



October 17, 2023

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**Re: Requirements Related to the Mental Health Parity and Addiction Equity Act  
RIN- 1210-AC11; RIN 1545 - BQ29; RIN 0938-AU-93**

Dear Administrator Brooks-LaSure, Assistant Secretary Gomez, and Commissioner Werfel:

The Association for Behavioral Health and Wellness (ABHW) appreciates the opportunity to submit comments on the U.S. Department of Labor (DOL), U.S. Department of Health and Human Services (HHS), and U.S. Department of Treasury (DOT), collectively, “the Tri-Departments” notice of proposed rulemaking (proposed rule or NPRM) Requirements Related to the Mental Health Parity and Addiction Equity Act (MHPAEA).

ABHW is the national voice for payers managing behavioral health (BH) insurance benefits. Our member companies provide coverage to approximately 200 million people in the public and private sectors to treat mental health (MH), substance use disorders (SUDs), and other behaviors that impact health and wellness.

Since its inception, ABHW has been at the forefront of and an advocate for MH and SUD parity. ABHW was instrumental in drafting the legislative language of the initial MHPAEA of 2008, and

our members have worked tirelessly over the past 15 years to implement parity for behavioral health services. For example, over the years, ABHW members have made the following changes that have improved access to behavioral health treatment, services, and providers:

- Established behavioral health co-payments that align with medical visit co-pays;
- Eliminated arbitrary treatment limitations on the number of days of coverage for a condition, as well as financial limits on annual and lifetime dollar caps;
- Reduced the application of prior authorization for mental health and substance use disorder services so that they are comparable to medical benefits;
- Integrated medical, pharmacy, and behavioral health benefits to increase consumer engagement and reduce overall medical costs;
- Expanded provider networks and increased accessibility via telehealth services;<sup>1</sup> and
- Removed separate deductibles for BH benefits and Medical /Surgical (M/S) benefits as a result of MHPAEA.

Our members have significantly modified their plan limitations as a result of MHPAEA. As an example, fewer mental health services at our member organizations are subject to prior authorizations than in the past. Numerous members have removed or decreased the application of prior authorization and other medical management reviews from most in-network outpatient and telehealth-delivered services. Additionally, ABHW member companies have taken a wide range of actions during the COVID-19 public health emergency (PHE) and after to help ensure that people with MH and SUDs receive the care they need. However, these enhancements are not reflected in the technical MHPAEA rubric. Some examples of how our members are enhancing patient behavioral health access include:

- Growing the Behavioral Health Workforce. Many plans are focused on growing the pool of licensed clinical behavioral health providers, such as licensed social workers, counselors, and peers, through grants for student loan forgiveness, advocating for federal and state governments to expand coverage options and remove barriers to practice, and other measures.
- Focus on Integrated Care. Our members have committed to enhancing the coordination between medical and behavioral healthcare since it is proven to increase mental health and SUD access to care and outcomes, including adopting and endorsing the Collaborative Care Model.
- Telehealth. Health plans have implemented innovative telehealth options to deliver substance use and mental health services and improve access to care.<sup>2</sup>
- Reviewing Crisis Service Capabilities. Our members are actively engaged in promoting effective, comprehensive crisis services and are reviewing crisis capabilities through increased coverage of and contracting with Community Crisis Behavioral Health Centers, for example.

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<sup>1</sup> Since the pandemic, ABHW members have increased their in-network behavioral health providers. Health plans are actively recruiting mental health care providers, including practitioners who reflect the diversity of the people they serve; The Journal of American Medicine Association (JAMA) Network available at <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2808748>

<sup>2</sup> *Id.* at <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2808748>

- Children and Young Adults. Plans are dedicated to addressing behavioral health for children and young adults. As an example, some members have deepened their relationships with schools to enhance school-based mental health services.

ABHW appreciates the significant efforts that went into the development of this NPRM. However, finalizing many of the provisions proposed in the NPRM would negatively impact patient health outcomes and quality while simultaneously increasing the cost of care for health plans and issuers, employers, and patients. As we explain in detail below, rather than providing clarity and specificity concerning what health plans and issuers must do and must document to comply with parity, the Tri-Departments' proposals, if finalized, would significantly and unnecessarily complicate and expand the burden on health plans and issuers to demonstrate compliance.

Moreover, the Tri-Departments fail to substantiate how the proposed changes in the NPRM would enhance parity or help achieve parity compliance. Instead, the Tri-Departments seem to assert that the proposed changes would cure a range of ills beyond those sought to be addressed under the MHPAEA law (for example, by enhancing access to MH and SUD providers).

The Tri-Departments' estimate of the administrative burden from implementing the proposed rules dramatically understates the additional resources, costs, and labor required to meet these documentation requirements. Importantly, the Tri-Departments fail to quantify the benefits that would come from the implementation of these proposals, which may be relatively minimal in practice based on enforcement outcomes to date. Nonetheless, the Tri-Departments conclude that the benefits justify the costs, with, as noted above, no quantitative analysis to support this conclusion.

The proposed rule, if finalized, would require a broad-reaching expansion of the information collection and data analyses health plans and issuers must complete to demonstrate parity compliance and the depth of the Tri-Departments' push into controlling how health plans and issuers define and operate health plan benefit packages and networks for mental health and substance use disorder coverage. We urge the Tri-Departments to consider the critical issues listed below and address them in the final rule.

While we provide detailed comments below, ABHW's critical concerns with the proposed rule are the following:

- **The "Substantially All – Predominant" Test:** These quantitative tests are inappropriate to apply to Non Quantitative Treatment Limits (NQTLs) for the following reasons and should be rescinded. (1) the statutory text does not support the application of quantitative testing to NQTLs, (2) the proposed quantitative testing requirement would overturn 15 years of guidance and enforcement, (3) the proposed guidance for applying quantitative testing to nonquantitative treatment limits is excessively complex and ambiguous and will inevitably lead to arbitrary and capricious enforcement, (4) the proposed quantitative testing does not allow for plans to apply reasonable and appropriate clinical reasoning to the management of MH/SUD benefits, (5) the quantitative testing requirements are unnecessary to resolve the identified concerns in all of the proposed examples, (6) will eliminate a wide range of reasonable and important NQTL types, and (7) identification of

“variations” and the predominant variation of an NQTL will be arbitrary and unpredictable.

- **Clinical Standards and Fraud, Waste, and Abuse Exceptions:** ABHW requests that the Tri-Departments specify what is required to show that the independent professional medical or clinical standards and the fraud, waste, and abuse exceptions were applied in a manner that meets the exception.
- **Additional Exceptions Needed:** ABHW requests that the Departments create exceptions for additional factor types, including, at minimum, factors based on (1) compliance with federal and state law and (2) quality and safety.
- **Material Difference in Outcomes Data and the Special Rule for Network Composition:** The Tri-Departments’ enforcement powers do not permit them to require corrective action in the absence of noncompliance; ABHW, therefore, recommends that these sections be revised to apply only where the plan is unable to rebut the presumption of noncompliance that is triggered by a material difference in a required data measure. ABHW is suggesting standard language for when a material difference should be applied. The special rule for network composition NQTLs is inappropriate and should be rescinded. ABHW opposes the proposal to determine compliance with MHPAEA for NQTLs related to provider network composition based solely on the outcomes of an undefined and untested set of measures.
- **NQTL Analyses and Documentation:** The regulations should require plans and issuers to routinely complete a comparative analysis only for those NQTLs explicitly identified in published guidance and should provide additional time for a plan or issuer to create a comparative analysis for any NQTL type that is not included in the published list and is requested by a regulator pursuant to a specifically identified concern.
- **Appeals Process:** ABHW requests the development of a procedural review process in cases of potential parity noncompliance. An appeals process is critical to maintaining checks and balances within the healthcare system.
- **Applicability Date:** The new content in the proposed rules significantly expands the scope of the 2013 final rule, and as a result, the applicability date should be extended to January 1, 2026, for group plans and issuers and January 1, 2027, for individual plan issuers.

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**Purpose Section – 26 CFR 54.9812-1(a)(1), 29 CFR 2590.712(a)(1), and 45 CFR 146.136(a)(1).**

The restatement of the fundamental purpose of the parity requirements emphasizes that the mental health parity law is intended to protect “participants and beneficiaries.” In other words, parity is not intended to be provider protection, and limits should be analyzed solely for their impact on participants and beneficiaries.

⇒ *ABHW supports the framing of this new purpose requirement.*

**Meaning of Terms – 26 CFR 54.9812-1(a)(2), 29 CFR 2590.712(a)(2), and 45 CFR 146.136(a)(2).**

Under the current regulations, the definition of “Mental Health Benefits” allows for plan discretion to determine that certain intellectual and neurodevelopmental disorders are not mental health conditions, including dementias, autism, and other intellectual and developmental disabilities. It

may be reasonable to justify definitions for “mental health conditions” that exclude intellectual and developmental disabilities based on the structure of the International Classification of Diseases (ICD-10), historical differences in provider types and financing and delivery systems, and state law definitions. The proposed rule would override these justifications and explicitly require plans to include all conditions in the Diagnostic and Statistical Manual of Mental Disorders (DSM) or the mental, behavioral, and neurodevelopmental disorders chapter of the ICD-10 in their definition for Mental Health Benefits.

⇒ *ABHW appreciates the clarity of this definition.*

Unfortunately, the proposed definition does not fully address the appropriate methodology for categorizing benefits for the purposes of plan design and operation. ABHW has previously requested that the Tri-Departments clarify the meaning of the key phrase “items or services for mental health conditions.” That letter is attached here as Appendix A. As ABHW’s letter noted, neither the 2013 MHPAEA Regulations nor any FAQ or other federal guidance directly addresses the proper application of parity to benefits with respect to treatments and services that can be delivered to care for both MH/SUD and M/S conditions, such as speech and occupational therapy, urgent care, and a wide range of other services. The most reasonable and practical interpretation of the current rules is that benefits “for” MH/SUD conditions are benefits for treatments and services that are generally delivered to treat MH/SUD conditions and that all other benefits are M/S benefits. The proposed rule provides no discussion of the application of parity to “cross-over services” that are delivered to treat both MH/SUD and M/S conditions or of the administrative and operational challenges that would arise from determining whether to treat each individual claim or authorization as a MH/SUD benefit or a M/S benefit based on the diagnosis code.

⇒ *ABHW requests that the final rules add the following language to the end of the proposed definitions for “Mental health benefits,” “Substance use disorder benefits,” and “Medical/surgical benefits”:*

**“[...] The plan or issuer must define items or services to be “for” mental health conditions according to a reasonable method, such as by determining:**

- **Whether the treatment or service is most commonly delivered to treat mental health conditions.**
- **Whether the treatment or service is most commonly delivered by mental health treatment providers and/or**
- **Whether administration of claims or coverage for the treatment or service is provided through a vendor contracted to administer medical/surgical benefits.**

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**The Tri-Departments should rescind all requirements regarding quantitative testing for NQTLs - 26 CFR 54.9812-1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i).**

ABHW requests that the Tri-Departments rescind the proposal to apply the “predominant” and “substantially all” quantitative tests to NQTLs.

Under the proposed rule, the Tri-Departments would reinterpret the MHPAEA statute to subject NQTLs to a modified version of the quantitative tests currently applied to quantitative treatment limits (“QTLs”). The Tri-Departments would require plans and issuers to ensure that NQTLs applied to MH/SUD benefits are “no more restrictive” than the “predominant” NQTL that applies to “substantially all” M/S benefits in a particular classification. These quantitative tests are inappropriate to apply to NQTLs for five reasons: (1) the statutory text does not support the application of quantitative testing to NQTLs, (2) the proposed quantitative testing requirement would overturn 15 years of guidance and enforcement of MHPAEA, (3) the proposed application for quantitative testing to nonquantitative treatment limits is excessively complex and ambiguous and will inevitably lead to arbitrary and capricious enforcement (4) the proposed quantitative testing does not allow for plans to apply reasonable and appropriate clinical reasoning to the management of MH/SUD benefits, (5) the quantitative testing requirements are unnecessary to resolve the identified concerns in all of the proposed examples, (6) would eliminate a wide range of reasonable and important NQTL types, and (7) identification of “variations” and the predominant variation of an NQTL will be arbitrary and unpredictable.

*(1) The statutory text does not support the application of quantitative testing to NQTLs.*

The Tri-Departments assert that their proposal to reinterpret the MHPAEA statute to apply quantitative testing to NQTLs is “consistent with the fundamental purpose of MHPAEA and more closely mirrors the statutory language in Code section 9812(a)(3)(A), ERISA section 712(a)(3)(A), and PHS Act 2726(a)(3)(A), which states that plans and issuers ‘...shall ensure that...the treatment limitations applicable to...mental health or substance use disorder benefits are no more restrictive than the predominant treatment limitations applied to substantially all medical and surgical benefits covered by the plan ([or coverage]) . . . .’”<sup>3</sup> The Tri-Departments do not identify any information from the legislative record, which includes three significant amendments to the MHPAEA statute,<sup>4</sup> or the numerous Congressional hearings on parity enforcement to support their sudden and surprising discovery that they have been misinterpreting the statute since the time that the Tri-Departments first introduced the concept of NQTLs in the 2010 Interim Final Rule (IFR). In addition, the Tri-Departments’ argument fails to acknowledge the definition of “treatment limitations” and conflicts with the requirements for NQTLs that are set forth elsewhere in the statute.

First, the requirements that the Tri-Departments refer to in Code section 9812(a)(3)(A), ERISA section 712(a)(3)(A), and PHS Act 2726(a)(3)(A) apply to “treatment limitations,” which is defined for the purposes of the applicable paragraph as follows: “The term ‘treatment limitation’ includes limits on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment.”<sup>5</sup> Each of these examples is clearly quantitative in nature, as would be expected regarding the quantitative testing requirement applied by this paragraph. *Nonquantitative* treatment limits, such as medical management standards based on medical necessity or appropriateness, provider network admission standards, and related health plan functions, are clearly not “similar” to the *quantitative* limits identified in the statutory

<sup>3</sup> NPRM, p. 240 <https://www.federalregister.gov/d/2023-15945/p-240>

<sup>4</sup> Pub. L. 111–148, title I, §§ 1001(2), 1563(c)(4), formerly § 1562(c)(4), title X, § 10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 265, 911; Pub. L. 114–255, div. B, title XIII, § 13001(a), (b), Dec. 13, 2016, 130 Stat. 1278, 1280; Pub. L. 116–260, div. BB, title II, § 203(a)(1), Dec. 27, 2020, 134 Stat. 2900.

<sup>5</sup> Code section 9812(a)(3)(B)(iii), ERISA section 712(a)(3)(B)(iii), and PHS Act 2726(a)(3)(B)(iii)

definition. Nor is there any indication in the statute or the many hundreds of pages of regulatory and sub-regulatory guidance that the Tri-Departments have issued since the 2010 IFR that would suggest that the quantitative test should apply to NQTLs.

Instead, both the statute and 13 years of guidance unequivocally establish that NQTLs are subject to a separate test. Congress specifically amended the statute in 2016 to require the Tri-Departments to publish guidance to demonstrate the appropriate methodology for determining compliance for NQTLs, including “clarifying information and illustrative examples of methods, processes, strategies, evidentiary standards, and other factors that group health plans and health insurance issuers offering group or individual health insurance coverage may use regarding the development and application of nonquantitative treatment limitations to ensure compliance with this section.”<sup>6</sup> This amendment would have been unnecessary if NQTLs were subject to the same quantitative testing requirements as quantitative limits and financial requirements. Congress again amended the statute in 2020 to set forth a new framework for documenting compliance for NQTLs based on the plan or issuer’s analysis of the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs.”<sup>7</sup> This 2020 amendment provides extensive detail regarding the content, scope, and enforcement of these new documentation requirements. It never once makes any allusion to the need for, or application of, quantitative testing to NQTLs. If Congress had determined that the Tri-Departments had failed to apply the quantitative test to NQTLs, they could have said so in either the 2016 or 2020 amendments requiring guidance on NQTLs. Instead, it is clear that Congress intended to, and did, establish an entirely different test for NQTLs.

*(2) The proposed quantitative testing requirement is arbitrary and capricious because it would overturn 13 years of guidance and enforcement without justification.*

The Administrative Procedure Act (APA) requires an agency to give a reasoned analysis for any decision to overturn previous guidance, including consideration for the legitimate interests of entities that have relied on that previous guidance.<sup>8</sup> Since the MHPAEA statute was passed, the Tri-Departments have issued an Interim Final Rule, final regulations, fourteen (14) sets of FAQs, a Self-Compliance Tool that has been updated at least three (3) times, seven (7) reports to Congress, two (2) published studies on compliance, a “Warning Signs” document, and nine (9) enforcement fact sheets, not to mention a variety of webinars and other publications on parity compliance. For 13 years, this guidance has been consistent: the “predominant” and “substantially all” quantitative testing requirements apply to quantitative limits and financial requirements only; the “comparability and stringency” test applies to the processes, strategies, evidentiary standards, and other factors that are used to design and apply an NQTL. The Tri-Departments do not justify their surprising new conclusion that the entirety of this previous guidance was wrong. Indeed, the entire premise for overturning their previous interpretation and creating extensive new and confusing requirements for applying quantitative testing to NQTLs is based on the brief assertion

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<sup>6</sup> Code section 9812(a)(7)(C), ERISA section 712(a)(7)(C), and PHS Act 2726(a)(7)(C)

<sup>7</sup> Code section 9812(a)(8)(A), ERISA section 712(a)(8)(A), and PHS Act 2726(a)(8)(A)

<sup>8</sup> See, e.g. *Smiley v. Citibank* (S.D.), N.A., 517 U.S. 735, 742 (1996) (“Sudden and unexplained change [...] or change that does not take account of legitimate reliance on prior interpretation [...] may be “arbitrary, capricious [or] an abuse of discretion”); *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 57, 103 S. Ct. 2856, 2874, 77 L. Ed. 2d 443 (1983) (“an agency changing its course must supply a reasoned analysis”).

that it “more closely mirrors the statutory language,”<sup>9</sup> with no explanation of why they spent 13 years misinterpreting or ignoring those same words. A change of this magnitude requires a reasoned justification. The Tri-Departments’ proposed rule also gives no consideration to the legitimate interests of the plans and issuers that have relied on existing guidance in developing NQTL design strategies, data systems, and operations that do not account for quantitative testing for NQTLs.

*(3) The proposed guidance for applying quantitative testing to nonquantitative treatment limits is excessively complex and ambiguous. It will lead to chaotic results for application when applying NQTLs to MH/SUD benefits.*

Considerable ambiguity exists relating to several aspects of the proposed quantitative testing requirements for NQTLs, as discussed in detail below. This ambiguity creates a challenging environment for health plans and carriers who must choose between regulatory conservativeness and market competitiveness. The proposed quantitative testing requirements are also likely to significantly increase the complexity and cost of the administration of plans and benefits for several reasons:

- Many common NQTLs would fail without an exception, and significant ambiguity regarding the proposed exceptions would make it highly challenging for plans to know with certainty whether they qualify for an exception.
- Some health plans and carriers may determine that certain NQTLs comply with the quantitative testing requirements for some plans and products but not others.
- Certain NQTLs may meet the quantitative testing requirements in some years but not others.
- Evolving guidance and enforcement regarding the quantitative testing requirements will likely create significant shifts over time about the application of many NQTLs.

All of this change, uncertainty, and inconsistency across payors, products, and plans will create significant administrative burdens and operational complexity for health plans and issuers. This will also create substantial confusion and burden on providers and consumers, who will be forced to deal with far greater complexity in determining whether or not a given NQTL applies to a given treatment or service under a given patient’s health plan in a given year.

*(4) The proposed quantitative testing does not allow for plans to apply reasonable and appropriate clinical and operational considerations to the management of MH/SUD benefits and would eliminate a wide range of reasonable and important NQTL types.*

Quantitative tests make sense to determine compliance for financial requirements and quantitative treatment limitations where such limits are measured in equal units and treat benefits as interchangeable widgets. Annual and lifetime coverage limits and cost-sharing are purely financial and bear little relationship to the patient’s need for the service. The context for developing NQTLs is completely different and is based on nuanced clinical and operational strategies. Health plans and issuers develop NQTLs to ensure that covered services are medically necessary, safe, and high quality while also avoiding spending on services that are likely to

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<sup>9</sup> NPRM, p. 240 <https://www.federalregister.gov/d/2023-15945/p-240>.



constitute low-value care or fraud, waste, or abuse. For this reason, the existing interpretation and enforcement of MHPAEA for NQTLs is more appropriate, focusing on the comparability of the underlying *methodology* to determine which benefits are subject to the limit and holding that “disparate results alone do not mean that the NQTLs in use fail to comply with these requirements.”<sup>10</sup> We recognize the Tri-Departments’ attempt to create safe harbors to preserve the ability to apply limits that are clinically reasonable and/or reasonably designed to avoid fraud, waste, and abuse. However, the safe harbors to the quantitative testing requirements are likely to be unavailing to many plans, for reasons explained in further detail in the section of this letter that addresses these exceptions.

