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Non-Quantitative Treatment Limitations Comparative Analysis: What Plan Fiduciaries Need to Know

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On September 9, 2024, the U.S. Departments of Health and Human Services (HHS), Labor, and the Treasury (HHS, Labor, and the Treasury, collectively, the Departments) issued final rules (the 2024 Final Regulations) to implement the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, as amended (the MHPAEA).[1] Included in the 2024 Final Regulations are new rules regarding the nonquantitative treatment limitation (NQTL) comparative analysis requirements under MHPAEA, as amended by the Consolidated Appropriations Act, 2021 (the CAA 2021). This NQTL comparative analysis requirement has created a significant level of angst among plan fiduciaries as they will now have to certify that they have engaged in a prudent process to select and monitor one or more qualified service providers to perform and document their NQTL comparative analyses in

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connection with the imposition of any NQTLs that apply to mental health and substance use disorder (MH/SUD) benefits under the plan in accordance with MHPAEA and its implementing regulations.[2] This certification will generally fall on health and welfare plan fiduciaries who have been tasked with overseeing and administering the plans. These fiduciaries should ideally form a committee and consult with ERISA counsel and familiarize themselves with the details of the NQTL comparative analysis requirements, so that they can document the steps that have taken in order to certify that they have satisfied their fiduciary obligations with respect to their NQTL comparative analyses.

This column provides an overview of NQTL comparative analyses that the Departments expect to be performed, including the review and audit process thereof. Though this column refers throughout to a "plan's" preparation of NQTL comparative analyses, for self-funded group health plans, the plan must conduct NQTL comparative analyses (a responsibility which, in most cases, ultimately falls to the plan sponsor), and for fully insured group health plans, the issuer is responsible for conducting NQTL comparative analyses.[3]

COMPARATIVE ANALYSES FOR NQTLS

A NQTL generally refers to a non-financial restriction on benefits that can limit the length or scope of covered treatment. Medical management standards, network tier designs, prescription drug formulary design, and conditioning benefits upon completion of a course of treatment all constitute possible NQTLs.[4] Under MHPAEA, a plan may not impose a NQTL with respect to MH/SUD benefits in the following classifications that is more restrictive, as written or in operation, than the predominant NQTL that applies to substantially all medical and surgical (M/S) benefits in the same classification:

- Inpatient in-network;
- Inpatient out-of-network;
- Outpatient in-network;
- Outpatient out-of-network;
- Emergency care; and
- Prescription drugs.[5]

In order to ensure that plans are complying with how they impose NQTLs, the 2024 Final Regulations specify what needs to be included in

a NQTL comparative analysis, including, at a minimum, the following elements (each, a Content Element):

- A description of each NQTL;
- Identification and definition of the factors and evidentiary standards used to design or apply each NQTL;
- A description of how factors are used in the design or application of each NQTL;
- A demonstration of comparability and stringency, as written;
- A demonstration of comparability and stringency, in operation; and
- Findings and conclusions.[6]

The NQTL comparative analysis must be performed with respect to each NQTL identified and, moreover, the Departments require that each plan must "prepare and make available to the [Departments], upon request, a written list of all [NQTLs] imposed under the plan or coverage."[7]

Description of Each NQTL

To satisfy the first Content Element of a NQTL comparative analysis, the plan must identify each NQTL and all benefits to which it applies (i.e., MH/SUD and/or M/S benefits).[8] As a threshold matter, however, under the 2024 Final Regulations, plans must first ensure that they appropriately define what constitutes a MH/SUD benefit and a M/S benefit.[9] To the extent there are any deviations within the plan(s) from the accepted definitions, plans should make any required amendments and communicate the same to all applicable third-parties (e.g., administrators).

Once definitions are deemed to be compliant, a NQTL comparative analysis must then identify each specific MH/SUD and/or M/S benefit to which the NQTL applies within each "classification."[10] Plans must also review and provide an exhaustive list of the applicable plan or coverage provisions, policies and guidelines, and/or clauses (e.g., within provider contracts) that cite or refer to a NQTL.[11] Plan fiduciaries should diligently review the list of reported NQTLs to ensure that it is comprehensive. These plan fiduciaries should consider engaging ERISA counsel to assist them with this review, which can include preparing diligence questions for third-party administrators and reviewing the responses provided thereto so that the plan fiduciaries can certify that they diligently investigated the list of NQTLs included in the analysis.

