 208.
24. Final Rule at p. 208.
25. 29 CFR 2590.712-1(c)(6)(vi).
26. Final Rule at p. 210.
27. Final Rule at pp. 210-211.
28. 42 U.S.C. 300gg-26(a)(8)(B)(iii)(bb)&(iv); 29 U.S.C. 1185a(a)(8)(B)(iii)(bb)&(iv); 26 U.S.C. 9812(a)(8)(B)(iii)(bb)&(iv).
29. 42 CFR 146.136 (c)(4)(v); 26 CFR 54.9812-1(c)(4)(v); 29 CFR 2590.712(c)(4)(v).
30. Final Rule at p. 132.
31. 42 CFR 146.136 (c)(4)(v); 26 CFR 54.9812-1(c)(4)(v); 29 CFR 2590.712(c)(4)(v).
32. 42 CFR 146.137(d)(1)&(2); 26 CFR 54.9812-2(d)(1)&(2); 29 CFR 2590.712-1(d)(1)&(2).
33. 26 CFR 54.9812-2(c); 29 CFR 2590.712-1(c); 45 CFR 146.137(c).
34. 26 CFR 54.9812-1(e)(2); 29 CFR 2590.712(e)(2)&(3); 45 CFR 146.136(e)(2).
35. U.S. Dept's of Labor, Health & Human Services, and Treasury, MHPAEA Comparative Analysis Report to Congress at p. 55 (2023), https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf.

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