To the extent that plans are unable to adequately demonstrate to regulators that their factors for applying an NQTL fit the narrow and potentially illusory safe harbors, they would be unable to apply the NQTL to any MH or SUD benefit unless the NQTL meets the “substantially all” tests as applied to M/S benefits. However, because many NQTLs are not appropriate to apply to substantially all M/S benefits, the quantitative testing requirement may lead to the elimination of a number of NQTLs that are appropriate and necessary to properly administer MH/SUD benefits. For example, few plans and issuers apply prior authorization, step therapy, quantity limits, or any other utilization management requirement to substantially all M/S drugs. Yet plans and issuers generally apply these limits for consistent and appropriate reasons and have no incentive to apply them disproportionately to MH/SUD drugs.

*(5) The quantitative testing requirements are unnecessary to resolve the identified concerns in all of the proposed examples.*

The Tri-Departments provide thirteen (13) examples in the proposed rule to demonstrate the intended application of the quantitative testing requirement.<sup>11</sup> In each example where the plan is found to violate the “substantially all” or “predominant” test, the Tri-Departments would already find, under existing guidance, that the NQTL violates the “as written” and/or “in operation” comparability requirements that are currently applied to NQTLs. Nowhere in the proposed rules do the Tri-Departments identify any concern that the current NQTL requirements are inadequate to ensure that such limits are designed or applied comparably and no more stringently to MH/SUD benefits relative to M/S benefits.

At a minimum, we request that the Tri-Departments better explain the intended difference between the new quantitative testing requirements and the existing comparability and stringency requirements by creating new examples in the final rules that would demonstrate scenarios where an NQTL would be permissible under the requirements for comparability of “processes, strategies, evidentiary standards, and other factors,” both “as written” and “in operation,” but would still be prohibited by the new quantitative testing requirements. We believe that such examples, if based on actual, common NQTL designs, will illustrate the perverse outcome of the proposed quantitative testing requirements and how it would extend beyond any reasonable interpretation of “parity” between MH/SUD and M/S benefits and would instead effectively privilege MH/SUD benefits while discriminating against M/S benefits.

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<sup>10</sup> 2013 Final Rules, Preamble p. 60, and again on p. 70 <https://www.federalregister.gov/d/2013-27086/p-60>.

<sup>11</sup> 26 CFR 54.9812-1(c)(4)(viii), 29 CFR 2590.712(c)(4)(viii), and 45 CFR 146.136(c)(4)(viii).

*(6) The quantitative testing requirement should be eliminated because the identification of “variations” and the predominant variation of an NQTL will be arbitrary and unpredictable.*

In order to find a way to apply the “predominant” test to NQTLs, the Tri-Departments introduce the new concept of “variations” of an NQTL and propose that ‘predominant’ means “the most common or frequent variation of an NQTL within a benefit classification.”<sup>12</sup> However, the proposed rules do not define the new term “variation” and provide little guidance about how a plan is expected to determine what a variation of an NQTL is, how many variations apply, or whether there is a variation at all. The scope of potential “variations” is limited only by one’s creativity. For example, for prior authorization, a plan or regulator could conceivably determine that “variations” include any or all of the following aspects: the credentials of the reviewer, the type or source of clinical criteria applied, the timing of the review (e.g. urgent vs. non-urgent), the modality of authorization submission (e.g. via electronic health record vs. fax or pdf form), the use of “gold carding,” the use of automated reviews, the type of units of authorization (e.g. days vs. service units), the volume of units authorized or frequency of review... and so on. The proposed requirement to apply quantitative testing for every different variation would be extremely burdensome at best, but the ambiguity about the breadth and scope of different variations that must be analyzed and documented makes it an impossible task for regulated health plans to fully comply with this requirement.

The Tri-Departments also propose in this and other sections to require plans to identify and distinguish between different NQTL types, different variations of the same NQTL, different factors for designing and applying the NQTL, and different variations of factors for applying the NQTL but do not define most of these terms and provide little to no guidance to determine how to characterize a given aspect of an NQTL. For example, to the extent that a plan’s application of prior authorization, concurrent review, and retrospective review differs only in the timing of the review relative to the service delivery, with all other aspects of the review being the same (e.g., same services, same reviewers, same clinical criteria, same consequences, etc.), how should a plan know whether to analyze these as different NQTL types, different variations of the same NQTL type, or different in-operation processes? Yet the distinction is critical given that each of these elements is subject to a different documentation and analysis requirement.

Thus, any definitions to distinguish NQTL types, variations, and factors would be arbitrary, and the analysis and documentation requirements would vary significantly based on such arbitrary distinctions. It is, therefore, reasonable and appropriate to instead maintain the current NQTL testing requirements, under which such distinctions would not exist or would be irrelevant to the compliance determination.

*(7) The requirement to apply quantitative testing at the plan level would be highly burdensome and would generate perverse results.*

This proposed methodology of determining the portion of plan payments is impractical and would generate perverse results for many issuers and health plan administrators. The regulations state that plan-level data is most appropriate to utilize, whenever possible, to determine the dollar amount expected to be paid for the purposes of the quantitative testing

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<sup>12</sup> *Id.* at 51571.

requirement.<sup>13</sup> However, where a health plan administrator or insurance carrier administers a number of different plans, it is rare for most NQTLs to vary by plan, in part due to the administrative complexity for both the administrator or insurer and the providers that it works with. Thus, for example, the design and application of prior authorization will likely be the same for all self-funded employer health plans administered by an insurance issuer or plan administrator. Yet by requiring testing to be applied at the plan level, it is possible and perhaps likely that random variability in member demographics and service utilization among plans would lead to a determination that an NQTL is permissible for some plans but not other plans (and/or that the NQTL is permissible for a plan in some years but not other years) even where the underlying strategy and application of the NQTL is otherwise identical across all plans (and/or years).

The administrative burden of conducting the substantially all test across many plans and the possibility of being regulatorily required to modify internal operations within some of an issuer's plans and not others to satisfy the substantially all test will impose enormous administrative and cost burden on issuers. The cost to operationalize changes at the plan level would require systems programming changes, staff training on variability between accounts, and the need to modify this year to year if the claims produce different results in subsequent years. This situation would also introduce uncertainty for members (e.g., by causing prior authorization lists to fluctuate significantly from year to year) and for providers (e.g., where providers would be required to comply with prior authorization requirements differently across a potentially very large number of plans that are all operated under a single product).

⇒ *For these reasons, ABHW recommends removing the quantitative testing requirements from the final regulations.*

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**Exceptions for Independent Professional Medical or Clinical Standards and Standards to Detect or Prevent and Prove Fraud, Waste, and Abuse - 26 CFR 54.9812-1(c)(4)(i)(E), 29 CFR 2590.712(c)(4)(i)(E), and 45 CFR 146.136(c)(4)(i)(E) and 26 CFR 54.9812-1(c)(4)(iv)(D), 29 CFR 2590.712(c)(4)(iv)(D), and 45 CFR 146.136(c)(4)(iv)(D).**

The Tri-Departments propose exceptions at (c)(4)(i)(E), which establish that if a plan applies an NQTL that “impartially applies independent professional medical or clinical standards or applies standards to detect or prevent and prove fraud, waste, and abuse” to MH/SUD benefits, then such NQTL will not be considered to violate the “no more restrictive” requirement. ABHW values both these proposed exceptions as they are critical to delivering patient safety and quality of care. However, ABHW is concerned that the scope of these exceptions, as proposed, may be insufficient to allow the operation of reasonable and appropriate NQTLs.

**(1) Independent Professional Medical or Clinical Standards**

Although the Tri-Departments assert that they “do not intend to interfere with a plan’s or issuer’s attempts to ensure that coverage for benefits for the treatment of [MH/SUD conditions] is

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<sup>13</sup> <https://www.federalregister.gov/d/2023-15945/p-243>

consistent with generally accepted independent professional medical or clinical standards,” it is not clear how many NQTLs would qualify for this exception in practice.

At (c)(4)(v)(A), the Tri-Departments state that, in order to qualify for the independent standards exception at (c)(4)(i)(E), an NQTL “must impartially apply generally recognized independent professional medical or clinical standards (consistent with generally accepted standards of care) to [M/S] benefits and [MH/SUD] benefits, and may not deviate from those standards in any way, such as by imposing additional or different requirements.”

In addition, the Tri-Departments provide no guidance as to which independent professional medical or clinical standards would meet this definition. Plans may rely on a variety of sources to determine what constitutes “generally accepted standards of care,” including but not limited to third-party criteria, such as Interqual, MCG, ASAM, LOCUS, CALOCUS-CASII, but also other third-party analyses, such as Hayes and ECRI evidence assessments, as well as peer-reviewed medical literature considered in the context of the breadth of scientific literature on the same subject (i.e., evaluating the weight of the evidence based on the quality and strength of findings); or the recommendations from independent expert panels that include representation from expert clinicians in the relevant field.

⇒ *ABHW requests that the Tri-Departments broadly interpret the phrase “independent professional medical or clinical standards” and provide examples of standards that would meet the exception.*

Further, the Tri-Departments provide no guidance on what it means to “apply” the independent professional medical or clinical standards for purposes of meeting the exception to the “no more restrictive” requirement. If the plan uses independent professional medical or clinical standards as medical necessity criteria for an NQTL related to utilization management, do the “strategy factors” used to determine which benefits to subject to the NQTL become irrelevant to the “no more restrictive” requirement? Generally, independent professional medical or clinical standards are drafted for clinical purposes, not for medical management or utilization review. For example, independent professional medical or clinical standards generally do not suggest which benefits or services should be subject to specific forms of utilization management. Many independent professional medical or clinical standards focus on minimum thresholds for the efficacy of a treatment or service and do not address upper bounds of efficacy (in terms of intensiveness, duration, staffing, dosage, etc.). Many independent professional medical or clinical standards also do not evaluate the cost-effectiveness of the treatment or service relative to therapeutic alternatives. Finally, independent professional medical or clinical standards generally do not address the appropriate duration of authorization or frequency of review. Accordingly, it is unclear if, for example, an independent professional medical or clinical standard can be used as a design factor for purposes of a prior authorization NQTL if such standard does not explicitly reference the application of prior authorization under the standard. If an NQTL defines processes used to apply the NQTL that are not addressed in the independent professional medical or clinical standard, does that mean that the plan is “imposing additional or different requirements”?

We note that Example 5 includes a conclusion that independent professional medical or clinical standards are impartially applied. However, the Example would be more useful if it explained

what standards the plan relied upon and how the plan was able to demonstrate that such standards were impartially applied to design and implement the NQTL.

⇒ *ABHW requests that the Tri-Departments specify that this exception includes the use of reasonable strategies to ensure that care is delivered in accordance with the identified independent professional medical or clinical standards and provide examples of how the exception would apply to the design of common NQTL types, such as medical necessity, prior authorization, and concurrent review.*

Example 3 makes clear that even where a plan utilizes “medical necessity standards [that] are based on independent professional medical or clinical standards” to make medical necessity determinations for both MH/SUD and M/S benefits, quantitative testing is still required where there is any variation in the plan’s application of the NQTL (in this example, relating to the use of peer-to-peer review, which is not a consideration that would generally be addressed by an independent professional medical or clinical standard)).<sup>14</sup> Given the uncertainty about what constitutes a “variation” in an NQTL and the fact that independent professional medical or clinical standards generally do not address a wide variety of operational considerations for the design and implementation of NQTLs, the scope of the exception to the quantitative testing requirement may be quite limited or illusory in reality.

⇒ *ABHW requests that the Tri-Departments clarify what is an impermissible deviation from a standard that would otherwise meet the exception and what is required to show that the plan did not “deviate” from the standard “in any way.”*

Moreover, the Tri-Departments do not explain how or whether the exception may apply if any design factors other than independent professional medical or clinical standards are used to determine which benefits to subject to the NQTL. Again, Example 5 includes an assumption that no other factors or evidentiary standards, aside from independent professional medical or clinical standards, are relied upon.<sup>15</sup> However, given that it is common to base decisions about whether and how to apply an NQTL on factors other than (or in addition to) the independent professional medical or clinical standards themselves (including evidence from peer-reviewed medical literature that may not constitute “independent professional medical or clinical standards” or state law mandates), it may in practice be rare for an NQTL to qualify for an exception to the “no more restrictive” requirement if the use of additional factors eliminates the plan’s ability to rely on the exception altogether.

## (2) Fraud, Waste, and Abuse Standards

At (c)(4)(v)(B), the Tri-Departments state that, in order to qualify for the fraud, waste, and abuse exception at (c)(4)(i)(E), 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 [MH/SUD] benefits.” Enforcement experience to date suggests that the Tri-Departments will set a relatively high bar for methodological rigor, and

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<sup>14</sup> 88 Fed. Reg. at 51,581.

<sup>15</sup> 88 Fed. Reg. at 51,581.

without further guidance with respect to what is expected to meet the fraud, waste, and abuse exception, many plans may find it onerous or impossible to gather and document “objective and unbiased” data in a consistent way across all benefits and services within a classification in order to demonstrate the consistent application of the plan’s criteria for reliably establishing indicia of fraud, waste, and abuse. For example, common indicia for fraud, waste, and abuse include referrals from members and providers, private audits and settlements, government audits, alerts and enforcement actions, and complex algorithmic analytical tools or artificial intelligence. In many cases, plans do not have the ability to obtain underlying data or to prove that these data are, in fact, objective and unbiased.<sup>16</sup> Thus, many common indicia for fraud, waste, and abuse that are currently relied upon may be insufficient to qualify for the proposed exception to the quantitative testing requirement, and the proposed regulations may stifle further innovation in the design and application of this vital activity.

- ⇒ *ABHW recommends that the Tri-Departments amend the proposed exception to apply to “other evidence” to provide further guidance to illustrate the expected design and data thresholds for a plan to show that it has met all of these requirements in order to rely upon the fraud, waste, and abuse exception, and to include examples to demonstrate that plan experts may rely on professional judgment to evaluate the reliability of identified indicia of fraud, waste, or abuse that are not established through objective and unbiased data.*
- ⇒ *ABHW also recommends that the Tri-Departments consult with their respective OIGs to ensure that the finalized exception permits reasonable strategies for detecting fraud, waste, and abuse.*

The proposed rules do not specify how a plan should account for changes to data or other indicators of fraud, waste, or abuse that occur over time.

- ⇒ *ABHW requests that the Tri-Departments provide clear guidance specifying that health plans may use any reasonable methodology to determine how often the fraud, waste, and abuse data or other indicia must be reanalyzed to show that the standard for reliance on the exception continues to be met.*

ABHW is also concerned that the requirement to document strategies for detecting fraud, waste, and abuse and to make such documentation publicly available (including to members upon request) will enable and embolden fraudulent actors to engineer new strategies to avoid detection. For the same reason that the Tri-Departments’ own Offices of the Inspector General (OIG) do not publish the details of their strategies to detect fraud, waste, and abuse, health plans rely on privacy and confidentiality to protect the effectiveness of their fraud, waste, and abuse monitoring strategies.

- ⇒ *ABHW requests that health plans be permitted to redact all narrative discussion and data regarding fraud, waste, and abuse monitoring and detection strategies from publicly disclosed versions of their parity compliance documentation and that the Tri-Departments honor plan requests to refrain from disclosing these proprietary and confidential details to any third party.*

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<sup>16</sup> Indeed, data sources such as referrals may not be “objective and unbiased,” but that does not mean that it is unreasonable for the plan to evaluate such referrals.

As the Tri-Departments consider ways to guide health plans in complying with these requirements, we submit the following example that satisfies the exception for standards to detect fraud, waste, and abuse for inclusion in the final rule:

A plan monitors all claims, OIG reports, and independent publications for potential instances of fraud, waste, and abuse. If potential fraud, waste, or abuse is identified through this monitoring, an investigation is conducted to determine if actual fraud, waste, or abuse is occurring. The plan has developed a graduated approach (e.g., targeting single providers to broader monitoring efforts) for preventing future fraud waste and abuse based on the scale and scope of the potential fraud. This approach applies to all providers and benefits.

As part of this process, the plan identifies extensive fraud, waste, and abuse occurring for Applied Behavior Analysis (ABA) services in a plan's service area. Based on its predetermined policy that applies when fraud costs more than a certain dollar threshold and includes a certain number of providers (e.g., \$1,000,000 and more than 25 providers), it implements a pre-payment review process to identify fraud, waste, and abuse for all ABA services. This process remains in place until the amount of waste, fraud, and abuse is reduced below a predetermined threshold (e.g., less than \$10,000 over six months), at which point the plan returns to post-payment review of claims.

This plan meets NQTL parity requirements under MHPAEA. Because it is 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 (as the pre-payment review was eliminated once fraud, waste and abuse could be mitigated). Because the plan also monitors the level of fraud, waste, and abuse of these services on an ongoing basis (to ensure the pre-payment review is still needed), it meets the relevant data and evaluation requirements.

### (3) Additional Exceptions are Needed

ABHW requests that the Tri-Departments create exceptions for additional factor types, including, at minimum, factors based on (1) compliance with federal and state law and (2) quality and safety.

For compliance with federal and state law, ABHW notes that many state laws either require or prohibit certain practices with regard to utilization management, provider credentialing, and other NQTL types. Federal and state law requirements may complement, alter, or even conflict with (and supersede) applicable independent clinical and medical standards and/or the plan's strategies to detect or prevent and prove fraud, waste, and abuse. In the interest of consistency and administrative simplicity, issuers and health plan administrators may also choose to apply the federal or state law requirement across markets, including, e.g., the application of standards or requirements set forth in state insurance law or set forth by CMS for Medicare Advantage products to all plans that the company administers. The federal regulations should acknowledge

the inherent reasonableness of such a strategy and not find that the plan loses access to the existing exceptions from the quantitative testing and non-discriminatory factor requirements merely because it applies a federal or state law to the design or operation of an NQTL.

ABHW also requests that an exception be created for factors designed to ensure the quality and safety of covered services. For example, we suggest that if health plans and issuers can show that the quality or safety of members may be directly harmed by the lifting of an NQTL (should it otherwise not meet the new three-part test), the NQTL would not be subject to the substantially all and predominance test, nor would it need to demonstrate equity in outcomes. For a plan or issuer to avail themselves of the quality or safety exception, there needs to be some professional judgment or explanation for the issue (e.g., medical management committee finding, clinical attestation, studies, or claims data analysis).

⇒ *ABHW requests that additional exceptions be added, at minimum, to cover factors based on (1) compliance with federal and state law and (2) ensuring the quality and safety of covered services.*

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**“Design and Application” Requirement for NQTLs - 26 CFR 54.9812-1(c)(4)(ii), 29 CFR 2590.712(c)(4)(ii), and 45 CFR 146.136(c)(4)(ii).**

**Prohibition on Discriminatory Factors and Evidentiary Standards - 26 CFR 54.9812-1(c)(4)(ii)(B), 29 CFR 2590.712(c)(4)(ii)(B), and 45 CFR 146.136(c)(4)(ii)(B)**

The Tri-Departments propose to add a new regulatory requirement at (c)(4)(ii)(B) for plans and issuers to ensure that they do not rely on any factor or evidentiary standard that is based on information, evidence, sources, or standards that discriminates against MH/SUD benefits as compared to M/S benefits. The Tri-Departments explain that “[v]arious factors and evidentiary standards that plans and issuers have previously relied on, or currently rely on, to design or apply NQTLs to [MH/SUD] benefits *might themselves discriminate* against [MH/SUD] benefits by treating them in a different and less favorable manner.”<sup>17</sup> The proposed rule establishes that “[i]nformation is considered to discriminate against [MH/SUD] benefits if it is *biased or not objective, in a manner that results in less favorable treatment of [MH/SUD] benefits, based on all the relevant facts and circumstances.*”<sup>18</sup>

This proposed new requirement should be eliminated for four reasons: (1) it contradicts previous guidance without a reasoned discussion of the reason for the policy change; (2) it would be extremely administratively burdensome to prove the absence of discrimination for every factor and evidentiary standard; (3) it would be impossible for plans to predict whether a regulator will determine that a difference in any given data measure is the result of “bias”; and (4) it is unnecessary because it is redundant with the proposed requirements to analyze outcomes data.

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<sup>17</sup> 88 Fed. Reg. at 51,573 (emphasis added).

<sup>18</sup> 88 Fed. Reg. at 51,573 (emphasis added).



First, the proposal to use outcomes data to determine that a factor or evidentiary standard is impermissible is counter to previous guidance issued by the Tri-Departments, in which the Tri-Departments have repeatedly stated that “results alone are not determinative of noncompliance” and that “outcomes are not determinative of a MHPAEA violation.”<sup>19</sup> The new non-discrimination requirement appears to flip this previous guidance on its head and instead states that – evidence of a disparate outcome means that the factor or evidentiary standard relied upon to design the NQTL is inherently biased or not objective and therefore discriminatory and the plan or issuer is thereby in violation of MHPAEA.