Identification and Definition of the Factors and Evidentiary Standards Used to Design or Apply the NQTL

With respect to the second Content Element for a NQTL comparative analysis, plans must enumerate each "factor"[12] considered or relied upon in determining which MH/SUD and/or M/S benefits are subject to each NQTL, each "evidentiary standard"[13] considered or relied upon in the design or application of each factor, and the sources from which each evidentiary standard derives, in order to justify the applicable NQTL on MH/SUD benefits and/or M/S benefits.

To impose a NQTL on MH/SUD benefits, the factors and evidentiary standards upon which such NQTL is based may not be discriminatory against MH/SUD benefits. A factor or evidentiary standard is discriminatory if, on the totality of circumstances, the information, evidence, sources, or standards upon which it is based systematically disfavor or are specifically designed to disfavor access to MH/SUD benefits.[14] Plans should also be mindful that, under the 2024 Final Regulations, a NQTL comparative analysis must detail, to the extent applicable, any exculpatory data, information, or sources, without consideration of which the factor or evidentiary standard underlying the NQTL would be deemed biased or unobjective.[15] Notably, the Departments deem unbiased/nondiscriminatory the following sources: (i) generally recognized independent professional medical or clinical standards that reflect the accepted standards of care and clinical practices in the relevant specialty, and (ii) carefully circumscribed measures designed to detect or prevent and prove fraud and abuse that are based upon objective data and narrowly tailored to minimize impact to access on MH/SUD benefits.[16]

Description of How Factors Are Used in the Design and Application of the NQTL

For the third Content Element, a NQTL comparative analysis must explain how each factor under the second Content Element above is used in the design or application of each NQTL to the applicable MH/SUD and/or M/S benefit.[17] To satisfy this requirement, the 2024 Final Regulations require a certain level of detail regarding each factor and evidentiary standard.

Specifically, plans must describe the following: (i) the decision-making process through which each factor is used to determine which benefits are subject to a NQTL, and (ii) an explanation of the evidentiary standards or other applicable sources "considered or relied upon in designing or applying the factors or relied upon in designing and applying a NQTL, including in the determination of whether and how benefits

are subject to a NQTL."[18] Moreover, if the administration of the applicable benefit, including specific decisions made thereunder, is contingent upon the application of a factor, a NQTL comparative analysis must also document the nature and timing of such administration decision and the professional designation and qualifications of the individuals who made such decision.[19]

Additionally, to the extent more than one factor enumerated under the second Content Element is identified, plans must examine:

- How the factors in question relate to one another;
- The order of application for each factor, including when they are applied;
- Whether and how any factors are given more weight than others;
- The reasons for such ordering or weighting; and
- Any deviations or variations from a factor, as applied to MH/SUD benefits as compared with M/S benefits or as defined.

In respect of the "deviations or variations" assessment, plans should also clarify how such a deviation or variation was developed.[20]

Demonstration of Comparability and Stringency, as Written

To satisfy the fourth content element for a NQTL comparative analysis, plans must assess whether, by the written terms of the benefit plan or health insurance coverage, as applicable, any "processes, strategies, evidentiary standards, or other factors" used to design and apply each NQTL to MH/SUD benefits are comparable to, and applied no more stringently than, those used to design and apply such NQTL to M/S benefits.[21]

As a practical matter, the fourth Content Element requires plans to document each factor applied in the second Content Element, including relevant quantitative data, calculations, or records documenting such factors, to compare how a NQTL, as written, is designed and applied to each MH/SUD and/or M/S benefit. The fourth Content Element also requires a plan to include documentation (e.g., the operative language from forms, checklists, procedures used to design and apply each NQTL or that address its application) regarding how such factors are comparably applied, as written, to each such type of benefit, to determine which offerings are subject to such NQTL. Furthermore, as above in the third Content Element, plans must assess any deviations or variations in the

application of a NQTL or a factor with respect thereto, and how such deviation or variation was established.[22]