Second, proving the absence of discrimination for every factor and evidentiary standard would be exceptionally administratively burdensome. According to the Tri-Departments, the “relevant facts and circumstances” that plans should evaluate to identify any discriminatory impact “include, but are not limited to, the source of information, the purpose or context of the information, and the content of the information.”<sup>20</sup> This is a massive expansion of the existing comparability analysis—effectively zooming in, fractal-like, on each factor and evidentiary standard in a comparability analysis and requiring a new, additional comparability analysis for that factor or evidentiary standard. The Tri-Departments provide a minimal discussion of what methodologies can or must be used to affirmatively demonstrate that each factor and the evidentiary standard is objective and not biased. In practice, it may be highly challenging for plans to identify facts or circumstances that *prove* the *absence* of bias about a given factor or evidentiary standard. Based on the proposed regulatory language, the only way to prove that information is “biased” or “not objective” is to demonstrate that the information does not “result in less favorable treatment” of MH/SUD benefits. The development of quantitative testing or other evidentiary support of the objectivity of every factor and evidentiary standard would be incredibly burdensome. Yet, the Tri-Departments do not identify any limiting concept to determine when such documentation would be required.

Third, it would be impossible for plans to predict whether a regulator will determine that a difference in any given data measure is the result of “bias.” Where the data outcome is unfavorable for MH/SUD benefits, the Tri-Departments merely propose to determine whether the plan’s justification is “legitimate” according to the totality of the circumstances. In other words, each regulator will make a purely subjective determination about the “legitimacy” of the plan’s attempt to investigate and explain the reason for an unexpected disparity in outcomes that resulted from a factor or evidentiary standard that was itself neutral on its face.

Given the subjectivity of this evaluation, it will be difficult for plans to predict whether a regulator will agree with the plan’s analysis. For example, many plans rely on the Medicare fee schedule as a basis for their reimbursement rate-setting methodology, but there is debate about the extent to which the Medicare fee schedule itself may be biased against behavioral health providers. An assertion that the Medicare fee schedule (or other factor) is “biased” can be supported or refuted by different data analyses. There is a significant likelihood that a plan could submit the same analysis to two different federal and state regulators, market conduct exam vendors, and/or other government contractors and receive opposite determinations about whether one or more factors

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<sup>19</sup> See, e.g., Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act (MHPAEA), U.S. Dep’t of Labor (2020) <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/self-compliance-tool.pdf>.

<sup>20</sup> 88 Fed. Reg. at 51,573.

or evidentiary standards are discriminatory or biased. This creates an untenable risk environment for plans that must prospectively design their fee schedules, utilization management requirements, and other NQTLs.

Fourth, the proposed requirement to evaluate whether factors and evidentiary standards are “discriminatory” is also unnecessary due to the redundancy with the Tri-Departments’ proposed requirement for plans to apply data measures to evaluate the impact of the NQTL in operation. The Tri-Departments provide no discussion of how the “discriminatory impact” analysis for factors and evidentiary standards under 26 CFR 54.9812-1(c)(4)(ii)(B), 29 CFR 2590.712(c)(4)(ii)(B), and 45 CFR 146.136(c)(4)(ii)(B) is different from the “discriminatory impact” analysis of outcomes data under 26 CFR 54.9812-1(c)(4)(iv), 29 CFR 2590.712(c)(4)(iv), and 45 CFR 146.136(c)(4)(iv).

For example, in the preamble, the Tri-Departments express special concern about plans that rely on historic fee schedules to develop provider reimbursement rates, to the extent that this reliance on historical rates results in less favorable treatment of mental health and substance use disorder benefits. But the “results” to be analyzed under section (c)(4)(ii)(B) would appear to be the same results that would be analyzed under section (c)(4)(iv)—in particular, whether the rates result in comparable network adequacy and access.

ABHW also understands, based on the 2023 MHPAEA Comparative Analysis Report to Congress, that the Tri-Departments may be concerned about health plans’ reliance on historic decision-making to justify certain utilization management strategies.<sup>21</sup> This concern highlights the extent to which the Tri-Departments propose creating new documentation requirements that extend beyond the comparative analysis requirements set forth in MHPAEA. For example, many plans have applied prior authorization to certain treatments and services for many years, pursuant to the same general strategy for prior authorization, and have not maintained documentation of the original decision-making. The Tri-Departments propose to require plans not simply to analyze the comparability of the plan’s prior authorization strategy, as required by MHPAEA, but also to recreate the underlying documentation. Further discussion of ABHW’s concerns about this new extra-statutory documentation requirement is provided below in the section of this comment letter titled “Content of Comparative Analyses – 26 CFR 54.9812-2(b) and (c), 29 CFR 2590.712-1(b) and (c), and 45 CFR 146.137(b) and (c).” For the purposes of section (c)(4)(ii)(B), we merely note that the analysis of the plan’s historical application of prior authorization is itself discriminatory and would appear to be identical to the analysis of whether the current application of prior authorization is discriminatory.

⇒ *Because the proposed requirement to apply an outcomes-based analysis of the objectivity and non-discriminatory nature of each factor and evidentiary standard (1) overturns previous guidance without a reasoned analysis or justification, (2) massively increases the administrative burden, (3) creates ambiguity that makes it impossible for plans to prospectively ensure compliance, and (4) is unnecessary because it is duplicative with*

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<sup>21</sup> E.g. “Examples of instances in which sufficient information was not provided include the following: • Much of the historical information and supporting documentation required as part of a comparative analysis was no longer accessible or had not been documented.” (p. 82).

*proposed requirements for in-operation data analyses, ABHW requests that the Tri-Departments eliminate this proposed requirement.*

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## **Comparability In-Operation and Use of Operations Measures under the “Relevant Data Evaluation” Requirement.**

### ***Introducing a “Material Differences” Standard for Outcomes Measures - 26 CFR 54.9812-1 (c)(4)(iv)(D), 29 CFR 2590.712(c)(4)(iv)(B), and 45 CFR 146.136(c)(4)(iv)(B).***

The Tri-Departments propose that if the data show a “material difference in access to [MH/SUD] benefits as compared to [M/S] benefits,”<sup>22</sup> the difference is considered to be a “strong indicator” that the plan or issuer violates parity. The proposed rule does not currently provide a definition or standard for “materiality” but does specifically seek comments on how “material difference” could be defined in a manner that translates into tangible quantitative research methods (e.g., based on the results of statistical testing).

ABHW asserts that the definition of “materiality” will vary according to a wide variety of factors that influence any expectation of consistency for the measure to ensure that the difference is somehow meaningful. Relevant factors for a given NQTL type and measure may include the size of the data pool (or sample size if a sampling methodology is used), variability of the measure over time within a population, variability of the measure across populations, availability of complementary measures that may reinforce or contradict the data outcome (and whether or not the results do in fact correlate or conflict), the degree of control that the plan has over the measured outcome, and other factors. Therefore, the specific methodology appropriate for determining “materiality” for any given measure will vary considerably by measure. Considerable time, resources, and expertise will be needed to create meaningful and non-arbitrary definitions of “materiality” for key measures for the wide variety of key NQTL types.

⇒ *ABHW recommends that the Tri-Departments convene a Technical Expert Panel to identify appropriate measures for common NQTL types, develop proposed definitions of “materiality” for each identified measure, and that the Tri-Departments publish draft measures and definitions of materiality for public comment.*

### ***The requirement to take action to mitigate “Material Differences” for Outcomes Measures - 26 CFR 54.9812-1 (c)(4)(iv)(B), 29 CFR 2590.712(c)(4)(iv)(B), and 45 CFR 146.136(c)(4)(iv)(B), and 26 CFR 54.9812-2 (c)(5)(iv), 29 CFR 2590.712-1(c)(5)(iv), and 45 CFR 146.137(c)(5)(iv).***

The Tri-Departments propose that where the results of a required data measure show a “material difference” in access to MH/SUD benefits, the plan or issuer “[m]ust take reasonable action to address the material differences in access as necessary to ensure compliance, in operation.”<sup>23</sup> This requirement to take corrective action where there is a “material difference” in a data outcome

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<sup>22</sup> *Id.* at 51568.

<sup>23</sup> 26 CFR 54.9812-1 (c)(4)(iv)(B)(1), 29 CFR 2590.712(c)(4)(iv)(B)(1), and 45 CFR 146.136(c)(4)(iv)(B)(1)

would apply even in the absence of noncompliance with regard to the underlying design or application of the NQTL. In the preamble to the NPRM, the Tri-Departments affirm, “While under this provision, material differences alone would not be dispositive (except, as discussed below, for NQTLs related to network composition), and would not automatically result in a finding of noncompliance, a plan or issuer would be required to take reasonable action to address any material differences in access as necessary to ensure compliance, in operation.”<sup>24</sup> This proposal to require plans to take action without any finding of noncompliance under MHPAEA clearly exceeds the scope of the statute.

This regulatory requirement for corrective action, even in the absence of an underlying disparity, conflicts with the Tri-Departments’ statement in the preamble that “This requirement would allow plans and issuers to explain why material differences in access demonstrated by the outcomes data should not result in a violation of the rules for NQTLs.”<sup>25</sup> The opportunity to rebut the presumption of noncompliance would be appropriate, given that material differences may not be attributable to differences in the comparability or relative stringency of the nonquantitative treatment limitation. Differences in data outcomes may instead result from a wide variety of reasons that do not indicate non-compliance, including random variability, provider or member behavior, changes to unrelated federal or state laws, or other factors that are outside of the plan or issuer’s control. But the regulatory text at 26 CFR 54.9812-1 (c)(4)(iv)(B)(1), 29 CFR 2590.712(c)(4)(iv)(B)(1), and 45 CFR 146.136(c)(4)(iv)(B)(1) clearly does not provide for any opportunity to rebut the data findings, and the regulatory text at 26 CFR 54.9812-2 (c)(5)(iv), 29 CFR 2590.712-1(c)(5)(iv), and 45 CFR 146.137(c)(5)(iv) re-incorporates by reference the requirements at 26 CFR 54.9812-1 (c)(4)(iv)(B)(1), 29 CFR 2590.712(c)(4)(iv)(B)(1), and 45 CFR 146.136(c)(4)(iv)(B)(1).

It would be an arbitrary and capricious exercise of the Tri-Departments’ authority and enforcement powers, in violation of the APA, to require corrective action in the absence of noncompliance. ABHW, therefore, recommends that these sections be revised to apply only where the plan is unable to rebut the presumption of noncompliance that is triggered by a “material difference” in a required data measure.

⇒ *ABHW recommends that the Tri-Departments revise the requirements at 26 CFR 54.9812-1 (c)(4)(iv)(D), 29 CFR 2590.712(c)(4)(iv)(B), and 45 CFR 146.136(c)(4)(iv)(B) to state: ... “[material] differences will be considered a strong indicator that the plan or issuer violates paragraph (c)(4)(i) or (ii) of this section. In such instances, To the extent that such differences are attributable to differences in the comparability or relative stringency of the nonquantitative treatment limitation, the plan or issuer: [...]*

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### ***Application to Provider Networks.***

ABHW opposes the proposal to determine compliance with MHPAEA for NQTLs related to provider network composition based solely on the outcomes of an undefined and untested set of

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<sup>24</sup> <https://www.federalregister.gov/d/2023-15945/p-290>.

<sup>25</sup> <https://www.federalregister.gov/d/2023-15945/p-291>.

measures. The proposed rule's approach to applying MHPAEA to the administration of provider networks includes numerous legal and policy flaws that we ask the Tri-Departments to carefully reconsider prior to finalizing this rule. If finalized, these changes would have significant implications for the manner in which insurers and managed care organizations develop and administer networks of participating providers, with little to no benefit to protect individuals with MH/SUD conditions from discrimination.

### **Analysis of Network Adequacy as an NQTL.**

Assessing network adequacy is undoubtedly an important part of assessing access to care. However, the Tri-Departments seek to invoke MHPAEA to create vague and complex new standards for network administration and network adequacy that significantly depart from and conflict with existing federal and state regulatory frameworks that already govern network adequacy for nearly all markets, including Medicare Advantage, Medicaid managed care, and fully insured health insurance products.

The new requirements for network management outlined in the proposed rule would preempt existing federal and state insurance regulations on network administration and would supplant existing accreditation standards. The Tri-Departments explicitly acknowledge this goal, stating, "The Departments are of the view that minimum time and distance standards set by a private accreditation organization or by other Federal or State programs [...] are often not designed with purposes of MHPAEA compliance in mind. Therefore, to comply with the relevant data evaluation requirements and the special rule for NQTLs related to network composition under these proposed rules, a plan or issuer may need to go beyond the minimum times and distances outlined in such standards and also ensure that they do not result in less favorable treatment for mental health and substance use disorder benefits under the plan or coverage, based on all the relevant facts and circumstances."<sup>26</sup> But this statement is at odds with the Tri-Departments' own admission that "parity across mental health and substance use disorder and medical/surgical networks does not necessarily mean equal number of providers in a classification."<sup>27</sup> Instead, the question is whether the network has a sufficient number of providers of each provider type to meet the service demands of the plan's membership. This is precisely the function of existing regulatory and accreditation requirements for network adequacy: to ensure that the provider network is sufficient to meet demand. The "common denominator" to assess the comparability of network adequacy across different provider types is whether the provider network meets the network adequacy standards for each provider type.<sup>28</sup>

In the Technical Release, the Tri-Departments pose several questions about how to alter or supplement existing network adequacy requirements to remedy perceived deficiencies with these requirements.<sup>29</sup> The Tri-Departments' attempt to leverage MHPAEA as a vehicle to create an

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<sup>26</sup> 88 FR 51577.

<sup>27</sup> 88 FR 51576.

<sup>28</sup> ABHW has heard it asserted that a health plan may violate parity if it exceeds the applicable network adequacy standards for some M/S provider types by a greater extent than it meets or exceeds the applicable network adequacy standards for MH/SUD providers. But not every *difference* is a *limit*. If the network is adequate to meet the plan population's MH/SUD service needs (as defined by the applicable network adequacy standards), then exceeding the network adequacy standards for other provider types does not somehow create a new limit on MH/SUD access.

<sup>29</sup> E.g. asking:

entirely new overlapping and divergent regulatory framework for network adequacy across markets is beyond the scope of what Congress enabled in enacting MHPAEA. These concerns are best raised with applicable legislative authorities, regulators, and accreditation organizations and can be addressed much more simply and efficiently through existing public comment processes on these existing regulatory and accreditation frameworks. Such sweeping preemption of a significant component of insurance market regulation should be done by Congress and not by regulation under an anti-discrimination law.

⇒ *ABHW recommends that the Tri-Departments withdraw their proposal to override existing network adequacy regulations by superimposing a new framework for evaluating network adequacy under MHPAEA and instead acknowledge that “comparability” under MHPAEA merely requires analysis of whether the provider network meets applicable regulatory and accreditation requirements that define the adequacy of the network for MH/SUD and M/S providers.*

### **The concept of an NQTL and the proposed approach to analysis is fundamentally misaligned with provider network composition strategies.**

MHPAEA applies to “treatment limitations.”<sup>30</sup> Where a plan makes a decision about whether or not to admit a provider to the network (e.g., based on whether the provider meets the plan’s credentialing criteria), this makes sense to analyze as an NQTL. However, the fundamental inapplicability of MHPAEA to most aspects of provider network composition is underlined by the fact that “limitations” can be eliminated if they do not comply with MHPAEA (e.g., an overly restrictive credentialing requirement could be removed), but plan operations related to provider network composition cannot simply be eliminated.

Moreover, MHPAEA applies to “treatment limitations” that are applied to “benefits,”<sup>31</sup> and these treatment limitations must be analyzed by classification.<sup>32</sup> These basic, fundamental requirements do not map to the provider network context, where participating providers deliver services that may be covered under a range of different MH/SUD and M/S benefits across multiple classifications. It is thus inaccurate to say that any specific “treatment limitations” apply to any specific “benefits” within specific “benefit classifications” with regard to provider networks. The

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- “How can the Tri-Departments account for any difficulties that underserved and minority groups face that may not be accounted for in traditional time and distance measures?
  - Should the time and distance metrics be adjusted to account for access to providers who offer telehealth services only or providers who offer telehealth in addition to in-person services in plans’ and issuers’ networks? If so, how?
  - How should the Tri-Departments develop specific [new] categories of MH/SUD and M/S providers for purposes of requiring plans and issuers to collect and evaluate these data as on time and distance [...]?
  - Are there other plan designs that may need additional guidance or alternatives for the relevant data on time and distance [...]?
  - Are there ways in which time and distance data are susceptible to manipulation [...]?
  - What terminology is important for the Tri-Departments to define precisely to facilitate the collection and evaluation of time and distance data?

<sup>30</sup> Code section 9812(a)(3)(A), ERISA section 712(a)(3)(A), and PHS Act 2726(a)(3)(A).

<sup>31</sup> *Id.*

<sup>32</sup> 26 CFR 54.9812-1(c)(2), 29 CFR 2590.712(c)(2), and 45 CFR 146.136(c)(2).

proposed rules provide no guidance to address several fundamental aspects of the parity compliance analysis that do not align with the provider network contracting context, including:

- Many professional providers treat both MH/SUD and M/S conditions. For example, many primary care providers deliver a significant volume of MH/SUD services, and many physicians have specialization in both MH/SUD and M/S areas.
- Many contracted provider entities, including health systems, independent provider associations, provider group practices, and other forms of contracted entities, employ or sub-contract with professionals with MH/SUD and M/S specialization.
- Many professionals and contracted provider entities deliver services across multiple benefit classifications. For example, a given physician may treat some patients in a facility on an inpatient basis, some in the same facility on an outpatient basis, and some in an office or clinic.
- Provider network contracting strategies for health systems and other large entities are fundamentally different from contracting strategies for contracting with individual and small group providers.

⇒ *ABHW asserts that it is inappropriate to characterize provider contracting and reimbursement strategies as NQTLs except to the extent that they govern a decision about whether to deny admission to the provider network.*

⇒ *To the extent that the Tri-Departments continue to characterize provider contracting and reimbursement methodologies as NQTLs, ABHW requests that the Tri-Departments propose new guidance to clarify these fundamental aspects of the application of MHPAEA to provider network composition before finalizing any regulations or guidance applicable to provider network composition.*

### **The definitions of “Factors,” “Sources,” and “Evidentiary Standards” are not coherent in their application to network contracting activities.**

The approach to the Factor identification and definition steps of the comparability analysis is designed primarily for utilization management NQTL use-cases with a binary of whether or not to apply an NQTL to some benefits.<sup>33</sup> To the extent that NQTLs related to network composition are related to a decision about whether to admit a provider to the network (e.g., regarding provider credentialing), the proposed framework for analysis makes sense (subject to other concerns raised in this letter). However, the proposed approach to the Factor identification and definition steps of the comparability analysis do not reasonably relate to developing reimbursement methodologies or most other network composition NQTLs. For most NQTLs related to network composition, the plan does not implement a binary decision about whether to apply the NQTL to a given benefit or service or even about whether to admit the provider to the network. Instead, the plan synthesizes a broad range of considerations to balance allocating a limited pool of resources to meet its network needs. This uncertainty about applying the Factors/Evidentiary Standards

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<sup>33</sup> For example, a plan might find that the evidentiary standard for one or more factors is “met” for a given service, and therefore decide to apply the utilization management NQTL to that service.

definitions to network administration and reimbursement methodology NQTLs means it is unclear how the new comparability analysis guidance would be applied.

For example, Example 4 within 26 CFR 54.9812-1(c)(4)(viii), 29 CFR 2590.712(c)(4)(viii), or 45 CFR 146.136(c)(4)(viii) gives examples of “providers’ required training, licensure, and expertise” as well as “nature of the service, provider type, number of providers qualified in the service area..., and market need (demand)” as Factors relied upon in setting reimbursement rates, which indicates both that they consider reimbursement rates themselves to be an independent NQTL type and that they consider all the components of a reimbursement rate development and negotiation to be “Factors.” None of these Factors would be “met” or “not met” by a given provider. There is no algorithmic approach to decision-making that can be documented using the proposed framework for defining these or other Factors, sources, and Evidentiary Standards to demonstrate how reimbursement fee schedules are set for a given provider type or how reimbursement rates are negotiated for a given provider. Please see Example 4 and additional Tri-Department proposed examples in Appendix B of this letter.

The proposed guidance does not provide any guidance for how the multitude of different activities involved in managing the construction of the provider network and provider reimbursement across different plan types, service settings, and reimbursement methodologies should be categorized into the “Factors,” “Sources,” and “Evidentiary Standards” typology.

⇒ *ABHW requests the Tri-Departments to either provide detailed guidance for how each step of the proposed six-step methodology applies to NQTLs related to provider network composition or to develop a new framework for analysis for these NQTLs.*

### **The quantitative parity test and discriminatory factor tests should not apply to network contracting NQTLs.**

As proposed, no network contracting activities would be eligible for either the independent standards exception or the fraud and abuse exception; as such, all network contracting and management activities would need to undergo the substantially all and predominant type tests, the discriminatory factor test, and the required use of outcomes data test. As proposed, this would, at minimum, impose a significant regulatory burden on network contracting operations and compliance staff and would create particularly severe challenges for plans that rely on delegated benefit management vendors, network leasing, independent practice associations, and related network contracting arrangements. Moreover, the proposal may have unintended consequences or be impossible to implement.

First, as noted above, most concepts that the Tri-Departments identify as potential “NQTLs” related to provider network composition are not “treatment limitations” that apply to “benefits” that can simply be eliminated if the identified strategy is determined to be more stringent as applied to MH/SUD providers. In particular, although ambiguity remains about the specific NQTL “types” and “variations” that the Tri-Departments may determine to apply to provider network composition strategies, it would be inappropriate and perverse to apply quantitative testing requirements to provider network composition strategies to determine that any such strategy simply cannot be applied to MH/SUD benefits.



Second, as described above, there is significant ambiguity between the concepts of “NQTL,” “variation,” “Factor,” and “Evidentiary Standard” for the purpose of network composition NQTL types with material implications for how this test should be implemented for these NQTL types. The array of potential NQTL types and “variations” of provider network composition that could be identified is overwhelming, and the Tri-Departments have not offered any guidance to explain what types of NQTLs should be analyzed or what types of common variations should generally be tested for common NQTL types.

Third, for many potential “variations” of reimbursement methodologies, it is unclear how to determine whether one variation is “more stringent” than another. For example, reimbursement based on a diagnosis-related group (DRG) or other case rate is not inherently more stringent or less stringent than reimbursement based on a per diem or other per unit basis. Similarly, reimbursement based on a value-based or risk-based payment methodology is not inherently more stringent or less stringent than reimbursement on a fee schedule basis with no risk.

Similarly, the newly proposed “discriminatory factors and evidentiary standards test” will likely create significant challenges for seeking to demonstrate parity compliance for network administration NQTLs. As discussed above, a plan may not rely upon any factor or evidentiary standard if the information, evidence, sources, or standards on which the factor or evidentiary standard is based discriminate against MH/SUD benefits compared to M/S benefits. Information is considered to be discriminatory if it is “biased or not objective, in a manner that results in less favorable treatment of mental health or substance use disorder benefits, based on all the relevant facts and circumstances including, but not limited to, the source of the information, the purpose or context of the information, and the content of the information.”<sup>5</sup> Network administration NQTLs are developed based on a dizzying array of complex business factors, including actuarial analysis, arms-length market negotiations, industry trends, government payor rate-setting (such as Medicare or Medicaid), among many other factors, and evidentiary standards. These factors also vary considerably by benefit, provider type, service setting, and region, and there is often no available data to assess the tendency of each factor for MH/SUD benefits compared to M/S benefits.

In addition, these business operations are generally not otherwise subject to documentation requirements, and it will impose a significant administrative burden on health plans to develop new business processes for documenting their decision-making processes and rationales in a manner that will be transparent and understandable to regulators that may have no pre-existing knowledge or experience regarding these highly complex strategies. The proposed rule is unclear about how the new discriminatory factors and evidentiary standards test should apply to these activities. It raises the likely prospect of needing to rebuild some or all of these functions around the need to prove that they are not discriminatory.

Examples 4 and 13 presume compliance with these requirements but do not walk through the details of the application. Example 8 indicates that each aspect of credentialing (in this case, supervised practice requirements) is a different “variation” for the purpose of the predominant variation test. This example of the application of the test is confusing as to how to distinguish between a Factor, Strategy, or “variation” for the purpose of network management NQTLs. More importantly, this example raises questions about how the “restrictiveness” of variations can be reasonably assessed.

⇒ For these reasons, ABHW requests that the Tri-Departments create another exception from the quantitative testing requirement and the discriminatory factor analysis for Provider Network Administration NQTLs.<sup>34</sup>

### **The Tri-Departments should not adopt the “special rule” for outcomes data related to network contracting NQTLs.**

The Tri-Departments propose to create a “special rule” for the application of outcomes data requirements to provider network composition NQTLs based on the flawed premise that challenges in access to MH/SUD services that are experienced by enrollees in commercial health plans and insurance are due to discriminatory coverage design or operations or are otherwise the fault of the plan or insurer.

The Tri-Departments misrepresent several of the key studies they rely on to support their premise. For example, the preamble states, “There is a significant disparity between how often participants and beneficiaries have little or no choice under their plan or coverage but to utilize out-of-network mental health and substance use disorder providers and facilities, as compared to medical/surgical providers and facilities.”<sup>35</sup> Yet the report cited to support this assertion provides no evidence and makes no commentary about the strength of the health plans’ MH/SUD provider networks or members’ ability to access in-network MH/SUD services.<sup>36</sup> The report merely provides data on the *rate* of out-of-network utilization. It provides no discussion of the wide range of reasons *why* members may seek out-of-network services, many of which are entirely beyond the plan’s control, including, e.g., idiosyncratic personal preferences that often underlie the highly personalized relationship between a consumer of MH/SUD services and their MH/SUD provider, a desire to maintain continuity when switching health plans, a desire to avoid making the member’s employer or family members aware of the treatment, and aggressive marketing and recruitment practices by certain MH/SUD providers, especially in “sunshine states” or luxury facilities.

Similarly, the Tri-Departments characterize a survey study as showing that “most plan participants reported choosing mental health services from out-of-network mental health providers based on provider quality issues.”<sup>37</sup> This is a highly misleading and inflammatory characterization of this study. The study’s authors surveyed patients who accessed out-of-network mental health care and grouped their reasons for accessing out-of-network care into “issues related to provider quality” and “issues related to network size and composition.” The authors coded most of the survey responses to fall within the “issues related to provider quality.” Within this category, the most common reason cited was that the respondent wished to continue seeing an existing provider—i.e., a measure of “quality” that has nothing to do with the quality of the plan’s in-network providers. More critical to the present context—i.e., the extent to which higher

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<sup>34</sup> 26 CFR 54.9812-1(c)(4)(i-ii), 29 CFR 2590.712(c)(4)(i-ii), and 45 CFR 146.136(c)(4)(i-ii).

<sup>35</sup> 88 FR 51575.

<sup>36</sup> Melek, S., Davenport, S., Gray, T. J. (2019). Addiction and mental health vs. physical health: Widening disparities in network use and provider reimbursement. Milliman. [https://assets.milliman.com/ektron/Addiction\\_and\\_mental\\_health\\_vs\\_physical\\_health\\_Widening\\_disparities\\_in\\_network\\_use\\_and\\_provider\\_reimbursement.pdf](https://assets.milliman.com/ektron/Addiction_and_mental_health_vs_physical_health_Widening_disparities_in_network_use_and_provider_reimbursement.pdf). The Departments specifically cite page 6 of this report.

<sup>37</sup> 88 FR 51554, citing Kelly A. Kyanko, Leslie A. Curry, and Susan H. Busch, Out-of-Network Providers Use More Likely in Mental Health than General Health Care Among Privately Insured, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4707657/>.

rates of out-of-network MH/SUD service utilization are due to inadequate MH/SUD provider networks—the Tri-Departments neglect to mention that the study found that “Fewer than 10% of respondents who used out-of-network mental health services reported that they went to an out-of-network mental health provider due to problems with the size or general composition of the network (as opposed to inclusion of a specific provider).” Most importantly, the Tri-Departments also omit that the study authors specifically stated, “we found no evidence that mental health networks were substantially less adequate than general medical networks.” ABHW respectfully requests that this key context be added to future discussions in order to provide an objective and non-polemical summary of the research base.

Furthermore, the Tri-Departments’ conclusion (i.e., that research regarding utilization of out-of-network MH/SUD providers by enrollees in commercial health plans and insurance products indicates a discriminatory approach to provider network composition or is otherwise the fault of commercial plans and insurers) fails to account for the key context that comparable differences exist across health insurance markets and programs. For example, a 2020 study concluded that a growing number of psychiatrists in the United States do not bill insurers for their services and only see patients who can pay upfront for office visits and either cover the cost out-of-pocket or submit claims to their health insurers (16 percent in 2007-2009 vs. 26 percent in 2014-2016). The authors also found that psychiatrists were less likely to accept all types of health insurance than other physicians.<sup>38</sup> Other studies have shown that psychiatrists are also less likely than other physicians to participate in Medicare and Medicaid. According to Bishop et al. (2014), between 2005-2010, the percentage of psychiatrists who accepted Medicare was lower than that of other physicians (55 percent vs. 86 percent), as was the percentage of psychiatrists who accepted Medicaid (43 percent vs. 73 percent).<sup>39</sup> Psychiatrists comprise only 4 percent of physicians nationally but account for 38 percent of physicians who opt out of Medicare (i.e., do not accept Medicare reimbursement as payment in full for their services). In the United States, 7 percent of psychiatrists had opted out of Medicare as of March 2017.<sup>40</sup> Comparable disparities in participation also exist in Tricare. One study found that only 36 percent of mental health providers (including psychiatrists and non-physician behavioral health professionals) who responded to the study’s survey accepted new Medicare patients, and 32 percent accepted new TRICARE patients. In contrast, 83 percent of physicians in specialties other than psychiatry accepted new Medicare patients, and 74 percent accepted new TRICARE patients.<sup>41</sup>

⇒ *ABHW requests that the Departments provide an objective, balanced, and non-polemical review of the evidence base to support its requirements for NQTLs related to provider network composition in the final rules.*

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<sup>38</sup> Benjenk I, Chen J. Trends in self-payment for outpatient psychiatrist visits. *JAMA Psychiatry*. 2020 Dec 1;77(12):1305-7.

<sup>39</sup> Bishop TF, Press MJ, Keyhani S, Pincus HA. Acceptance of insurance by psychiatrists and the implications for access to mental health care. *JAMA Psychiatry*. 2014 Feb 1;71(2):176-81.

<sup>40</sup> Bocutti C, Neuman P. Private contracts between doctors and Medicare patients: key questions and implications of proposed policy changes. Kaiser Family Foundation. 2017.

<sup>41</sup> Anand P, Ben-Shalom Y, Schone E. Factors associated with the acceptance of new TRICARE and Medicare patients by health Care providers. *Medical Care Research and Review*. 2021 Oct;78(5):627-37.

The proposal to require a *per se* non-compliance finding based on outcomes only would be a new frontier in MHPAEA regulation.<sup>42</sup> Where the outcomes data for network composition NQTLs show “material differences in access to in-network [MH/SUD] benefits as compared to in-network [M/S] benefits in a classification,” the proposed rules would find *per se* noncompliance (as opposed to merely being a “strong indicator” of noncompliance). This approach is the *opposite* of a safe harbor—that is, under the currently proposed approach, data would be used to indicate non-compliance, but where the data do support a finding of compliance, the plan still has to satisfy the quantitative parity test, discriminatory factor/evidentiary standard test, and to develop and defend a comparative analysis of the strategies, processes, evidentiary standards, and other factors that are used to apply network composition NQTLs.

Under the current regulatory regime, regulations are clear that MHPAEA does not require equality in outcomes, only equity in the underlying strategy and methodology, meaning that differences, even “material” ones, would not be a *per se* violation of MHPAEA, provided the comparability and stringency analysis effectively provided a non-discriminatory justification for the difference. The new “special rule for NQTLs related to network composition” will eliminate the potential for regulated entities to explain differences in access that may persist, notwithstanding anything the regulated entity can do in administering the network, even where the difference arises from factors that are wholly unrelated to plan limitations. For example, compliance determinations should account for markets where inadequate numbers of licensed MH/SUD providers exist or where material numbers of providers refuse to contract with the plan at any price. Compliance determinations should also account for a variety of important distinctions between MH/SUD and M/S provider networks, including:

- Mental health professionals often practice via telehealth and across state lines. The rule does not include or account for telehealth in its network adequacy data requirements. As the Tri-Departments acknowledge, telehealth has become vital to providing health care, particularly mental health care. Telehealth must be incorporated into the proposed rules’ network adequacy standards and data collection requirements. The metrics around time and distance are much less relevant when a significant amount of mental health care is delivered virtually.
- Medical/surgical professionals are more likely to practice in large integrated groups and value-based payment models, which may skew reimbursement data.
- There are newer, non-licensed specialties in mental health (e.g., non-licensed peer support specialists non-licensed behavioral analysts providing therapy to individuals with autism spectrum disorder) that may require additional medical management or oversight.
- Mental health professionals are more often in small or solo practices with limited back-office support and, as a result, less willing to take on the administrative burden of joining networks or increasing patient loads, an administrative burden that is often driven to a large extent by regulatory and accreditation requirements on providers that are outside of the health plan’s control.
- There are new out-of-network access points for the delivery of mental health care that policies should encourage, including crisis care delivery systems and school-based care, but that could impact out-of-network utilization (and data).

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<sup>42</sup> See 26 CFR 54.9812-1(c)(4)(iv)(C), 29 CFR 2590.712(c)(4)(iv)(C), or 45 CFR 146.136(c)(4)(iv)(C).

Commentary in the preamble suggests that the Tri-Departments will exercise enforcement discretion where a plan takes reasonable actions to mitigate a data outcome that suggests a material difference in access but is unable to fully resolve the disparity. However, considerable ambiguity exists about how the Tri-Departments will determine whether the disparity is the “fault” of the health plan.

The proposed rule currently contemplates that, in the case of a final determination of non-compliance, the default position would be that plans must cease to implement an NQTL at all. The NPRM contemplates that for certain NQTLs that are necessary for plan operations (presumably such as network administration), alternative arrangements would be allowed, but the proposed rule is not clear that this exception would apply to network NQTLs (because these NQTLs are not defined), or what these alternatives will be in the case where an insufficient volume of providers are available to contract with. The NPRM only provides that the Tri-Departments may exercise enforcement discretion if the plan either remedies the difference or where, “despite taking appropriate action, the relevant data continues to reveal material differences in access, such as, because of provider shortages that the plan or issuer cannot effectively address through no fault of its own.”<sup>43</sup> This opens the door for the Tri-Departments to assume responsibility for operational oversight of health plan network contracting and negotiations for an indefinite period of time (presumably multiple years at minimum) until the Tri-Departments can be convinced that “appropriate actions” have been taken and the persistent material differences are not the plan’s responsibility.

⇒ *For these reasons, ABHW requests that the Tri-Departments rescind the proposal to implement a special rule for network contracting NQTLs.*

**The Tri-Departments should not impose any regulatory enforcement for an NQTL prior to defining the NQTL type, establishing data measures with technical specifications, and defining “material difference” for each applicable measure.**

As discussed above, the lack of any clear indication of what the Tri-Departments will use to determine what constitutes a “material difference” for measuring NQTL outcomes data is a massive gap in the proposed rule with particularly significant implications for network contracting activities. Even for NQTL types not subject to the special rule for network contracting, it will be impossible to implement a compliance program to establish oversight of operational data when the industry has no idea what the Tri-Departments will consider “material.”

⇒ *ABHW requests that the Tri-Departments refrain from applying any special rule or compliance findings for any NQTL type until the Tri-Departments have finalized, following public comment, an NQTL definition, specific measure set with technical specifications, and benchmark for what they will consider to be “material difference” for each NQTL type.*

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<sup>43</sup> *Id.* at 51577.

## **Regulated entities should not be required to analyze Network Contracting NQTLs for the Emergency and Prescription Drug services classifications.**

As drafted, the proposed rule requirements for network management NQTLs apply to all classifications of benefits, including emergency services and prescription drugs. This includes the quantitative parity and the discriminatory factor/evidentiary standard tests. However, none of the examples provided in the NPRM and none of the initial metrics released in the Technical Release apply to emergency services or prescription drugs. This leaves considerable ambiguity as to whether the Tri-Departments actually intend to apply these requirements to the administration of the network for emergency services or prescription drugs.

Strong policy reasons exist to exempt these benefit classifications from requirements to analyze and document comparative analyses for these NQTLs. Virtually all retail pharmacies deliver both MH/SUD and M/S drugs without distinction. Accordingly, pharmacy benefit management companies (PBM) design drug pricing, rebate, and payment methodologies without regard to diagnosis and often contract with retail pharmacies on an any-willing-provider basis. Similar considerations apply to the application of provider network composition NQTLs to emergency benefits, given that these services are delivered primarily through hospital emergency departments and urgent care centers that nearly universally treat both MH/SUD and M/S conditions and contract with plan networks without regard to the conditions being treated.

⇒ *For these reasons, ABHW requests that the Tri-Departments expressly exempt the emergency and prescription drug classifications from analysis under the network administration NQTL types.*

## **Unique Concerns for Integrated Delivery Systems/Value-Based Payment.**

The proposed rule could inadvertently undermine significant progress that public and private payors have made to develop and implement integrated delivery and value-based payment models if changes are not made. Integrated delivery systems are designed to provide value-based healthcare through two care delivery models: (1) within a self-contained delivery system where providers operate within the same organization, allowing care to be delivered with very few NQTLs, and (2) with a contracted network of community providers ensuring adequate access. We maintain that these distinct care delivery models warrant separate comparative NQTL analyses. Similar concerns apply to the application of these rules to value-based payment programs. Just as the existing MHPAEA regulations recognize that tiered networks warrant similar but separate analysis for QTLs, the Tri-Departments should provide for integrated delivery systems and value-based payment models to be analyzed separately from other contracting models. This would permit integrated health plans to maintain their unique delivery systems while also expanding their overall networks to include contracted community providers.

⇒ *ABHW requests that the Tri-Departments revise the proposed regulations to allow integrated health plans to conduct similar but separate analyses for NQTLs of (1) their integrated care delivery models and (2) their community contracted networks.*

Taken together, the proposed rule's approach to regulating network contracting (and reimbursement NQTLs) has the unfortunate characteristic of being both extremely onerous and

unclear. These functions are generally the domain of non-clinical business professionals working to maintain viable premiums for subscribers through difficult negotiations with hospital and physician group adversaries. The proposed rule will require all of these professionals to dramatically complicate their activities in order to adapt their business strategies in a manner designed to allow the rebuttal of the Tri-Departments' presumption of discrimination. We request that the Tri-Departments fundamentally reconsider the approach to network contracting NQTLs outlined in this NPRM.

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## **Enforcement Strategies and Processes**

### **Requirements related to submission of comparative analyses to the Secretary upon request – 26 CFR 54.9812-2(d), 29 CFR 2590.712-1(d), and 45 CFR 146.137(d).**

The Tri-Departments propose to require plans and issuers to provide a comparative analysis within ten (10) business days of a receipt of a regulator's request unless additional time is specified. This proposed timeline is exceedingly short. We understand the Tri-Departments' intent to ensure that plans and issuers proactively develop comparative analyses as required by the statute and to use this very short turnaround time for responses to identify and punish plans that fail to do so. However, this ten-day response period creates problems even for plans that are attempting in good faith to comply with the documentation requirements in at least two different situations: (1) where the Tri-Departments request a comparative analysis for a novel NQTL type that the plan had no reasonable notice would require a comparative analysis, and (2) where outcomes data have evolved since the previous update to the NQTL.

- (1) The definition of an "NQTL" is explicitly unbounded, making it functionally impossible for plans and issuers to develop and document comparative analyses for every NQTL type.

Given that regulators can request an NQTL analysis for any aspect of plan design or operations that is determined to constitute an NQTL and given that the list of NQTL types that regulators actually investigate is ever-changing, the requirement for plans and issuers to produce a comparative analysis for any NQTL type within ten business days is unreasonable.

The Tri-Departments have emphasized in multiple pieces of guidance that the "illustrative list" of NQTLs that are identified in regulations and guidance are non-exhaustive and that any aspect of plan design or operations that is determined to constitute an NQTL is subject to MHPAEA. The Tri-Departments' MHPAEA Self-Compliance Tool identifies twelve different NQTL types, along with a thirteenth "catch-all" category for "Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the plan or coverage." Recent Reports to Congress and other guidance have identified some number of additional NQTL types—the specific number varies depending on how the different NQTL types are counted. For example, the Tri-Departments identify "Exclusions of specific treatments for certain conditions" as an NQTL type in the Self-Compliance Tool but identify a variety of coverage exclusions or limits on specific benefits as separate and distinct NQTL types in the Reports to Congress. Similarly, the Tri-Departments identify "Standards for provider admission to a network, including reimbursement rates" as an NQTL type in the 2013

regulations and Self-Compliance Tool but identify “Network provider admission standards” and “Provider qualification or billing restrictions” as separate and distinct NQTL types in the Reports to Congress and provide extensive guidance in the Self-Compliance Tool that analyzes provider reimbursement rate-setting methodologies as a separate NQTL type. Other novel NQTL types have also been introduced in nearly every new piece of guidance that the Tri-Departments have published, including “Virtual or telephonic visit restrictions” and “Limitations based on the likelihood of improvement or progress.” The latest NPRM itself introduces several new NQTL types, including “billing restrictions, such as a requirement for a licensed provider to bill through or under the supervision of another type of licensed provider” and “refusal to cover treatment until completion of a comprehensive assessment by specific providers.” Moreover, in making requests for comparative analyses, regulators frequently request that these identified NQTL types be sub-divided into additional separate analyses, or re-formulate identified NQTL types to vary the framing, emphasis, or scope of the analysis (e.g., in guidance released in the past two years alone, one NQTL concept has been variously formulated as “Exclusions based on chronicity or treatability of condition, the likelihood of improvement, or functional progress,” “Limitations based on the likelihood of improvement or progress,” and “Limitations based on the expectation of improvement, the likelihood of progress, or demonstration of progress”). In practice, the number of NQTL types that may be identified is nearly endless. One health plan has identified a list of approximately eighty (80) different NQTL types.