Demonstration of Comparability and Stringency, in Operation

Whereas the fourth Content Element requires analysis of any NQTLs with respect to the written terms of a plan, the fifth Content Element examines the design and application of the NQTL in operation of a plan or applicable benefit. The difference is rooted in the evaluation of data, as the Departments require hereunder a fulsome explanation regarding the "comparability and stringency" of such processes, strategies, evidentiary standards, and factors, including how the plan sponsor evaluates whether, in operation, such considerations to design and apply each NQTL to MH/SUD benefits are comparable to, and applied no more stringently than, those with respect to M/S benefits.[23] In order to satisfy the burden of this Content Element, a NQTL comparative analysis must explain the processes, policies and supporting data to demonstrate the application of each NQTL, the sample period, calculations, defined terms, and any other relevant criteria upon which the decision to apply such NQTL is made.[24]

In addition to the above requirements, under the 2024 Final Regulations, certain additional requirements take effect in January 2026.

First, for newly implemented NQTLs for which supporting data is limited or temporarily unavailable, a NQTL comparative analysis must address the lack thereof, the basis for such an outcome absent relevant data, and how the plan sponsor intends to rectify the same.[25]

Second, for NQTLs for which reasoned methodologies and data are unavailable and may not, in the aggregate, become available, the Departments require a "reasoned justification" as to why no data can be measured on a NQTL's impact on coverage, the data considered and the rationale for its rejection, as well as support for any precautions or mechanisms through which the plan can ensure such NQTL complies with the MHPAEA.[26]

Third, a NQTL comparative analysis must identify and explain the relevant data collected and assessed in addition to documented outcomes of applying a NQTL to MH/SUD benefits relative to M/S benefits (e.g., data on claim denials, provider reimbursement rates, in- and out-of-network utilization rates, and network adequacy metrics).[27]

Finally, beginning in 2026, a NQTL comparative analysis must document the demonstrable outcomes of the application of the NQTL to MH/SUD benefits versus M/S benefits, including (i) a justification as to why the plan concluded that any differences in the resulting data do or do not indicate that the NQTL contributes to material differences in access, under a totality of circumstances;[28] (ii) an explanation of the material

differences in access; and (iii) any actions planned or taken to address such differences.[29]

Findings and Conclusions

Under the sixth content element, a NQTL comparative analysis must summarize its findings and conclusions with respect to the comparability and relative stringency of the "processes, strategies, evidentiary standards, and other factors used" in the design and application of each NQTL as well as whether the plan or coverage at issue complies or does not comply with the MHPAEA. To the extent a NQTL comparative analysis consults experts, the sixth Content Element requires not only the conclusions of such experts with respect to the data evaluated, but also an indication of whether the plan sponsor ultimately relied on such evaluations. Experts need not be named in the analysis.[30]

A NQTL comparative analysis will not be deemed completed until it is certified by at least one named plan fiduciary. Included in this certification, the plan fiduciary must attest that he or she has engaged in a "prudent process" to select qualified providers to conduct a NQTL comparative analysis with respect to the imposition of all NQTLs and that the fiduciary has sufficiently monitored the provider and process.[31] The Departments require that the plan fiduciary: (i) review the NQTL comparative analysis; (ii) pose questions and engage in a discussion with the provider to understand its implications and findings; and (iii) ensure that the applicable provider assures that the NQTLs and comparative analysis comply with the MHPAEA and its regulations.[32] This means that a plan fiduciary cannot simply rubberstamp an analysis prepared by a provider or third-party administrator. A plan fiduciary should work with their ERISA counsel to document their review, including the dialogue they had with their providers and third-party administrators regarding the fiduciary's questions and comments on the analysis. This certification process should be included into a committee's annual agenda that it develops with its counsel to help it document its compliance with its fiduciary obligations.

REQUEST AND REVIEW PROCESS

Upon request by any of the Departments, a plan must disclose its NQTL comparative analysis within 10 business days of its receipt of the request.[33] A plan may also be required to share the NQTL comparative analysis with (i) applicable state authorities; (ii) participants or beneficiaries thereof who have received adverse determinations with respect to coverage of MH/SUD benefits; or (iii) participants or their beneficiaries, generally, at any time, under Section 104 of ERISA.[34] Furthermore, upon

request for any additional information by the requesting Department, plans have only an additional 10 business days to provide such information.[35]

Although extensions may be granted to produce a compliant NQTL comparative analysis, it is unlikely that any granted extension would be long enough to permit a plan to conduct a fulsome NQTL comparative analysis.