In contrast to the extensive list of different NQTL types that the Tri-Departments have identified in guidance to date, in the Regulatory Impact Analysis, the Tri-Departments assume that plans will analyze only four different NQTL types each year and issuers will analyze only eight different NQTL types each year.<sup>44</sup> ABHW respectfully requests that the Tri-Departments identify these 8 NQTL types that they expect to be analyzed and explain the basis for the assumption that this would be determined to be sufficient (in the absence of further guidance to determine which NQTL types require a documented comparative analysis).

⇒ *ABHW requests that the final regulations stipulate that the ten-day period for plans and issuers to provide a comparative analysis applies only to NQTL types that are explicitly enumerated in regulations or an FAQ. ABHW also requests that the regulations stipulate that plans and issuers have at least sixty (60) days to submit a comparative analysis for any NQTL type that has not been explicitly enumerated in regulations or an FAQ.*

(2) Ten days is insufficient time to make all necessary updates to the narrative analyses that are relevant to the requested NQTL types.

First, significant changes to the design or application of the NQTL may have occurred since the previous refresh of the documentation or may be in progress. Although we recognize and agree with the need for plans and issuers to ensure that such changes are designed and implemented with the explicit goal of maintaining parity compliance, given the extremely detailed documentation requirements for NQTLs, it is often impractical for comparative analyses for relevant NQTLs to be updated until the changes are finalized, and the process for making such updates to the documentation may be time-consuming. The Tri-Departments may understand

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<sup>44</sup> 88 FR 51608.



from their own experience with clearance processes that the process for obtaining leadership sign-off for final revisions to the comparative analyses can also be time-consuming.

In addition, many data measures that are used for MHPAEA are labor-intensive to develop. For example, common plan arrangements require coordination of input from a variety of operating units, data platforms, and/or contracted vendors for updates to the range of data measures that may be used for the requested analyses. Coordination across these different operating units, data platforms, and/or contracted vendors can be time-consuming for a variety of reasons, including the need to follow multi-step chains of communication. Further investigation or analysis may be needed where the data results are unexpected. Leadership clearance for any significant changes to the data and corresponding analyses can further extend the timeline to finalize the comparative analyses.

⇒ *ABHW requests that the final regulations stipulate that a comparative analysis that is produced within the ten-day deadline meets the documentation requirement if it has been updated within the past twelve (12) months. ABHW also requests that the regulations stipulate that plans and issuers have at least sixty (60) days to make any updates to the requested comparative analyses that might be necessary to bring them fully up to date with current operations and data.*

**Requirement to notify participants and beneficiaries of final determination of noncompliance within seven days - 26 CFR 54.9812-2(d)(4), 29 CFR 2590.712-1(d)(4), and 45 CFR 146.137(d)(4).**

If the relevant Tri-Department makes a final determination that the plan or issuer is not in compliance, the Tri- Departments propose that, within seven (7) calendar days of the receipt of the final determination of noncompliance, the plan or issuer must provide a standalone notice to all enrollees that the plan or issuer is not in compliance with the requirements of the Rule. Seven calendar days is not a sufficient period of time for an insurer to compile and provide the information (other than the proposed standard notice) required by the proposed rules, which include:

- A summary of any changes made as part of the corrective action plan specified to the Secretary following the initial determination of noncompliance, including an explanation of any opportunity for a participant or beneficiary to have a claim for benefits re-processed;
- A summary of the Secretary's final determination that the plan or issuer is not in compliance with MHPAEA, including any provisions or practices identified to be in violation of MHPAEA, any additional corrective actions identified by the Secretary in the final determination notice, and information on how participants and beneficiaries can obtain a copy of the final determination of noncompliance from the plan or issuer;
- Any other actions the plan or issuer is taking to come into compliance with MHPAEA;
- Information on when the plan or issuer will take (or has taken) such actions;
- A clear and accurate statement explaining whether the Secretary has indicated that those actions if completed, will result in compliance; and
- Contact information for questions and complaints, with a statement explaining how participants and beneficiaries can obtain more information about the notice, including a

phone number and an email or web portal address for the plan or issuer, and contact information for the relevant Department.

It would be extremely difficult and burdensome to develop and publish notices that include all of the required content within the proposed deadline. Seven (7) calendar days provide only five (5) business days in a non-holiday week and can provide as few as three (3) business days in some holiday weeks. Moreover, these are significant requirements that necessitate thoughtful planning and drafting. The required content will often require input and clearance from multiple departments within a plan or issuer and may involve the coordination of multiple contracted entities. The simple act of coordinating the printing and mailing of notices to all members or beneficiaries generally requires several days and often involves coordination with one or more vendors. In addition, the extreme urgency is unnecessary. Investigations by the Tri-Departments generally take many months—sometimes well over a year. Given the extremely protracted timeline for these investigations, it is difficult to assert that there is a legitimate public interest or policy goal to be served by providing a mere seven calendar days for the plan or issuer to undertake all of the steps necessary to draft, print, and mail the required notices.

⇒ *ABHW recommends that the regulations provide for the notice of non-compliance to be mailed within 30 calendar days.*

The Tri-Departments also propose that the plan or issuer must provide a copy of the notice to the Secretary, any service provider involved in the claims process, and any fiduciary responsible for deciding benefit claims within the same time frame.

⇒ *ABHW recommends that the regulations define what is meant by the service provider or fiduciary in this context.*

**Requests for a copy of a comparative analysis – 26 CFR 54.9812-2(e), 29 CFR 2590.712-1(e), and 45 CFR 146.137(e).**

The Tri-Departments emphasize that the proposed rule also would require that plans and issuers must disclose information as required by MHPAEA to participants and beneficiaries “regardless of whether such information is ‘proprietary’ and/or has ‘commercial value.’”<sup>45</sup> In support of this requirement, the Tri-Departments cite a 2015 FAQ, which in turn cites a 1996 Department of Labor Advisory Opinion. This Advisory Opinion identifies the schedule of “usual and customary” fees, which is used as a basis for the dollar amount that will be paid for health claims made under a welfare benefit plan, as a “document or instrument that specifies procedures, formulas, methodologies, or schedules to be applied in determining or calculating a participant’s or beneficiary’s benefit entitlement under an employee benefit plan,” which in turn constitutes an “instrument under which the plan is established or operated.” ABHW understands the logic by which an instrument must be disclosed that directly impacts the amount that the plan will pay for an out-of-network benefit, i.e., that defines the scope of the coverage. This is very different from the Tri-Departments’ proposal to make the entirety of each NQTL analysis available upon request, where the majority of the content has no bearing on the actual scope of coverage (other than Step

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<sup>45</sup> <https://www.federalregister.gov/d/2023-15945/p-420>

1, in which the benefit limit is defined and the set of benefits subject to the limit are listed) and instead generally focuses on the business strategy to develop and design the limit.

The Tri-Departments also describe in the 2023 MHPAEA Report to Congress their interpretation of the MHPAEA to require plans and issuers to stipulate and analyze the strategies that they use to negotiate with providers to determine contractual reimbursement rates. The Tri-Departments assert that plans and issuers must “adequately explain whether and how the negotiation processes are comparable or explain any constraints on the negotiating process or its results that ensured parity.” The proposed rules and other guidance also set forth detailed requirements regarding the need to provide clearly defined evidentiary standards for all NQTL factors, including quantified standards for quantifiable factors. In short, the Tri-Departments propose to require plans and issuers to define a predictable, algorithmic approach to provider reimbursement negotiations and to make that algorithm available to providers. This requirement is antithetical to the free-market principles that currently define business contract negotiations in the United States and eliminates the ability for plans and providers to come to voluntary agreement about individualized terms for provider participation in a network. Instead, the Tri-Departments’ proposal would transform provider participation agreements into adherence contracts with uniform rates for all providers that meet defined criteria that providers must either take or leave. The information in question does not define the scope of the benefit or the amount that the plan will pay and, therefore, is clearly distinct from the authority that the Tri-Departments cite to support the proposed requirement.

⇒ *ABHW requests that the Tri-Departments clarify that the specific criteria for provider contract negotiations are not “factors” that are subject to documentation under MHPAEA.*

Similarly, information regarding the processes and strategies that plans use to identify, deter, and recoup reimbursement for treatments and services that are determined to constitute fraud, waste, and abuse should not be considered a “plan instrument” that must be disclosed regardless of the proprietary or confidential nature of the information. As noted above, ABHW is concerned that this requirement will enable and embolden fraudulent actors to engineer new strategies to avoid detection. For the same reason that the Tri-Departments’ own Offices of the Inspector General do not publish the details of their strategies to detect fraud, waste, and abuse, plans rely on privacy and confidentiality to protect the effectiveness of their fraud, waste, and abuse monitoring strategies.

⇒ *ABHW requests that plans be permitted to redact all narrative discussion and data regarding fraud, waste, and abuse monitoring and detection strategies from publicly disclosed versions of their parity compliance documentation and that the Tri-Departments honor plan requests to refrain from disclosing these proprietary and confidential details to any third party.*

### ***Absence of an appeals process***

The Tri-Departments do not propose to provide an appeals process for plans that are deemed non-compliant under a “final determination.” Failing to include an appeals process goes against the typical regulatory administrative grain of providing an appeals process and assumes the Secretary’s decision is without error despite the exceedingly complex and ambiguous standards

for compliance and documentation, as well as raising issues of constitutional due process. As ABHW noted in its May 2023 letter to the Tri-Departments (attached below as Appendix C to this letter), a right to an appeal, including an opportunity for an administrative hearing, should be granted because a determination that MHPAEA has been violated can cause substantial reputational and financial harm and plans and issuers should have an adequate opportunity to respond.

⇒ *ABHW recommends that the Tri-Departments adopt a MHPAEA appeals process modeled on the process for appeals of civil monetary penalties for Medicare Advantage Organizations.*

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## **NQTL Analyses and Documentation**

### ***Content of Comparative Analyses – 26 CFR 54.9812-2(b) and (c), 29 CFR 2590.712-1(b) and (c), and 45 CFR 146.137(b) and (c).***

The regulations should require plans and issuers to perform and document comparative analyses only for NQTL types that the Tri-Departments enumerate and define in the MHPAEA regulations or guidance to require a comparative analysis or for which a regulator specifically requests a comparative analysis.

The MHPAEA statute requires plans and issuers to “perform and document comparative analyses of the design and application of NQTLs” and make such analyses available to regulators upon request.<sup>46</sup> The statute does not further specify the range of NQTLs that must be documented, and in particular, does not specify the range of NQTLs that must be documented proactively in the absence of a regulator request. The Tri-Departments propose to interpret this statutory requirement to mean that plans and issuers must develop a comparative analysis for “each” NQTL that a health plan applies to MH/SUD benefits.<sup>47</sup>

As ABHW stated in a letter to the Tri-Departments in response to the promulgation of FAQ 45 describing the Tri-Departments’ interpretation of this statutory requirement, the statute does not specify which NQTL analyses must be documented. A copy of that letter is attached to this letter as Appendix D. As described in further detail above, the Tri-Departments have repeatedly emphasized that it is not possible to identify all possible NQTL types, guidance and enforcement have varied significantly with regard to the number, scope, and formulation of NQTL types that regulators have identified, and regulators continue to identify new NQTL types.<sup>48</sup> Given the inherently unknowable number and scope of NQTLs to analyze, it is arbitrary and capricious to require plans and issuers to perform and document comparative analyses for “each” NQTL that is applied to MH/SUD benefits. Instead, the Tri-Departments should impose reasonable limits on the scope of the requirement to “perform and document comparative analyses of the design and application of NQTLs” by interpreting this statutory language to mean that plans and issuers must

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<sup>46</sup> Code section 9812(a)(8)(A), ERISA section 712(a)(8)(A), and PHS Act 2726(a)(8)(A).

<sup>47</sup> 26 CFR 54.9812-2(b) and (c), 29 CFR 2590.712-1(b) and (c), and 45 CFR 146.137(b) and (c).

<sup>48</sup> See discussion above in the section regarding requests for a copy of a comparative analysis – 26 CFR 54.9812-2(e), 29 CFR 2590.712-1(e), and 45 CFR 146.137(e).

create comparative analyses for the common NQTL types that are defined by the Tri-Departments in guidance and/or that are specifically requested by a regulator.<sup>49</sup>

⇒ *ABHW requests that the final regulations stipulate that the plan or issuer must perform and document comparative analyses of the design and application of the NQTL types that the Tri-Departments define in guidance to require a comparative analysis and/or that a regulator specifically requests the plan or issuer to analyze.*

The Tri-Departments should limit documentation requirements and enforcement to apply only to the comparability of the NQTL, as written and in operation, and should not attempt to require plans and issuers to follow prescribed methodologies for decision-making.

A primary overarching concern regarding the proposed requirements for comparative analyses is that the scope of the documentation requirements proposed in this NPRM and described or alluded to in the accompanying 2023 Report to Congress far exceeds the requirements of the underlying statute. Where the statutory requirement focuses merely on the comparability of the design and application of the NQTL and documentation of the comparative analysis itself, the proposed rules and enforcement experience to date (including as described in the 2023 Report) would prescribe the process and documentation for the decision-making that the plan uses to create the NQTL—in essence prohibiting plans from applying any factor to NQTL design or operation that is not grounded in documented evidence deemed acceptable to the Tri-Departments.

As an example of the way in which regulators are extending the scope of enforcement beyond the statutory requirement for comparative analyses to also create requirements regarding supporting documentation, the 2023 Report states that a plan fails to comply with the documentation requirement where “the historical information and supporting documentation *required as part of a comparative analysis* was no longer accessible or had not been documented.”<sup>50</sup> This Report refers forty-one different times to requirements for plans to provide sufficient “supporting documentation,” despite the absence of any statutory requirement for plans to develop such documentation.

The scope of the supporting documentation that the Tri-Departments would require for a comparative analysis to be deemed sufficient is clearly broad but is never defined and appears to be limited only by the subjective judgment of the individual regulator or investigator. Notably, the Tri-Departments appear to assert that plans and issuers must document the evidence relied upon for their determination with regard to every factor that is applied to every service to determine whether and how to subject the service to an NQTL—i.e., that “comparability” cannot be established in the absence of factor-by-factor documentation for every service.<sup>51</sup> The finding that a

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<sup>49</sup> As discussed above, ABHW does not propose to prevent a regulator from requesting a comparative analysis of an NQTL type that has not been previously defined in guidance to require a comparative analysis. However, plans should not be penalized if they do not prospectively prepare a comparative analysis for any and all additional NQTL types, and regulators should grant additional time to the plan or issuer to perform and document the requested analysis for these NQTLs that are not included in the standard list that the Tri - Departments define in guidance.

<sup>50</sup> 2023 Report to Congress, p. 82.

<sup>51</sup> Presumably, the Tri-Departments’ logic would require documentation for every service, including for services that are not subject to the NQTL, in order to demonstrate that the identified factors are not triggered for these services.

plan violated the documentation requirement by relying on previous decision-making for which documentation was not developed or is no longer available creates a new interpretation that plans can only “demonstrate” comparability by documenting the results of a re-analysis of every factor for every service that is subject to the NQTL. This interpretation imposes a vast new paperwork requirement. For the prescription drugs classification, for which plans design NQTLs that apply to thousands of covered drugs, depending on the number of NQTL analyses for which the Tri-Departments require documentation and the number of factors that plans use to design these NQTLs, this requirement to “re-paper” existing decision-making may require documentation of the evidence relied upon for hundreds of thousands of decisions. In creating these new requirements for documentation outside the scope of the comparative analysis itself, the Tri-Departments would exceed their statutory authority and would significantly increase the administrative cost of health plan operations.

The statute does not refer to underlying documentation or require plans to provide the specific evidence that is relied on for every factor for every service for every NQTL and instead governs only the comparability of the general strategy. Much of the existing guidance also refers appropriately to “any” underlying documentation—i.e., requiring plans and issuers to produce only the documentation that they have already created in their normal course of business. The absence of documentation is expected where health plan professionals appropriately rely on their professional experience and judgment to evaluate NQTL factors. The Tri-Departments have also identified a wide range of aspects of requirements for plans and issuers to evaluate the comparability of the NQTL strategy and implementation as designed and in operation. Where a regulator has reason to doubt whether the identified factors support the application of an NQTL to a given service, the regulator can require the plan or issuer to produce evidence to support its determination. This approach would not limit the Tri-Departments’ ability to ensure compliance in any way and would conform to the statutory authority while also significantly mitigating the paperwork requirements for plans and issuers.

⇒ *ABHW recommends that the Tri-Departments regulate only the content of the comparative analyses and not exceed their statutory authority by attempting to regulate the underlying plan decision-making process or to create new documentation requirements that are not prescribed by the statute.*

*ABHW, therefore, recommends that the Tri-Departments amend the text of the proposed regulatory requirements to clarify that they do not create new documentation requirements beyond the scope of the comparability analysis. For example, ABHW recommends the following edits to 26 CFR 54.9812-2(c)(4), 29 CFR 2590.712-1 (c)(4), and 45 CFR 146.137(c)(4):*

*(i)(A) **Any** [q]uantitative data, calculations, or other analyses **that the plan or issuer has created in the normal course of business** showing whether, in each classification in which the nonquantitative treatment limitation applies, mental health or substance use disorder benefits and medical/surgical benefits met or did not meet any applicable threshold identified in the relevant evidentiary standard [...]; and*

(B) **Any** [r]ecords maintained by the plan or issuer documenting the consideration and application of all factors and evidentiary standards, as well as the results of their application;

[...]

(iii) ~~Documentation~~ **An analysis** demonstrating how the factors are comparably applied, as written, to mental health or substance use disorder benefits and medical/surgical benefits in each classification to determine which benefits are subject to the nonquantitative treatment limitation;

Step 1: Description of the nonquantitative treatment limitation - 26 CFR 54.9812-2(c)(1), 29 CFR 2590.712-1(c)(1), and 45 CFR 146.137(c)(1)

The proposed guidance for this step significantly expands the reach of the documentation to include not just definitions and discussion of the NQTL in the plan booklet or summary plan document but also any reference to the NQTL in “the policies or guidelines (internal or external) in which the nonquantitative treatment limitation appears or is described, and the applicable sections of any other relevant documents, such as provider contracts.” This requirement is likely to be onerous to fulfill, given the very wide range of documents that a plan or issuer might have that refer in any way to an NQTL. The requirement to identify any reference to the NQTL in any provider contract alone may require the plan or issuer to review and summarize or cite language from dozens or even hundreds of agreements (noting that plans and issuers generally do not maintain a master list of every amendment to every agreement), despite the fact that such language is very unlikely to supersede language in the plan document or applicable policies and procedures. This expanded requirement is also unnecessary, given that the vast majority of these references are not controlling and are subject first to any definition or requirement that is set forth in the plan document and second to any formal plan policy or procedure that governs the NQTL.

⇒ *ABHW recommends the requirement at 26 CFR 54.9812-2(c)(1)(i), 29 CFR 2590.712-1(c)(1)(i), and 45 CFR 146.137(c)(1)(i) be revised to require:*

*(i) Identification of the nonquantitative treatment limitation, including the specific terms of the plan **document, policies, or procedures that govern** or coverage or other relevant terms regarding the nonquantitative treatment limitation, ~~the policies or guidelines (internal or external) in which the nonquantitative treatment limitation appears or is described, and the applicable sections of any other relevant documents, such as provider contracts, that describe the nonquantitative treatment limitation;~~*

Step 2: Identification and definition of the factors used to design or apply the NQTL - 26 CFR 54.9812-2(c)(2), 29 CFR 2590.712-1(c)(2), and 45 CFR 146.137(c)(2)

The Tri-Departments exceed the statutory authority and current guidance by creating a new requirement to define and analyze “process factors.” The proposed regulations would define “Factors” to mean “all information, including processes and strategies 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 or coverage.” The preamble elaborates on the distinction between “process factors” and “strategy factors,” stating “the Tri-Departments would define ‘processes’ as relating to the application of an NQTL, while ‘strategies’ would relate to the design of an NQTL.”<sup>52</sup>

This new requirement to analyze “process factors” does not make sense in the context of the requirement to identify an “evidentiary standard” and “source” for every factor. The Tri-Departments identify a number of examples of “process factors,” including:

- Procedures to submit information to authorize coverage for an item or service prior to receiving the benefit or while treatment is ongoing;
- Requirements for peer or expert clinical review of [authorization request] information;
- Provider referral requirements; and
- The development and approval of a treatment plan;

It is highly uncertain what types of “specific benchmarks or thresholds” could be identified as “evidentiary standards” for these processes or what “sources” would be used to evaluate such evidentiary standards. Indeed, it is clear that the framework for analyzing “factors,” “sources,” and “evidentiary standards” was designed with “strategy factors” in mind and that this framework is unsuited to the newly conceived concept of “process factors.”