Furthermore, upon a determination by the Department(s) of noncompliance, in addition to continued monitoring by the Department(s) to ensure that plans comply with the MHPAEA, plans must provide written notice of the same to plan participants and their beneficiaries within seven (7) business days and include the remedial actions the plan intends to take to rectify such noncompliance.[36]

For these reasons, to avoid noncompliance, proactivity and diligence to prepare for and properly conduct NQTL comparative analyses is paramount to successfully navigate this changing landscape. Because of the certification requirement, plan fiduciaries – even more so than plan sponsors, insurers, and third-party administrators – will need to understand their obligations, marketplace trends, and the resources available to them to ensure that a NQTL comparative analysis complies with its obligations.

KEY TAKEAWAYS FOR PLAN FIDUCIARIES

As demonstrated above, the process of preparing a compliant NQTL comparative analysis can be arduous and complex. As the landscape around NQTL comparative analyses develops, plan fiduciaries must understand not only their roles but the roles of the various stakeholders with whom plan fiduciaries will work to complete the NQTL comparative analyses so that they can confidently complete their certification.

Specifically, plan fiduciaries will need to focus on the following facets of NQTL comparative analyses:

(1) *Analyzing all NQTLs*. Because plans must assess every applicable NQTL, the onus is on plan fiduciaries to ensure their NQTL comparative analyses cover all NQTLs including, under the fifth Content Element, those in operation that may not appear in the terms of a plan document or contract provision. To understand any such limitations on coverage and ensure that a NQTL comparative analysis is comprehensive, plan fiduciaries should work with their ERISA counsel to develop a list of questions for plan service providers to confirm that all NQTLs are covered.

(2) *Document the Process (and People)*. To defend a plan's NQTL comparative analysis on audit, plan fiduciaries should demonstrate that they engaged in the "prudent process" of selecting and monitoring stakeholders in their completion of the

NQTL comparative analysis. Plan fiduciaries should engage ERISA counsel to assist them with documenting how they: (i) selected third-party administrators, pharmacy benefit managers, and coverage providers; (ii) maintained communications with these stakeholders; (iii) rigorously reviewed the resulting NQTL comparative analysis; and (iv) evaluated third-party consultants and experts who may be involved in the preparation of the NQTL comparative analysis.

(3) *Review Contracts with Service Providers*. Documenting, collecting data, and undertaking a comprehensive review of NQTLs poses significant burdens on all stakeholders involved. Plan fiduciaries should coordinate with ERISA counsel to assess whether contracts with any third-party administrators, issuers, and other stakeholders should be amended with operative language to reflect these heightened obligations and confirm that such stakeholders will appropriately support a plan sponsor with its compliance with the MHPAEA.

Notes

1. Fact Sheet, Dept. of Labor, Final Rules under the Mental Health Parity and Addiction Equity Act (Sept. 2024) [hereinafter DOL Fact Sheet].

2. 29 C.F.R. § 2590.712-1(c)(6)(vi).

3. Requirements Related to the Mental Health Parity and Addiction Equity Act, 89 Fed. Reg. 77586, 77613 (Sept. 23, 2024).

4. 26 C.F.R. § 54.9812-1(c)(4)(i); 29 C.F.R. § 2590.712(c)(4)(ii); 45 C.F.R. § 146.136(c)(4)(ii).

5. 26 C.F.R. § 54.9812-1(c)(2)(ii); 29 C.F.R. § 2590.712(c)(2)(ii)(A); 45 C.F.R. § 146.136(c)(2)(ii)(A).

6. 26 C.F.R. § 54.9812-2(c); 29 C.F.R. § 2590.712-1(c); 45 C.F.R. § 146.137(c)(4).

7. 26 C.F.R. § 54.9812-2(d)(1); 29 C.F.R. § 2590.712-1(d)(1), and 45 C.F.R. § 146.137(d); see also DOL Fact Sheet.

8. The terms "mental health benefits", "substance use disorder benefits" and "medical/surgical benefits" are defined in 26 C.F.R. § 54.9812-1(a)(2); 29 C.F.R. § 2590.712(a)(2); 45 C.F.R. § 146.136(a)(2).