The statute requires plans to analyze “The factors used to determine that the NQTLs will apply to [MH/SUD] benefits and [M/S] benefits.” This requirement aligns with the part of the proposed definition for factors that addresses “strategies” that a plan or issuer “considered or relied upon to design” an NQTL. This also aligns with current guidance and enforcement, which have generally interpreted the statutory requirement to mean that plans must identify the factors used to determine which benefits will be subject to the limit. However, to extend beyond this definition to also create a new requirement to identify and analyze “process factors” is not supported by the statute. Instead, the statute is clear that “processes” to apply the NQTL “in operation” are to be analyzed under a separate step of the analysis.<sup>53</sup>

ABHW is also concerned about the Tri- Departments’ proposed interpretation of the term “factors” to include “information (but generally not evidentiary standards) that the plan or issuer considered but rejected.”<sup>54</sup> At a minimum, it is essential for the Tri-Departments to clarify what it means for a plan to “consider but reject” a factor. Perhaps the Tri-Departments intend to stipulate that where a plan determines that a given benefit or service does not meet a given factor that the plan has identified in its comparative analysis, the plan must be prepared to explain why the factor was not met for that benefit or service? ABHW requests the Tri- Departments clarify that there is no need for plans to analyze factors that have been rejected and are not applied to determine the scope or application of the NQTL, given that factors that are not applied are wholly irrelevant to the design and application of the limit and to the comparative analysis.

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<sup>52</sup> <https://www.federalregister.gov/d/2023-15945/p-220>.

<sup>53</sup> The requirement to analyze processes “in operation” is set forth in the statute within the fourth step of the comparative analysis; the Tri-Departments propose to sub-divide this step into step 4 and a new step 5.

<sup>54</sup> 88 FR 51567.



- ⇒ *ABHW requests that the definition of “factors” be revised to mean “~~all information, including processes and strategies 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 or coverage.~~”*

Step 3: Description of how factors are used in the design and application of the NQTL - 26 CFR 54.9812-2(c)(3), 29 CFR 2590.712-1(c)(3), and 45 CFR 146.137(c)(3)

The Tri-Departments devote considerable discussion in the preamble to the need to analyze the decision-making process itself (“the nature and timing of the decisions”) as well as “the professional designations and qualifications of each decision maker” for each factor. However, no examples are provided of how the Tri-Departments would identify a disparity for these elements, nor is there any indication in the guidance or enforcement to date that disparities of this nature exist or that any such disparity is posing practical barriers to access or coverage for MH/SUD services. It is, therefore, unclear what types of process details the Tri-Departments consider to be relevant to the comparative analysis. To the extent that this requirement primarily boils down to ensuring that clinicians with MH/SUD expertise are used for making clinical determinations in the design or implementation of NQTLs and that the frequency of concurrent review is based on valid scientific evidence, this would be useful to clarify. To the extent that there are additional concerns that the Tri-Departments wish to address for specific NQTL types, it would be helpful for the Tri-Departments to elaborate on the nature of these concerns.

- ⇒ *To enhance compliance and help to ensure that analyses of decision-making processes efficiently target information that will be useful to determinations of comparability and stringency that may reasonably impact member access, ABHW requests that the Tri-Departments provide further examples of the types of information that must be included regarding “the nature and timing of decisions” and the types of disparities that plans and issuers should seek to avoid with regard to such processes.*

The Tri-Departments also propose to require comparative analyses to document “whether and how any factors are given more weight than others” and “the reasons for the ordering or weighting of the factors.” However, the guidance seems to presume that a formal analytical framework for weighting exists and remains silent on the common and reasonable practice of applying professional judgment to weigh the strength of the evidence for each factor and arrive at a net conclusion.

- ⇒ *ABHW requests that the Tri-Departments specifically acknowledge that subject matter experts may apply professional judgment to evaluate the net result of the identified factors according to the totality of the evidence.*

Step 4: Demonstration of comparability and stringency as written - 26 CFR 54.9812-2(c)(4), 29 CFR 2590.712-1(c)(4), and 45 CFR 146.137(c)(4)

In Step 4, the Tri-Departments propose to require plans to provide “Documentation of each factor,” including “Quantitative data, calculations, or other analyses showing whether [...] benefits met or did not meet any applicable threshold in the relevant evidentiary standard.” The proposed guidance and enforcement experience to date suggests that plans would be unable to meet the

comparative analysis requirement unless they are able to identify quantitative data, pinpoint citations in the medical literature, or other external evidence to support each conclusion for each factor for each service for each NQTL.

The Tri-Departments' interpretation of the statutory requirement to demonstrate "comparability" to mean that plans must document the evidence to support their determinations for every factor for every NQTL type is likely to exponentially increase the operating and administrative costs for many health plans. For example, many plans currently rely on their experts' ability to make context-specific decisions based on their general knowledge of the evidence, professional experience, or professional judgment. This reliance on professional knowledge, experience, and judgment is often appropriate and consistent with efficient business practices. For example, published evidence that is directly on point to a given determination may be difficult to locate or may not exist where the determination in question is widely accepted or otherwise does not support research agendas. Data and other evidence may be reviewed from databases or platforms that are burdensome or impossible to excerpt. Professionals may remember evidence from other contexts but be unable to efficiently obtain copies of such evidence. To restrict plan decision-making to rely only on evidence that they can document would impermissibly restrict the role of professional knowledge, experience, and judgment and would dramatically increase the administrative costs of developing and maintaining NQTLs that are important to health plan operations.

The Tri-Departments also propose a requirement for plans to provide "Documentation demonstrating how the factors are comparably applied, as written...to determine which benefits are subject to the NQTL." It is unclear how this requirement differs from the service-by-service documentation requirement for each factor or what exactly health plans must provide to fulfill this requirement.

⇒ *ABHW requests that the Tri-Departments specifically acknowledge that subject matter experts may rely on professional knowledge, experience, and judgment to evaluate the evidentiary standard for the identified factors.*

The proposed rules are also inconsistent regarding the need to include or attach documentation of the specific evidence relied upon to evaluate every factor for every service for every NQTL. In the introductory paragraph at 26 CFR 54.9812-2(c), 29 CFR 2590.712-1(c), and 45 CFR 146.137(c), the Tri-Departments propose to require comparative analyses to include "a general description of any information considered or relied upon by the plan or issuer in preparing the comparative analysis for each nonquantitative treatment limitation." Similarly, the preamble discussion of Step 2 states, "The Tri-Departments stress that when identifying the evidence or sources from which an evidentiary standard is derived, the plan or issuer should be prepared to provide the copies of the actual evidence or source used, as well as the date and relevant citation for the correct version of the document used."<sup>55</sup> In contrast, the proposed regulations for Step 4 stipulate that "The comparative analysis must include [...] (i) Documentation of each factor [...], including, as relevant (A) quantitative data, calculations, or other analyses" showing whether or not benefits met the evidentiary standard for each factor, and "(B) Records maintained by the plan or issuer

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<sup>55</sup> <https://www.federalregister.gov/d/2023-15945/p-396>.

documenting the consideration and application of all factors and evidentiary standards, as well as the results of their application.”

The volume of the evidence relied upon to evaluate the application of every factor to every service for every NQTL type, in addition to all related records maintained by the plan or issuer, is likely to be immense. As previously noted, for prescription drugs alone, this would require the plan or issuer to provide documentation of hundreds of thousands of determinations in order to encompass the evaluation of every factor for every NQTL for every drug. To say that including all such information within the scope of Step 4 of each comparative analysis would exponentially increase the length of these analyses is an understatement. To duplicate every relevant “record” within the scope of relevant comparative analyses would be exceedingly burdensome. It is difficult to understand the value that the Tri-Departments would derive from this draconian interpretation of the statutory requirement to create comparative analyses demonstrating that NQTLs are “comparable.”

⇒ *ABHW recommends that the Tri-Departments eliminate the requirement at 26 CFR 54.9812-2(c)(4)(i), 29 CFR 2590.712-1(c)(4)(i), and 45 CFR 146.137(c)(4)(i) for comparative analyses to include the actual evidence relied upon to evaluate every factor for every service for every NQTL and related records, and instead require that such evidence be available upon request.*

Step 5: Demonstration of comparability and relative stringency in operation - 26 CFR 54.9812-2(c)(5), 29 CFR 2590.712-1(c)(5), and 45 CFR 146.137(c)(5)

The proposed guidance repeatedly emphasizes that the analysis of comparability and stringency in operation must be comprehensive. This standard for compliance is not present in the MHPAEA statute and is newly proposed by the Tri-Departments in this guidance. The guidance does not provide any discussion of what it means to be comprehensive or what types of analyses might fall short of being comprehensive. This requirement appears to suggest that a plan would be non-compliant if it fails to proactively identify and address every aspect of comparability that a regulator might possibly conceive of for every aspect of the processes, strategies, evidentiary standards, or other factors used in designing or applying the NQTL. This is an impossible standard.

⇒ *ABHW requests that the Tri-Departments strike the word “comprehensive” at 26 CFR 54.9812-2(c)(5)(i), 29 CFR 2590.712-1(c)(5)(i), and 45 CFR 146.137(c)(5)(i)*

Two separate provisions are set forth to require data to demonstrate comparability in operation—in sections (5)(i)(A) and (5)(ii)<sup>56</sup>—but there is no discussion in the regulatory text or preamble to explain how the two requirements differ or whether the same data may be used to fulfill both requirements. There is also no discussion of how the Tri-Departments will determine whether the measure types that are selected by the plan are appropriate and sufficient.

⇒ *For clarity, ABHW recommends that the Tri-Departments combine the requirements in sections (5)(i)(A) and (5)(ii) as follows:*

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<sup>56</sup> Section (5)(ii) incorporates by reference the outcomes data requirements at 26 CFR 54.9812-1 (c)(4)(iv)(D), 29 CFR 2590.712(c)(4)(iv)(B), and 45 CFR 146.136(c)(4)(iv)(B).

(i) [...]

(A) an explanation of any methodology and underlying data used to demonstrate the application of the nonquantitative treatment limitation in operation, **including the relevant data collected and evaluated as required under § 146.136(c)(4)(iv)(A)**; and

(B) the sample period, inputs used in any calculations, definitions of terms used, and any criteria used to select the mental health or substance use disorder benefits and medical/surgical benefits to which the nonquantitative treatment limitation is applicable;

(ii) — *Identification of the relevant data collected and evaluated as required under § 146.136(c)(4)(iv)(A)*;

Step 6: Findings and conclusions - 26 CFR 54.9812-2(c)(6), 29 CFR 2590.712-1(c)(6), and 45 CFR 146.137(c)(6)

Although the proposed rules require plans to self-report “Any findings or conclusions indicating that the plan or coverage is not (or might not be) in compliance” with the parity requirements, no guidance is provided regarding the impact of that self-reporting. The Tri-Departments should explain the extent to which they will make an immediate determination of non-compliance or whether they will allow plans that provide a reasonable, good faith corrective action plan to remediate the self-identified disparity. ABHW notes that if regulators punish plans for self-identifying potential noncompliance, this disincentivizes plans from seeking to remediate the potential disparity and instead incentivizes plans to seek any possible evidence or justification to support a determination that the identified difference does not constitute a disparity. ABHW, therefore, recommends that the Tri-Departments instead stipulate that plans and issuers that identify and take reasonable actions to mitigate a disparity will not be found to violate MHPAEA. This approach incentivizes plans to proactively pursue compliance.

⇒ *ABHW recommends that the Tri-Departments stipulate that plans and issuers that proactively identify and take reasonable actions to mitigate a potential disparity will not be found to violate MHPAEA.*

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## **Regulatory Impact Analysis**

We have significant concerns with the Tri-Departments’ estimate of the cost that plans and issuers would bear in implementing the regulations as they have been proposed. Specifically, we believe that the Tri-Departments’ estimate that such implementation would cost approximately \$291.0 million in the first year for collecting and analyzing data and documenting comparative analyses and approximately \$117.6 million in each subsequent year, grossly undercounts the resources that would be required for such implementation. Moreover, the estimates provided do not account for the efforts that will be required by vendors and contractors to the plans and issuers, which will also impact the level of effort needed by the plans and issuers to synthesize vendors’ and

contractors' data with their own. All such costs are significant and will be borne by consumers in the form of increased premiums and administrative fees.

The financial estimates raise further questions based on ambiguities in the preamble and Regulatory Impact Analysis discussion. The Tri-Departments underestimate the staffing needs and level of effort for completing the data gathering and analyses that would be required for each NQTL. Moreover, the Tri-Departments calculate the burden using an estimate that, on an annual basis, plans would complete 4 NQTL analyses, and issuers would complete 8.<sup>57</sup> It is unclear why the number of NQTLs analyzed each year would differ between plans and issuers. More importantly, it is unclear how the Tri-Departments arrived at such low numbers. ABHW notes that the Tri-Departments have identified at least 18 different NQTL types in guidance to date (several of which are stipulated to include a number of sub-categories that may be required to be analyzed as a separate NQTL) and continue to identify new NQTL types in each successive new piece of guidance. There is particular uncertainty about how many separate comparative analyses will be required for NQTL types related to provider network composition. As discussed in the proposed rule, it appears that the network composition category will require multiple NQTL analyses for various subcategories, for example, credentialing, reimbursement rates, and access standards, and may also require additional subcategories such as "provider billing restrictions," provider experience beyond licensure, and potentially others. ABHW requests that the Tri-Departments identify a sample list of the 4 NQTLs that a plan would develop and a sample list of the 8 NQTLs that an issuer would develop and achieve compliance with the proposed requirements.

The Tri-Departments state that issuers and third-party administrators are the entities most likely performing the work to evaluate NQTLs and provide the comparative analysis and required data. While we do not question this assertion, we disagree with the Tri-Departments' underlying assumption that plans' reliance on TPAs and other administrative services organizations will lower the cost of plan compliance with the proposed rule. Reliance on TPAs and other administrative services-only entities increases the burden of cost as health plans and issuers must increase the level of coordination and collaboration to complete a unified comparative analysis.

The Tri-Departments assert without support that significant benefits would arise from implementing the proposed rule, including greater access to MH and SUD services, better health outcomes among those with MH or SUD conditions, and reduced adverse impacts on the families, friends, and coworkers of people who suffer from untreated or poorly managed MH or SUD conditions. Further, even if such benefits would accrue, without the ability to quantify the value of these benefits, it is impossible to assess whether the burden posed outweighs the benefits.

Regulators estimate that for plans and issuers preparing their own comparative analyses, the proposed rule would add "an incremental burden of 10 hours per NQTL in the first year," resulting in an increased cost of approximately \$291.0 million. This cost is likely a gross underestimate as it is calculated using the assumption that plans would complete 4 NQTL analyses and issuers would complete 8. In the absence of guidance to delineate and limit the requirement to create comparative analyses for all NQTL types, plans, and issuers would need to review and update comparative analyses for a much larger number of NQTLs, including the multi-pronged medical management and network composition limitations, resulting in the likely need to complete the

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<sup>57</sup> 88 FR 51608.

newly proposed steps and analyses for more than 15 NQTLs at minimum. Using the 10-hour incremental burden estimate (which we believe itself is low), with the need to complete more than 15 NQTLs, if implemented as proposed, the NPRM would result in a cost burden that is nearly double the estimated provided by the Tri-Departments.

It is also our experience that 10 hours is an extreme underestimate of the burden of updating plans' comparative analysis to meet the proposed requirements. Even under present guidance, for most NQTLs, plans and issuers typically need, on average, a team of *at least* six individuals to work on analyzing and preparing the proposed changes to each comparative analysis. For example, a typical NQTL will involve 3-5 subject matter experts, 1-2 compliance officials, a project manager, 1-3 attorneys or consultants with specialized MHPAEA expertise (often including costly outside firms), and review and sign-off by at least one Vice President-level plan official. Each of the team members currently invests, on average, *at least* 10 hours for such effort, for a total of 60 hours per comparative analysis. Many NQTL types cut across traditional operating units and/or involve the use of vendors or contractors, significantly increasing the number of people involved, the complexity, and the time burden of the work.

The proposed regulations substantially revise and expand upon the documentation requirements that were added to MHPAEA by the Consolidated Appropriations Act of 2021 and will require plans and issuers to significantly revise each step of their existing comparative analyses (to account for the additional clarifications of existing requirements for each step) and to add a variety of burdensome new steps (including the new quantitative testing requirements, analyses for the newly-identified "process factors," analyses to identify discriminatory factors, and new outcomes measure data requirements). We estimate that the effort to complete these wholesale revisions and additions to each comparative analysis will be, *at minimum*, as great as the initial burden to create them (as detailed in the previous paragraph), i.e., at least 60 hours, on average, per NQTL type. This would place the first-year cost burden per NQTL at six times the estimated burden provided by the Tri-Departments.

Thus, due to the Tri-Departments' underestimation of the number of NQTL types that will need documentation by approximately 2x and the Tri-Departments' underestimation of the number of staff hours per NQTL type by approximately 6x, we believe that a more realistic estimate of the administrative burden to be imposed by the proposed rules would be closer to \$3.49 billion in the first year.

Further, the regulatory burden estimate does not explicitly mention or appear to account for the cost of requiring health plans and issuers' decision-makers to identify and document evidence to support their evaluation of every factor as applied to every service for every NQTL, as discussed in more detail above. Because these service-by-service analyses are separate from the overarching NQTL analyses, the Tri-Departments' cost estimates do not appear to account for the costs of hiring additional staff to undertake this research and documentation work. We estimate that issuers will have to hire at least three full-time equivalent new staff members to assist with this documentation requirement for NQTL types across medical management, prescription drug benefits, and provider contracting domains. These costs, multiplied across regulated plans and issuers, should be added to the \$3.49 billion dollar estimate above.

The estimate of the incremental burden for subsequent years is similarly low at \$117.6 million. The Tri-Departments predict that plans and issuers would require 4 hours annually per NQTL to update their analysis. However, health plans and issuers must update their NQTL strategies and data on at least a yearly basis in order to remain current with the medical literature, account for evolving trends in utilization, cost, and other factors, and remain competitive in the market. Plans and issuers will also need to update the outcomes data for each NQTL. Due to both the significant effort to create all of these updates and the number of people who must coordinate to create them, we believe that a more accurate estimate would be closer to 12 hours per NQTL type.

With respect to the Paperwork Reduction Act (PRA) review, DOL regulators estimate that plans to complete their own analyses (rather than relying on Third Party Administrators (TPAs), would on average perform 4 NQTL analyses, requiring 20 hours for each NQTL analysis across benefit classifications (4 manager hours and 16 operational staff hours). Based on these assumptions, DOL projects a total hourly burden for compliance with current and proposed parity requirements of approximately 2.2 million hours at a cost of \$252 million. Annual updates to these analyses, needed only when changes are made to the terms of the plan or the way NQTLs are applied, are estimated to take 10 hours per NQTL, resulting in a total hourly burden of approximately 1 million hours at a cost of \$126 million. As stated previously, our assessment is that the estimated average significantly understates the reality currently experienced by plans and issuers and the expected level of effort and cost of future implementation.

On the PRA assessment, as it impacts issuers in the individual and small group markets, HHS assessed the hourly burden of completing each of 8 NQTL analyses in the first year to be 20 hours, resulting in an annual hourly burden of 240,000 hours at a cost of \$27.5 million. In subsequent years, HHS projects the hourly burden at 10 hours per NQTL analysis, with an annual hourly burden of 120,000 hours at a cost of \$13.7 million. As with the DOL estimate above, we believe this does not capture the full scope of the expected level of effort and cost of future implementation.

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### **Compliance deadline**

Due to the significant operational changes proposed by these regulations along with the need for enhanced definitions, clarifications, and guidance from the Tri-Departments, ABHW requests an extension of the compliance date to January 1, 2026, for group plans and issuers and January 1, 2027, for individual plan issuers.

## **Conclusion**

Thank you for your efforts and your consideration of our comments on the NPRM. ABHW welcomes the opportunity to meet with the Tri-Departments to discuss our response and suggestions. If you have questions, please contact Kathryn Cohen, Senior Director of Regulatory Affairs, at [cohen@abhw.org](mailto:cohen@abhw.org).

Sincerely,

A handwritten signature in cursive script that reads "Pamela Greenberg".

Pamela Greenberg, M.P.P.  
President and CEO



**RE: PROPOSED AMENDMENTS TO REGULATORY DEFINITIONS FOR “BENEFITS” UNDER THE MENTAL HEALTH PARITY AND ADDICTION EQUITY ACT(MHPAEA)**

We request that the Tri-Departments add the underlined language below to the regulatory definitions for “Mental health benefits,” “SUD benefits,” and “Medical/Surgical benefits”:

*“Medical/surgical benefits means benefits with respect to items or services for medical conditions or surgical procedures, as defined under the terms of the plan or health insurance coverage and in accordance with applicable Federal and State law, but does not include mental health or substance use disorder benefits. The plan or issuer must define items or services to be “for” medical conditions or surgical procedures according to a reasonable method, such as by determining:*

- Whether the treatment or service is most commonly delivered to treat medical/surgical conditions.
- Whether the treatment or service is most commonly delivered by medical or surgical providers and/or
- Whether administration of claims or coverage for the treatment or service is provided through a vendor that is contracted to administer medical/surgical benefits.

Any condition defined by the plan or coverage as being or as not being a medical/surgical condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), the most current version of the ICD, or State guidelines).”

*“Mental health benefits means benefits with respect to items or services for mental health conditions, as defined under the terms of the plan or health insurance coverage and in accordance with applicable Federal and State law. The plan or issuer must define items or services to be “for” mental health conditions according to a reasonable method, such as by determining:*

- Whether the treatment or service is most commonly delivered to treat mental health conditions.
- Whether the treatment or service is most commonly delivered by mental health treatment providers and/or
- Whether administration of claims or coverage for the treatment or service is provided through a vendor that is contracted to administer medical/surgical benefits.