9. To ensure applicable definitions under the plan(s) comply with applicable law, plans must (i) define any conditions, disorders, or procedures listed within each category of MH/SUD and M/S consistently with the "generally recognized independent standards of current medical practice" (e.g., the most current International Classification of Diseases (the ICD)) or, if not addressed therein, then under applicable law; and (ii) confirm that for all MH and SUD benefits the plan definition(s) include all conditions or mental or behavioral disorders so classified within the ICD or listed in the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders. 26 C.F.R.

§ 54.9812-1(a)(2); 29 C.F.R. § 2590.712(a)(2); 45 C.F.R. § 146.136(a)(2); see 89 Fed. Reg. at 77594 and 77738 (Sept. 23, 2024) (confirming that gender dysphoria, eating disorders, and autism spectrum disorders are interpreted as mental health conditions).

10. "Classifications" refer broadly to the following types of benefits: (1) inpatient, in-network, (2) inpatient, out-of-network, (3) outpatient, in-network, (4) outpatient, out-of-network, (5) emergency care, and (6) prescription drugs. 26 C.F.R. § 54.9812-1(c)(2)(ii); 29 C.F.R. § 2590.712(c)(2)(ii)(A); 45 C.F.R. § 146.136(c)(2)(ii)(A).

11. Plans need not provide fulsome copies of the policies, guidelines, or contracts from which such references derive unless requested on review. 89 Fed. Reg. at 77639 (Sept. 23, 2024).

12. "Factor" means "all information, including processes and strategies (but not evidentiary standards), that a group health plan considered or relied upon to design a nonquantitative treatment limitation, or to determine whether or how the nonquantitative treatment limitation applies to benefits under the plan. Examples of factors include, but are not limited to: 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." 26 C.F.R. § 54.9812-1(a)(2); 29 C.F.R. § 2590.712(a)(2); 45 C.F.R. § 146.136(a)(2).

13. "Evidentiary Standard" means "are any evidence, sources, or standards that a group health plan considered or relied upon in designing or applying a factor with respect to a nonquantitative treatment limitation, including specific benchmarks or thresholds. Evidentiary standards may be empirical, statistical, or clinical in nature, and include: sources acquired or originating from an objective third party, such as recognized medical literature, professional standards and protocols (which may include comparative effectiveness studies and clinical trials), 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), and clinical treatment guidelines; internal plan data, such as claims or utilization data or criteria for assuring a sufficient mix and number of network providers; and benchmarks or thresholds, such as measures of excessive utilization, cost levels, time or distance standards, or network participation percentage thresholds." 26 C.F.R. § 54.9812-1(a)(2); 29 C.F.R. § 2590.712(a)(2); 45 C.F.R. § 146.136(a)(2).

14. 26 C.F.R. § 54.9812-1(c)(4)(i)(B)(1); 29 C.F.R. § 2590.712(c)(4)(i)(B)(1); 45 C.F.R. § 146.136(c)(4)(i)(B)(1); see 89 Fed. Reg. at 77708 (Sept. 23, 2024).

15. 26 C.F.R. § 54.9812-1(c)(4)(i)(B)(1); 29 C.F.R. § 2590.712(c)(4)(i)(B)(1); 45 C.F.R. § 146.136(c)(4)(i)(B)(1); see 89 Fed. Reg. at 77708 (Sept. 23, 2024).

16. 26 C.F.R. § 54.9812-1(c)(4)(i)(B)(3); 29 C.F.R. § 2590.712(c)(4)(i)(B)(3); 45 C.F.R. § 146.136(c)(4)(i)(B)(3); see 89 Fed. Reg. at 77709 (Sept. 23, 2024).

17. 26 C.F.R. § 54.9812-2(c)(3); 29 C.F.R. § 2590.712-1(c)(3); 45 C.F.R. § 146.137(c)(3).

18. 26 C.F.R. § 54.9812-2(c)(3); 29 C.F.R. § 2590.712-1(c)(3); 45 C.F.R. § 146.137(c)(3).

19. 26 C.F.R. § 54.9812-2(c)(3)(iii); 29 C.F.R. § 2590.712-1(c)(3)(iii); 45 C.F.R. § 146.137(c)(3)(iii).