Any condition defined by the plan or coverage as being or as not being a mental health condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), the most current version of the ICD, or State guidelines).”

*Substance use disorder benefits* means benefits with respect to items or services for substance use disorders, as defined under the terms of the plan or health insurance coverage and in accordance with applicable Federal and State law. The plan or issuer must define items or services to be for substance use disorders according to a reasonable method, such as by determining:

- Whether the treatment or service is most commonly delivered to treat substance use disorders,
- Whether the treatment or service is most commonly delivered by substance use disorder treatment providers and/or
- Whether administration of claims or coverage for the treatment or service is provided through a vendor that is contracted to administer medical/surgical benefits.

Any disorder defined by the plan as being or as not being a substance use disorder must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the DSM, the most current version of the ICD, or State guidelines)

### *Rationale*

The MHPAEA regulations currently state that “*Mental health benefits* means benefits with respect to items or services for mental health conditions, as defined under the terms of the plan or health insurance coverage and in accordance with applicable Federal and State law. Any condition defined by the plan or coverage as being or as not being a mental health condition must be defined to be consistent with generally recognized independent standards of current medical practice.”<sup>58</sup> Parallel definitions are provided for SUD benefits and for M/S benefits.

Neither the MHPAEA regulations nor any FAQ or other federal guidance directly addresses the proper application of parity to benefits for treatments and services that can be delivered to care for both MH/SUD and M/S conditions. However, in making compliance determinations, regulators are taking the position that parity applies to claims for benefits with a primary diagnostic code that has been defined by the plan to be a MH or SUD condition. This position creates a number of sweeping downstream consequences that will be extremely burdensome and legally challenging to address.

Under this interpretation, treatment limits or cost-sharing requirements for the same service rendered by the same provider may differ solely based on the condition being treated. For example, if a plan applies a higher copay to x-rays than to other outpatient services and that higher copay does not meet the predominant test, then the higher copay may not be applied when the provider indicates a MH or SUD diagnosis code for the x-ray (e.g., to screen a person with tobacco use disorder for lung cancer). The practical result of this interpretation can, therefore, be to require that benefits for members with MH/SUD conditions be more generous than benefits for members with M/S conditions, in contradiction to the plain text of the statute, which merely requires parity.

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<sup>58</sup> 29 CFR 2590.712(a)

Key considerations include:

- The scope of the parity protection may be arbitrary in practice, given relatively arbitrary current practices for determining which diagnosis to list as “primary” in the context of comorbid conditions and/or complex etiologies. There is little formal guidance or consistency in practice about how providers should determine which diagnosis is “primary” and whether the claim should be properly considered to be “for” the MH/SUD condition or the M/S condition. The question can be complex in practice. For example, the ranking of diagnoses may be essentially arbitrary for urgent care, office visits, and other services to treat a patient with co-morbid depression, tobacco use disorder, obesity, hyperlipidemia, and chronic obstructive pulmonary disorder. Ranking of diagnoses may also be unclear for patients who need treatment for physical injuries that result from MH or SUD conditions (e.g., self-harm) or for patients with MH and SUD conditions that result from M/S conditions (e.g., psychosis caused by HIV). In these and other situations, parity enforcement may also create incentives for providers to inappropriately prioritize MH/SUD diagnoses over M/S diagnoses in claims coding to avoid treatment limits and/or to reduce patient cost-sharing obligations. It is unwise to base the parity compliance determinations on such ambiguous and unreliable foundations.
- This interpretation will require many payors to make costly investments to update their claims systems to account for diagnostic codes when processing and adjudicating claims. The scope of services for which a provider may list a MH or SUD diagnosis code is uncertain and difficult to predict. A wide range of emergency services, urgent care services, office visits and therapy services, and screening and diagnostic services are commonly delivered to treat patients with both M/S and MH/SUD conditions. In addition, for the reasons described above, providers may assign MH/SUD diagnoses to claims for services that are rarely delivered to treat MH/SUD conditions. In this context, a parity compliance strategy cannot rely on a defined set of MH/SUD service codes; instead, the only practical way for Plans to ensure that cost-sharing and limits comply with parity is to differentiate claims adjudication based on the primary diagnosis code for all services. Unfortunately, many claims systems are not currently set up to differentiate cost-sharing or treatment limits by diagnosis code.
- Plans will have to update their actuarial projections of spending by benefit for the purposes of evaluating compliance with the “predominant” and “substantially all” tests. Regulators, in some instances, have determined that a Plan’s actuarial testing methodology for parity compliance was insufficient where the Plan failed to remove claims for services with an MH or SUD diagnosis code from the dataset used to project spending on M/S benefits. Unfortunately, many claims platforms are not currently set up to systematically account for diagnosis codes.
- This interpretation will require many Plans to make costly investments to update their utilization management platforms to account for diagnostic codes when processing authorization requests and appeals. Regulators, in some instances, have determined that a Plan’s methodology for analyzing denial and appeal rates for its comparative analyses of relevant NQTLs was insufficient where the Plan failed to assign all authorization requests

to the MH/SUD or M/S datasets based on the diagnosis code rather than the service or provider type. Unfortunately, many utilization management platforms are not currently set up to systematically account for diagnosis codes.

- Where the parity test requires that a cost-sharing requirement or treatment limit for a service be adjusted regarding the treatment of MH/SUD conditions, making the MH/SUD coverage more generous than coverage for M/S conditions, the differential coverage may be interpreted to discriminate against individuals with disabilities based on a M/S condition that needs the service for the treatment of their M/S condition. Such discrimination may violate the terms of the Americans with Disabilities Act (ADA).

For all of these reasons, the current approach to interpreting ambiguous regulatory language is unnecessarily complex and burdensome. In addition, the current enforcement approach contravenes the language of the MHPAEA rules, which offer broad flexibility for plans and issuers to define their benefits under the terms of the plan or coverage (constrained only by federal and state law).<sup>59</sup>

Fortunately, the language of the MHPAEA regulations suggests a more straightforward and common-sense solution. The most reasonable and practical interpretation of the final rules is that benefits “for” MH/SUD conditions are benefits for treatments and services that are generally delivered to treat MH/SUD conditions and that all other benefits are M/S benefits. This approach would align with standard plan and coverage terms as currently designed and set forth in the MH/SUD sections of the standard plan description, plan contract or coverage policy, and related plan or coverage materials and would align with standard claims processing procedures as currently operated.

This approach would also align with guidance issued by the Centers for Medicare & Medicaid Services (“CMS”) regarding the application of parity to long-term services and support for Medicaid and CHIP enrollees. The CMS guidance allows Plans to define benefits that can be used to treat either medical or behavioral conditions by means of a reasonable method, such as looking at the services and treatment spent and determining whether the service is predominantly used for a medical diagnosis, or a mental health/substance use disorder diagnosis and defining it accordingly.<sup>60</sup>

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<sup>59</sup> The clear deference to plans and issuers to create their own definitions for “MH benefits,” “SUD benefits,” and “M/S benefits” under the terms of the plan or coverage stands in contrast to the narrow instruction for plans and issuers to use “generally recognized independent standards of medical practice” to define “MH conditions,” “SUD conditions,” and “M/S conditions.”

<sup>60</sup> Centers for Medicare and Medicaid Services, *Frequently Asked Questions: Mental Health and Substance Use Disorder Parity Final Rule for Medicaid and CHIP*, October 11, 2017, Q4. <https://www.medicaid.gov/federal-policy-guidance/downloads/faq101117.pdf>:

“A variety of LTSS benefits, such as personal care and respite care, could be defined as either MH/SUD or medical/surgical (M/S), depending on the condition of the beneficiary being treated. For these benefits, the state may define the benefit as MH/SUD or M/S for the entire beneficiary population using a reasonable method, such as whether the service is most commonly or frequently provided due to a MH/SUD or M/S condition. For example, if more than 50% of spending on personal care is for beneficiaries who are receiving the service due to M/S conditions, the state may reasonably define personal care services as a M/S benefit for the purposes of the parity analysis.”

Explicit guidance is critically needed to clarify whether it is necessary for Plans to make the significant capital investments that would be needed to update software platforms and data systems to identify every claim and authorization as either an “MH/SUD benefit” or a “M/S benefit.” As noted above, many utilization management and claims adjudication platforms are not currently equipped to do so. To the extent that the Departments decide to formalize the interpretation that services must be covered as “MH/SUD benefits” or “M/S benefits” based on the condition being treated, the economic impact and paperwork burden of this guidance should be assessed pursuant to Executive Orders 12866 (Regulatory Planning and Review, September 30, 1993) and 13563 (Improving Regulation and Regulatory Review, February 2, 2011).

## APPENDIX B – COMMENTS ON THE PROPOSED EXAMPLES

### **Examples - 26 CFR 54.9812-1 I(4)(viii), 29 CFR 2590.712(c)(4)(viii), and 45 CFR 146.136(c)(4)(viii)**

#### Example 1 (More restrictive prior authorization requirement in operation).

This example would illustrate the intended application of the quantitative testing requirement for NQTLs by analyzing a plan that authorizes inpatient benefits for periods of 1, 3, or 7 days. This example would treat inpatient services for the treatment of different conditions or illnesses as interchangeable widgets that are unrelated to the underlying clinical context for a given patient and the necessary services for the treatment of that patient's condition. The Tri-Departments fail to acknowledge or analyze the reasons why approvals of 7 days are most common for M/S conditions or the reasons why approvals of 1 day are routine for MH/SUD benefits. For example, the Tri-Departments fail to acknowledge that the length of stay for some conditions is highly consistent across providers and patients while the length of stay for other conditions is highly variable. Similarly, the Tri-Departments fail to acknowledge the differing reimbursement methodologies and incentives that may apply to the extent that longer authorizations are routinely granted to providers and services that are reimbursed on a case rate basis or otherwise share financial risk for over-utilization (which is the case for the majority of medical/surgical inpatient benefits) whereas shorter authorizations may be more common for providers and services that are reimbursed on a per diem or per unit basis (which is far more common in the context of mental health and substance use treatment) and are therefore financially incentivized to maximize utilization.

It may be reasonable for an analysis of the comparability of the duration of authorizations in the identified fact pattern to conclude that the plan's strategy for determining the length of authorizations violates MHPAEA, but the Tri-Departments should account for reasonable and appropriate clinical and business considerations that influence such determinations rather than applying a mechanical quantitative analysis that treats all MH/SUD and M/S services as interchangeable commodities.

- ⇒ *ABHW requests that the Tri-Departments identify a different fact pattern that illustrates an NQTL that more clearly demonstrates a violation of the "more restrictive" requirement in operation.*
- ⇒ *In addition, ABHW also requests that the Tri-Departments provide a fact pattern that demonstrates the application of quantitative testing to an NQTL type that is not generally linked to claims data, such as network composition standards or medical necessity criteria development.*
- ⇒ *ABHW also requests that the Tri-Departments withdraw the proposal to apply quantitative testing to aspects of NQTL design and operations that are based on reasonable and appropriate clinical or business factors.*

#### Example 2 (More restrictive peer-to-peer concurrent review requirements in operation).

This example addresses a plan that routinely initiates peer-to-peer calls to inpatient MH/SUD providers when the first-level reviewer is unable to approve a concurrent review request but does not do the same for inpatient M/S providers. The example concludes that the plan applies concurrent review more stringently to MH/SUD benefits because the plan is “compelling an additional action” to access MH/SUD benefits. This conclusion seems counter-intuitive. First, the example does not acknowledge that the inpatient MH/SUD provider is not obligated to take the plan’s call, meaning that any additional time burden is strictly optional. Second, it would seem just as logical to conclude that the NQTL is applied more stringently to *M/S benefits* because the M/S providers are not routinely afforded the opportunity to supplement the existing medical record in cases where the first-level reviewer is unable to approve the request.

ABHW understands the concerns raised by many MH/SUD providers that authorization determination processes are more time-consuming for some inpatient MH/SUD services than processes for some inpatient M/S services. However, any difference in burden often results from (1) the relatively complex and subjective medical necessity requirements for inpatient and residential MH/SUD services as compared to relatively straightforward medical necessity criteria for many inpatient and sub-acute M/S services and (2) the more widespread adoption and generally more sophisticated implementation of electronic medical record (EMR) platforms by inpatient M/S providers relative to inpatient MH/SUD providers. However, where the plan’s medical necessity criteria for both MH/SUD and M/S services are based on national standards, differences in the relative complexity or subjectivity of such standards should not be a basis for finding a disparity. Similarly, because provider adoption of EMRs is beyond the plan or issuer’s control, any consequences for the provider regarding the inefficiency of using other methods to transmit medical records should not be a basis for finding a disparity.

- ⇒ *ABHW requests that the Tri-Departments identify a different fact pattern that illustrates an NQTL that more clearly demonstrates a violation of the “more restrictive” requirement in operation.*
- ⇒ *ABHW also requests that the Tri-Departments apply enforcement discretion with regard to differences in the design or application of NQTLs that are outside of the plan or issuer’s control and/or do not, in fact, clearly impede or disadvantage access to MH/SUD benefits.*

Example 3 (More restrictive peer-to-peer review medical necessity standard in operation; deviation from independent professional medical and clinical standards).

This example helps to illustrate the limits of the “safe harbor” for quantitative testing based on “independent professional medical or clinical standards.” The example notes that the plan has not identified independent professional medical or clinical standards that require peer-to-peer review. It is not the role of independent professional medical or clinical standards to establish guidelines for the operationalization of medical necessity determinations. This example thus helps to illustrate that the “independent professional medical or clinical standards” safe harbor is generally inapplicable for “processes” to implement NQTLs and that, by extension, the quantitative testing requirement can prohibit reasonable and appropriate operational processes that would otherwise satisfy existing “comparability” and “stringency” requirements. Instead, the Tri-Departments propose to require plans and issuers to design all “processes” on the

presumption that the underlying services are interchangeable commodities for which the clinical and business context is irrelevant.

- ⇒ *ABHW requests that the Tri-Departments identify a different fact pattern that illustrates an NQTL that more clearly demonstrates a violation of the “more restrictive” requirement in operation.*
- ⇒ *ABHW also requests that the Tri-Departments withdraw the proposal to apply quantitative testing to NQTL processes that are based on reasonable and appropriate clinical or business factors.*

Example 4 (Not comparable and more stringent methods for determining reimbursement rates in operation).

This example provides that a plan violates parity where it systematically discounts reimbursement rates for non-physician MH/SUD providers but not for non-physician M/S providers. The example would be improved by clarifying that the analysis applies to non-physician MH/SUD and M/S providers that submit claims under their own billing ID and not “incident to” a physician service or otherwise appropriately submitted under a physician provider’s ID. Nonetheless, ABHW appreciates the general clarity of the example and agrees with the conclusion of the analysis.

Example 5 (Exception for impartially applied generally recognized independent professional medical or clinical standards).

This example provides that higher denial rates for MH/SUD services do not create non-compliance where the plan impartially applies independent professional medical or clinical standards for both M/S benefits and MH/SUD benefits. ABHW appreciates the clarity of the example and agrees with the conclusion of the analysis.

Example 6 (More restrictive prior authorization requirement; exception for impartially applied generally recognized independent professional medical or clinical standards not met).

In this example, as with Example 3, the Tri-Departments illustrate the fact that independent professional medical or clinical standards generally do not establish guidelines for the administration of health plan benefits or the operationalization of medical necessity determinations. Here, the Tri-Departments focus on prior authorization requirements and again presume that such requirements should treat all services as interchangeable without regard to the clinical or operational contexts that would otherwise influence the determination of the appropriate duration of authorizations. For example, the Tri-Departments’ approach would ignore considerations regarding the potential for overdose, misuse, or diversion, aspects of the condition being treated, including acuity, chronicity, and expected duration of treatment, and other reasonable and appropriate considerations.

Importantly, the Tri-Departments also assert that “The most common or frequent variation of this nonquantitative treatment limitation (the predominant nonquantitative treatment limitation) applicable to substantially all medical/surgical benefits is following generally



recognized independent professional medical and clinical standards (consistent with generally accepted standards of care).” ABHW is confused about how this could be true, given that “independent professional medical and clinical standards” generally do not address the appropriate duration of authorizations for M/S services any more than they do for MH/SUD services. Plans may reasonably rely on their own data or industry benchmarks regarding the average duration of treatment for applicable services to determine appropriate duration or service quantities for authorizations, but these data would not appear to fit within the Tri-Departments’ (undefined) use of the term “independent professional medical and clinical standards.”

⇒ *ABHW requests that the Tri-Departments withdraw the proposal to apply quantitative testing to NQTL processes that are based on reasonable and appropriate clinical or business factors.*

Example 7 (Impermissible nonquantitative treatment limitation imposed following a final determination of noncompliance and direction by the Secretary).

ABHW agrees that it may violate MHPAEA for a plan to continue to apply an NQTL after the Secretary has made a final determination that the NQTL violates MHPAEA and has directed the plan to stop imposing it on MH/SUD benefits. However, as discussed above, MHPAEA does not authorize the regulators to direct a plan to stop applying an NQTL. This is new in the regulations and may exceed the statutory authority.

ABHW also requests that the Tri-Departments use this example or a different example to describe the reasoning that the Secretary would apply to determine whether or not to require the plan to stop applying the NQTL. For example, when a step therapy requirement or quantity limit is applied to a MH/SUD drug with a significant risk of severe patient harm, but the Secretary has determined that the limit, as formulated, is applied in a manner that is more restrictive than the application to M/S drugs (e.g., because the plan imposes a greater number of steps or a lower quantity limit than the identified evidence supports), it would be useful to explain the reasoning that the Secretary would follow in determining whether to require the plan to eliminate the NQTL.

Example 8 (Provider network admission standards not more restrictive and compliant with requirements for design and application of NQTLs).

ABHW agrees that it is appropriate to find that a plan complies with parity where it applies a provider contracting requirement that is identical for all contracted providers and where the plan also meets a wide range of in-operation data measures.

Example 9 (A more restrictive requirement for primary caregiver participation applied to ABA therapy).

This example asserts that a requirement for family or caregiver participation in ABA therapy deviates from independent medical or clinical standards. This is inaccurate: ABA Practice

Guidelines published by the Council of Autism Service Providers (CASP) require family/caregiver participation as an essential practice element for ABA therapy.<sup>61</sup>

This example also shows that there are no similar medical necessity criteria requiring evidence of primary caregiver participation in order to receive coverage of any medical/surgical benefits. This is also inaccurate, given that a variety of M/S benefits to treat children and adolescents typically also require family or caregiver participation through training or awareness to manage and support care, including treatment for diabetes<sup>62</sup> and asthma<sup>63</sup>.

⇒ *ABHW requests that the Tri-Departments either delete this example or revise it to better align with independent medical or clinical standards for ABA and relevant M/S services.*

Example 10 (More restrictive exclusion for experimental or investigative treatment applied to Applied Behavior Analysis (ABA) therapy).

ABHW acknowledges and agrees with the analysis that where an MH or SUD service does not meet the plan's evidentiary standard for defining experimental or investigative ("E/I") services, the plan would violate parity if it nonetheless excludes coverage for that MH or SUD service based on an insufficiently-supported determination that the service was E/I.

ABHW notes that the example evidentiary standard is reductive and arguably inappropriate and that the example would be stronger if a more realistic and more scientifically appropriate evidentiary standard were used. To base medical necessity or E/I determinations based purely on the quantity of studies available (here, "fewer than two randomized controlled trials") without accounting for the quality of the studies or the strength of their conclusions and without considering what other forms of evidence may be available departs from appropriate scientific principles for evaluating medical evidence. A more realistic and appropriate example would be based on the evaluation of the totality of the evidence, including but not limited to the quality of the applicable research and the strength of those findings.

Examples 11 & 12. ABHW has no comment on examples 11 and 12.

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<sup>61</sup> See, e.g., *Applied Behavior Analysis Treatment of Autism Spectrum Disorder: Practice Guidelines for Healthcare Funders and Managers*, The Council of Autism Service Providers, second ed., p. 11.

<sup>62</sup> The American Diabetes Association requires parental/family in the management of child and adolescent diabetes: Self-management in pediatric diabetes involves both the youth and their parents/adult caregivers. No matter how sound the medical plan is, it can only be effective if the family and/or affected individuals are able to implement it. Family involvement is a vital component of optimal diabetes management throughout childhood and adolescence. As parents/caregivers are critical to diabetes self-management in youth, diabetes care requires an approach that places the youth and their parents/caregivers at the center of the care model. The pediatric diabetes care team must be capable of evaluating the educational, behavioral, emotional, and psychosocial factors that impact the implementation of a treatment plan and must work with the youth and family to overcome barriers or redefine goals as appropriate. *Diabetes Care* 2023;46(Supplement\_1):S230–S253. <https://doi.org/10.2337/dc23-S014>

<sup>63</sup> Crucial to a successful asthma education program are a partnership between patient/carer and health care providers, with a high level of agreement regarding the goals of treatment for the child, and intensive follow-up (Evidence D). Please see *Global Initiative for Asthma, Asthma Action Plan, 2023*, p. 186

Example 13 (Standards for provider admission to a network).