20. 26 C.F.R. § 54.9812-2(c)(3)(v); 29 C.F.R. § 2590.712-1(c)(3)(v); 45 C.F.R. § 146.137(c)(3)(v); see 89 Fed. Reg. at 77716 (Sept. 23, 2024).

21. 26 C.F.R. § 54.9812-2(c)(4); 29 C.F.R. § 2590.712-1(c)(4); 45 C.F.R. § 146.137(c)(4).

22. 26C.F.R.§54.9812-2(c)(4)(iv);29C.F.R.§2590.712-1(c)(4)(iv);45C.F.R.§146.137(c)(4)(iv); see 89 Fed. Reg. at 77716 (Sept. 23, 2024).

23. 26 C.F.R. § 54.9812-2(c)(5); 29 C.F.R. § 2590.712-1(c)(5); 45 C.F.R. § 146.137(c)(5).

24. 26 C.F.R. § 54.9812-2(c)(5)(i); 29 C.F.R. § 2590.712-1(c)(5)(i); 45 C.F.R. § 146.137(c)(5)(i).

25. 26 C.F.R. § 54.9812-2(c)(5)(i)(C); 29 C.F.R. § 2590.712-1(c)(5)(i)(C); 45 C.F.R. § 146.137(c)(5)(i)(C).

26. 26 C.F.R. § 54.9812-2(c)(5)(i)(D); 29 C.F.R. § 2590.712-1(c)(5)(i)(D); 45 C.F.R. § 146.137(c)(5)(i)(D); see 89 Fed. Reg. at 77646 (Sept. 23, 2024) (explaining the rationale of the Departments for why such explanation is relevant to their review of a NQTL comparative analysis).

27. 26 C.F.R. § 54.9812-2(c)(5)(ii); 29 C.F.R. § 2590.712-1(c)(5)(ii); 45 C.F.R. § 146.137(c)(5)(ii); see 89 Fed. Reg. at 77646 (Sept. 23, 2024) (framing how the Departments aim to encourage plans to critically review the extent to which access to benefits is shaped by particular NQTLs in order to drive effective mitigation strategies to mitigate material differences); for relevant data to be included, see, e.g., 26 C.F.R. §§ 54.9812-1(c)(4)(iii).

28. 26 C.F.R. § 54.9812-2(c)(5)(iii)(B); 29 C.F.R. § 2590.712-1(c)(5)(iii)(B); 45 C.F.R. § 146.137(c)(5)(iii)(B). The Departments enumerate the following non-exhaustive list of facts and circumstances as dispositive: the terms of the NQTL, the quality or limitations of the applicable data, causal explanations and analyses, evidence as to recurring or nonrecurring results, and the magnitude of disparities. 89 Fed. Reg. at 77710 (Sept. 23, 2024).

29. 26 C.F.R. § 54.9812-2(c)(5)(v); 29 C.F.R. § 2590.712-1(c)(5)(v); 45 C.F.R. § 146.137(c)(5)(v).

30. 26 C.F.R. § 54.9812-2(c)(6); 29 C.F.R. § 2590.712-1(c)(6); 45 C.F.R. § 146.137(c)(6); see 89 Fed. Reg. at 77647 (Sept. 23, 2024).

31. 29 C.F.R. § 2590.712-1(c)(6)(vi).

32. 29 C.F.R. § 2590.712-1(c)(6)(vi); see 89 Fed. Reg. at 77647-77648 (Sept. 23, 2024).

33. 26 C.F.R. § 54.9812-2(d) and (e), 29 C.F.R. § 2590.712–1(d) and (e), and 45 C.F.R. § 146.137(d) and (e).

34. 26 C.F.R. § 54.9812-2(d) and (e); 89 Fed. Reg. at 77651 (Sept. 23, 2024).

35. 26 C.F.R. § 54.9812-2(d)(2); 29 C.F.R. § 2590.712–1(d)(2); 45 C.F.R. § 146.137(d)(2); see 89 Fed. Reg. at 77649 (Sept. 23, 2024).

36. 26 C.F.R. § 54.9812-2(d)(4); 29 C.F.R. § 2590.712–1(d)(4); 45 C.F.R. § 146.137(d)(4).