This example sets forth a long list of data measures that appear to comprise the Tri-Departments' gold standard for determining comparability with regard to standards for provider admission to a network. ABHW appreciates the policy goal articulated in this example and agrees that a provider network that meets all of these standards should be determined to comply with parity.

⇒ *ABHW requests that the Tri-Departments revise this example to clarify that a plan will not be found to violate parity merely because it fails to evaluate and "pass" every identified measure and to explain which aspects of the example the Tri-Departments consider to be essential (vs. aspirational) and where the Tri-Departments intend to draw the line for determining compliance in practice.*

APPENDIX C - ABHW Proposal Establishing an Appeals Process for Determinations of MHPAEA  
Non-Compliance  
Submitted to Tri-Departments on May 17, 2023

**ESTABLISHING AN APPEALS PROCESS FOR DETERMINATIONS OF MHPAEA NON-  
COMPLIANCE**

*Statement of the Problem*

As discussed at length in previous letters from the Association for Behavioral Health and Wellness to the Tri-Departments, determinations of “comparability” and “stringency” of the design and application of non-quantitative treatment limits are often subjective, and the threshold for compliance is highly ambiguous across a wide range of key aspects of the comparative analysis requirements.

The consequences of a determination that a Plan has violated MHPAEA can be substantial. First, regulators may demand that the Plan make changes to plan design or operations as part of a corrective action plan, and these changes may entail significant costs or administrative burdens. Second, the requirement for the Plan to notify all plan members of the violation and for the plan to be identified in the annual Report to Congress has the potential to cause significant member confusion and reputational harm. Third, the publication of the Tri-Departments’ findings of non-compliance may provide the basis for private litigation that may be unwarranted. In an effort to minimize or remove these consequences, a proposed solution follows for consideration.

*Proposed Solution*

An appeals process should be established to provide plans adequate opportunity to contest findings of non-compliance that are not adequately substantiated by the MHPAEA statute and guidance.

Federal regulations governing appeals of civil monetary penalties (CMPs) for Medicare Advantage Organizations (MAOs) provide a model for health plan appeals under MHPAEA.<sup>64</sup> The CMP appeals process was first established by the Centers for Medicare and Medicaid Services (CMS) in 2007 and is familiar to many health plans and carriers and to many federal regulators. The CMP appeals process is also comparable to other appeals processes that are available to MAOs, including the appeals processes for Risk Adjustment Data Validation (RADV) audits<sup>65</sup> and for Recovery Audit Contractor (RAC) audits.<sup>66</sup>

Key components of the Medicare CMP appeals process should be available to health plans contesting a regulator determination of noncompliance with MHPAEA, including:

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<sup>64</sup> See 42 CFR Part 422, Subpart T – Appeal procedures for Civil Money Penalties.

<sup>65</sup> See 42 CFR § 422.311 – RADV audit dispute and appeal processes.

<sup>66</sup> See 42 CFR Part 422, Subpart Z—Part C Recovery Audit Contractor Appeals Process

1. **Level 1: Agency Hearing.** Before a CMP is imposed, MAOs have the right to request a hearing before a hearing officer that is designated by the agency who was not involved in the initial determination.<sup>67</sup>
  - A request for a hearing must be filed within 15 calendar days after the receipt of the notice of the sanction, and the hearing must be scheduled within 30 days after the receipt of the request for a hearing.
  - The MAO has the burden of proving by a preponderance of the evidence that the agency's determination was inconsistent with the applicable regulatory requirements.
  - The MAO has the right to present evidence and arguments to the hearing officer and to cross-examine witnesses presented by the government.
  - The hearing officer issues a written decision that is based upon the evidence of record and contains separately numbered findings of fact and conclusions of law.
  
2. **Level 2: ALJ Appeal.** At this level, MAOs have the right to request a hearing before an administrative law judge (ALJ).
  - The ALJ appeal must be filed within 30 days of receiving the notice of imposition of the CMP. The ALJ conducts a hearing and makes a decision within 90 days of receiving the request for a hearing.
  - The MAO has the right to present evidence and arguments to the ALJ and to cross-examine witnesses presented by the government.
  - The ALJ must provide a written decision that includes findings of fact and conclusions of law and must explain the basis for the decision.
  - If the ALJ decides in favor of the MAO, the CMP is canceled, and the MAO is not required to pay it. If the ALJ decides against the MAO, the MAO can proceed to the Level 3 Appeal.
  
3. **Level 3: DAB Appeal.** If the MAO is not satisfied with the ALJ's decision, it can request a review by the Departmental Appeals Board (DAB) within 30 days of receiving the ALJ's decision. The DAB reviews the case and issues a decision within 90 days.
  - The DAB is a Board established in the Office of the Secretary to provide an impartial review of disputed decisions made by the operating components of the Department.
  - The DAB may review the case based on the record from the Level 1 Appeal or may allow the parties to submit additional evidence or arguments.
  - The DAB must issue a written decision that includes findings of fact and conclusions of law and must explain the basis for the decision.

If the MAO is not satisfied with the DAB's decision, it can appeal to a federal district court within 60 days of receiving the DAB's decision. The district court reviews the case and issues a decision.

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<sup>67</sup> Full details regarding the requirements and processes for the agency hearing are set forth in 42 CFR Part 422, Subpart N—Medicare Contract Determinations and Appeals

### *Tolling of the Corrective Action Period*

The MHPAEA statute provides that if the Tri-Departments determine that a health plan is not in compliance with parity, the plan has 45 days to specify the actions that it will take to be in compliance and to submit additional comparative analyses that demonstrate compliance. This 45-day corrective action period should be tolled upon initiation of any appeal of the determination of non-compliance and should reset upon a determination by the ALJ, DAB, or court to uphold the finding of non-compliance.

APPENDIX D – ABHW Letter Requesting Additional Guidance Necessary for Parity Compliance  
Pursuant to the Consolidated Appropriations Act of 2021 (appendix of letter not attached)

Submitted to Tri-Department on July 16, 2021

Dear Ms. Turner, Mr. Khawar, Ms. Rivers, Mr. Ackerman, Mr. Knopf and Ms. Levin,

The Association for Behavioral Health and Wellness (ABHW) appreciates the Frequently Asked Questions (FAQ) document published by the tri-Departments in April 2021 to clarify the new requirements of the Consolidated Appropriations Act (CAA). While we view this additional guidance as a step forward, we write to bring attention to some gaps we identified in these FAQs.

As you know, we have always supported efforts related to mental health parity and continue to strive to ensure patients are receiving the behavioral health services they need in a manner that complies with parity requirements.

Since the passage of the Mental Health Parity and Addiction Equity Act (MHPAEA), ABHW member companies have diligently worked to drive consistent interpretation and enforcement of the law across the United States. ABHW members have:

- Improved access to behavioral health treatment, services, and providers;
- Aligned behavioral health co-payments with medical visit co-pays;
- Eliminated arbitrary treatment limitations on the number of days of coverage for a condition, as well as financial limits on annual and lifetime dollar caps;
- Adjusted prior authorization requirements for mental health and substance use disorder services so that they are comparable to those applied to medical benefits; and
- Integrated medical, pharmacy, and behavioral health benefits to increase consumer engagement and reduce overall medical costs.

Ultimately, issuers and plans are responsible for achieving compliance with mental health parity and proving the same by documenting the analyses that demonstrate compliance. When performing these compliance analyses, non-quantitative treatment limitations (NQTLs) present the most complex challenges for plans and issuers. Accordingly, we appreciate that the CAA affords parity stakeholders an opportunity for further clarifications by requiring that the Department of Labor (DOL), U.S. Department of Health and Human Services (HHS), and Department of Treasury (collectively “the tri-Departments”) promulgate regulations on NQTL analyses and compliance. Under such rulemaking efforts, we urge the tri-Departments to consider the following actions to comply with the CAA mandate and help issuers and plans better understand the regulators’ expectations with respect to NQTLs:

- Define a set of standard or “core” NQTLs that issuers and plans must analyze and document and provide a best-practice example analysis for each

- Set forth rules for examination that further describe the process outlined in the CAA by which regulators will evaluate NQTL analyses; and
- Provide guidance on a number of additional issues.

While we recognize that developing regulations and/or more guidance presents additional work for the tri-Departments, the clarity we seek will ultimately facilitate issuers and plans' compliance with NQTL requirements and will make it easier for regulators to enforce when they identify a lack of compliance. Most importantly, making it easier for all stakeholders to understand expectations for MHPAEA compliance will ensure consumers are receiving the benefits of parity.

**1. *Develop a core list of NQTLs for which documentation may be expected to be available upon request.***

It is not possible for plans and issuers to develop 5-step analyses for “all” NQTLs proactively (i.e., in advance of a specific request and available on demand) without guidance to establish which NQTLs must be analyzed and documented. The current definition of an NQTL can conceivably involve almost any aspect of plan design and operations. The final rules define “Treatment limitations” to be “limits on the scope or duration of treatment,” and define NQTLs somewhat circularly to be treatment limits that “otherwise limit the scope or duration of benefits for treatment under a plan or coverage.”<sup>68</sup> However, no guidance has been provided to define or provide any boundaries to what can constitute a “limit on the scope or duration of treatment,” and the NQTL types that regulators have focused on for enforcement have varied over time. ABHW members appreciate the clarity and specificity of FAQ 45, Q8, in which the tri-Departments identify the four specific NQTLs they intend to focus on for the near future. In the long term, ABHW reiterates its request for regulators to define a set of NQTLs on which issuers and plans are expected to have documented analyses prepared for submission within a very short timeframe upon request.<sup>69</sup> Defining such a list will facilitate plans' responsiveness to regulator requests for information relating to the core NQTLs, particularly upon short notice, and would in no way prevent regulators from requesting documentation on other non-core NQTLs should a complaint or specific compliance concern arise.

Specifically, we urge the tri-Departments to focus on the following core NQTLs:

1. Prior Authorization

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<sup>68</sup> [“Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically \(such as 50 outpatient visits per year\), and nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under a plan or coverage. \(See paragraph \(c\)\(4\)\(ii\) of this section for an illustrative list of nonquantitative treatment limitations.\) A permanent exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of this definition.”](#) 29 CFR § 2590.712(a), 45 CFR § 146.136(a), and 26 CFR § 54.9812-1(a).

<sup>69</sup> See [Implications of parity documentation requirements and examination processes and standards under CAA](#), ABHW, March 3, 2021.



2. Formulary/PDL Design
3. Concurrent Review
4. Retrospective Review
5. Outlier Management
6. Medical Necessity Criteria
7. Experimental/Investigational Determinations
8. Provider Type Exclusion
9. Network Provider Contracting
10. Process for Assessment of New Technologies

Furthermore, if the list of NQTLs were to change at any point, there must be a clearly defined process of updating the information collection request to add or delete NQTLs. To that end, ABHW proposes that the tri-Departments consult a group of experts, including issuers and plans, to determine if an NQTL should be added to the list of those on which federal regulators will focus their compliance efforts and provide stakeholders with one year's notice before a new NQTL is officially added to the list. Updates to lists for both federal and state examinations should happen concurrently and with enough time to scale effective compliance operations.

***2. Provide a clear, comprehensive example NQTL analysis that would meet the tri-Department's standards under the requirements of the CAA for each NQTL on the focused list.***

The CAA requirement to document the plan's compliance analysis mandating the utilization of the 5-step framework is new.<sup>70</sup> Moreover, the 5-step framework mandated by the CAA differs materially from existing guidance in the DOL Self Compliance Guide,<sup>71</sup> and guidance in FAQ 45 on the documentation requirements of the CAA expands substantially on the substantive compliance considerations set forth in previous guidance. No example is available of a complete NQTL analysis that the tri-Departments would consider compliant with the CAA requirements. When ABHW and its members met with the tri-Departments in March, the regulators informed us that, to-date, they had not seen what they would consider a model NQTL analysis. To be clear, because the "step-wise" approach was only a suggestion before the CAA, not all plans opted to take that suggestion. Significant ambiguity remains about the actual breadth and depth of details and supporting documentation required for each component of the CAA's five-step analyses. Model NQTL analyses would help clarify expectations, promote uniformity, and ultimately improve parity compliance. Accordingly, for each NQTL on the focused list, we believe the tri-Departments should also provide at least one complete example of a compliant analysis.

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<sup>70</sup> See attached Appendix A: Timeline of Federal Guidance Regarding a Step-Wise Approach to MHPAEA Compliance.

<sup>71</sup> See [Implications of parity documentation requirements and examination processes and standards under CAA](#), ABHW, March 3, 2021, p. 4-5.

**3. Define a standard by which NQTL analyses are evaluated and a process by which examinations are pursued.**

In FAQ 45, Q2 and Q4, the tri-Departments address the information plans and issuers must make available to regulators and the types of documents issuers and plans should be prepared to submit in support of a given NQTL analysis. In practice, however, ABHW's members have found that the back and forth with the regulators during examinations can be confusing due to the lack of a defined process for NQTL documentation requests. We request that guidance be issued by the tri-Departments to clarify the following points:

- Evaluation of a plan's parity compliance with respect to an NQTL should be based on the 5-step analysis completed by the plan as outlined in the CAA. Reviewers should request additional documents only if there are questions raised by the content within the 5-step analysis or as necessary to validate information therein.
- The Self-Compliance Tool states that "[operations measure] outcomes are NOT determinative of compliance," and instructs reviewers: "Do not focus solely on results. Look at the underlying processes and strategies used in applying NQTLs."<sup>72</sup> ABHW appreciates the clarity of this guidance. Nonetheless, it is the experience of some ABHW members that some regulators do effectively apply operations measures data as determinative of compliance and do not base their ultimate findings or conclusions on the 5-step analysis. ABHW requests a specific FAQ or regulation to more clearly explain the standard for compliance; a standard that reflects the appropriate weight of results versus underlying processes and can be used consistently by regulators. Specifically, if an NQTL "operations measure" produces a significant quantitative disparity between mental health/substance use disorders (MH/SUD) and medical/surgical (M/S) data, then the tri-Departments should consider whether the plan or issuer has provided a reasonable explanation for its determination that the underlying factors, sources, or evidentiary standards were in fact applied in a way that was comparable and no more stringent, as written and in operation, notwithstanding the disparity in the quantitative metric. If the examiner needs additional information to understand and/or validate the plan or issuer's explanation of how the quantitative difference in the operations measure data arose from processes, strategies, evidentiary standards, and/or other factors that were comparable and no more stringent, then the tri-Departments should request that the issuer or plan provide the relevant information (e.g. narrative discussion, supporting policies and procedures, additional operations data, clinical studies, scientific evidence, peer reviewed literature, or comparable information).
- If an operations measure reveals a quantitative disparity between M/S and MH/SUD data and there is a difference in the processes, strategies, evidentiary standards, or other factors

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<sup>72</sup> Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act (MHPAEA), 2020, p. 27, 28.

that an issuer or plan applies to MH/SUD benefits compared to M/S, as written or in operation, that does not appear to be inherently discriminatory or more stringent, regulators should consider whether the issuer or plan has implemented a corrective action plan or other measures to mitigate the impact of the difference and ensure comparability in access under the NQTL. This approach could be modeled on the weight that auditors in the HHS Office of Civil Rights attribute to well-documented risk analyses by covered entities under HIPAA.

- For any NQTL not on the core list that is being investigated due to specific complaints or evidence of non-compliance, we request that the tri-Departments clearly and specifically identify the compliance concern and provide at least a 60-day timeframe to enable issuers and plans to develop the required 5-step analysis and compile supporting documentation.

ABHW members strive to provide the tri-Departments with the information that they need in order to ensure proper compliance with MHPAEA. To help ensure that issuers or plans are producing accurate and relevant information, we request that the tri-Departments clearly define and narrow the scope of documents to the key materials relevant to assessing MHPAEA compliance. A clearly defined rubric for evaluation of issuers and plans' compliance analyses and a foreseeable process for follow-up questions will not only help issuers or plans develop their analyses in a systematic manner, it will also help regulators in conducting the NQTL analyses and, where appropriate, identifying MHPAEA violations. Ultimately, better defined guidance and enforcement will move us all closer to the goals of the parity legislation.

#### ***4. Proactively promote uniformity between state and federal requirements.***

It is also critical to note that some state parity policies and compliance approaches differ significantly from federal policies and enforcement even when based upon federal parity standards, creating confusion for issuers and plans in understanding how to achieve and demonstrate compliance at the state level even if federal requirements are clarified. In fact, there are discrepancies on how NQTLs are interpreted not only between a federal and state level and across states, but *within states as well*.<sup>73</sup> During our March 17<sup>th</sup> meeting with the tri-Departments, the regulators agreed that uniformity with the states would be beneficial for all involved parties. Closer alignment at the state level is necessary to allow recent and upcoming federal changes to have meaningful impact. As such, we urge the tri-Departments to proactively coordinate with state regulators to help ease the issues surrounding parity compliance.

#### ***5. Additional clarifications.***

We recognize that it will undoubtedly take time and require the dedication of staff resources for the tri-Departments to define an NQTL examination process, articulate a list of NQTLs, and

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<sup>73</sup> Medicaid and CHIP Payment and Access Commission, *Implementation of the Mental Health Parity and Addiction Equity Act in Medicaid and CHIP*, p. 13, January 29, 2021, slide 14: "Some interviewees noted that non-quantitative treatment limitations were assessed and interpreted differently both within and across states."

<https://www.macpac.gov/wp-content/uploads/2021/01/Implementation-of-the-Mental-Health-Parity-and-Addiction-Equity-Act-in-Medicaid-and-CHIP.pdf>, last visited May 21, 2021.

provide best practice analysis examples. The efforts to implement the CAA, however, also provide an opportunity for the tri-Departments to clarify a number of other more narrow but outstanding questions in the immediate future. In FAQ7, the tri-Departments state that they will work with stakeholders to determine what other guidance may be needed to ensure compliance. In response, we offer the following suggestions for areas of additional guidance.

- **Definition of “Benefits”:** Members have seen some state regulators adopt the position that *any* service rendered in connection with a MH/SUD treatment must be considered as a MH/SUD benefit, irrespective of the nature of the service. The implication of this position is two-fold. First, it creates two separate cost-sharing requirements applied to the same service received from the same provider. Second, a plan or issuer would have to apply the cost-sharing requirement that passes parity quantitative testing to all claims submitted by a provider to ensure that no claims submitted with a MH/SUD diagnosis (whether primary, secondary, or tertiary on the claim) would be subject to a cost-sharing requirement that did not pass testing. Ultimately, this may negatively impact enrollees because they would either be subject to two different cost-sharing requirements for the same service by the same provider (creating disparate treatment) or plans and issuers would have to change plan designs in a manner that adversely impacts enrollees, even those without MH/SUD conditions. Therefore, we propose that the tri-Departments adopt the Centers for Medicare & Medicaid Services’ position on long term services and supports which recognized that some services and treatments can be both medical/surgical benefits and mental health and substance use disorder benefits but that plans must be able to design benefits prospectively. The CMS guidance allows plans to define benefits that can be used to treat either medical or behavioral conditions by means of a reasonable method such as looking at the services and treatment spend and determining whether the services is predominantly used for a medical diagnosis or a mental health/substance use disorder diagnosis and defining it accordingly.
- **Basis for Analysis:** We propose that the tri-Departments clarify that the NQTL analysis is based on factors and evidentiary standards compared by classification and not by individual service-by-service crosswalks.
- **Network Adequacy:** Since many factors that contribute to the nationwide shortage of behavioral health providers are beyond the health plan’s control, we propose that the tri-Departments expressly clarify that while plans may use network adequacy metrics to help assess “provider network admissions standards, including reimbursement rates,” federal regulators will not require plans to produce NQTL compliance analyses for network adequacy as an independent limit applied to a beneficiary or member’s benefits.
- **Classifications and NQTL Comparisons.** We request the tri-Departments acknowledge that a given NQTL analysis cannot assess and compare an NQTL across or between classifications. For example, a concurrent review analysis cannot compare inpatient, in-

network concurrent review and an inpatient, out-of-network concurrent review. While this may be a basic tenet of parity, some of our members have experienced reviews in which regulators made comparison across classifications. Any analysis that purports to compare an NQTL across classifications is invalid and inconsistent with MHPAEA, which expressly requires analysis WITHIN a classification. Metrics for an in-operation analysis of an NQTL as an element of the NQTL analysis also cannot be compared across classifications.

- **“Green-flags” Document:** We request from the tri-Departments a green-flags document to give issuers and plans insight on what compliance entails and to educate consumers, providers, and states on what to expect from mental health parity requirements.

## 6. *Conclusion.*

ABHW believes that consumers have the right to non-discriminatory mental health and substance use disorder coverage. We hope to work closely with the tri-Departments to identify gaps and develop clarity on the issues discussed within this letter. We would appreciate a meeting with you to discuss this content and address any questions you may have. We will reach out under separate cover to offer scheduling information. Please do not hesitate to contact Deepti Loharikar at [loharikar@abhw.org](mailto:loharikar@abhw.org) or 202-505-1834 with any concerns in the meantime. We appreciate your time and efforts on this important issue and look forward to continuing to be a strong partner as we all move forward.

Sincerely,



Pamela Greenberg, MPP  
President and CEO