GROOM LAW GROUP

October 17, 2023

Submitted via http://www.regulations.gov

The Honorable Janet Yellen
Secretary of the Treasury
1500 Pennsylvania Avenue, NW
Washington, D.C. 20220

The Honorable Xavier Becerra
Secretary of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

The Honorable Julie Su
Acting Secretary of Labor
200 Constitution Avenue, NW
Washington, D.C. 20210

RE: Requirements Related to the Mental Health Parity and Addiction Equity Act ("MHPAEA")

Dear Secretaries Su, Becerra, and Yellen:

We write on behalf of the undersigned Coalition to provide comments on the Proposed Rule, "Requirements Related to the Mental Health Parity and Addiction Equity Act," as published in the Federal Register by the Departments of Labor ("DOL"), Health and Human Services ("HHS"), and the Treasury (collectively, "Tri-Agencies") on August 3, 2023 (88 Fed. Reg. 51552).

The Coalition is a unique and broad alliance of stakeholders. Through its membership, the Coalition provides mental health and substance use disorder ("MH/SUD") benefits to the *vast majority of Americans* covered by private health insurance plans, both self-insured and insured. As such, Coalition members represent the largest community of entities subject to MHPAEA who collectively are responsible for providing and paying for vital, comprehensive, and high-quality MH/SUD services for millions of American families.

It is essential to emphasize that Coalition members understand the value and importance of MH/SUD services and are deeply committed to providing coverage for these important benefits. Within the past several years, Coalition members have:

- prioritized eliminating barriers to MH/SUD benefits that are within their control, including removing limitations and exclusions on MH/SUD services, which are no longer serving the members' best interest;
- reduced, and in some cases eliminated, cost sharing on MH/SUD services;
- offered expanded telehealth for MH/SUD services;
- expanded MH/SUD provider networks;

- increased MH/SUD provider reimbursement rates;
- reduced MH/SUD services subject to prior authorization; and
- expanded voluntary care management programs that provide education and support to enrollees with MH/SUD conditions.

Coalition members have devoted extensive, ongoing resources to ensure that their plans and coverage meet MHPAEA's requirements. We have done so even while factors beyond our control, such as the nationwide shortage of MH/SUD providers, have created barriers to access to these critical services. These efforts demonstrate our commitment to meeting the MHPAEA's goals.

The Coalition members have reviewed the Tri-Agencies' proposals and appreciate and share the goal of improving access and breaking down barriers to MH/SUD services. However, Coalition members have significant concerns that some of the proposals could inadvertently reduce the quality and efficacy of the MH/SUD care received by patients by restricting health plans' ability to protect patients through plan standards that ensure high-quality providers and safe, effective treatment for patients. For example, the application of the substantially all/predominant test to nonquantitative treatment limitations ("NQTLs") could eliminate the ability of plans and issuers to apply medical management tools used to ensure that the services, prescription drugs, and devices patients receive are supported by current, credible medical evidence and are administered by a qualified clinician with the appropriate expertise and training. If these tools are restricted, patients will pay more for treatment that varies widely in quality and efficacy. Similarly, we are also concerned that the proposed network composition NQTL standards would force plans to accept lesser credentialed providers into their networks, which would compromise outcomes and patient safety.

This comment letter provides the consensus views on the issues of most importance to the Coalition members. Many of the individual members of the Coalition are submitting separate comments that further explain their views and address other issues not included in this letter. In addition, this comment letter is not addressing Technical Release 2023-01P, but some individual members of the Coalition are submitting separate comments that address the Technical Release. Finally, there are some aspects of the Proposed Rule that we think would benefit from continued engagement with the Tri-agencies (for example, development of definitions and a defined set of outcomes data). We encourage the Tri-Agencies to consult with industry experts through the creation of a working group of key industry stakeholders or issuance of a Request for Information. The Coalition believes that an ongoing dialogue with the Tri-Agencies will be the most effective way to provide feedback as policies are further developed.

As we explain in more detail in the enclosure, the Coalition's comments focus on the following provisions in the Proposed Rule:

- **The list of NQTLs:** The Tri-Agencies propose a non-exhaustive list of NQTLs that would be subject to the Proposed Rule's new requirements but indicate there could be other NQTLs as well, not listed. If finalized, due to the open-ended definition of NQTL and the lack of a clear list of NQTLs, the Proposed Rule could require that plans and

issuers have dozens of detailed NQTL comparative analyses ready to provide to the Tri-Agencies, upon request, or face findings of violating MHPAEA and the Consolidated Appropriations Act, 2021 ("CAA"). The Coalition recommends the Tri-Agencies codify a defined list of NQTLs to support plans' and issuers' compliance efforts. The Coalition supports a provision that makes clear that the Tri-Agencies can request an NQTL that is not defined as a NQTL in the MHPAEA regulations, but will provide additional time for a plan or issuer to provide the comparative analysis. Furthermore, for any NQTLs not listed in the MHPAEA regulations as a defined NQTL, the regulation could state that the Tri-Agencies would work with the plan or issuer to determine whether a certain plan or issuer activity is considered an NQTL before requiring a comparative analysis. These recommendations would avoid confusion about what is or is not an NQTL, promote nationally standardized MHPAEA compliance, and prevent plans and issuers from creating NQTL analyses for plan provisions or processes the Tri-Agencies would *not* view as an NQTL.

- **The "no more restrictive" requirement and accompanying tests for NQTLs applied to MH/SUD benefits:** The Tri-Agencies propose to require that the NQTLs applied to MH/SUD benefits pass a series of tests, including a test to demonstrate that the NQTL is applied to at least two-thirds of the M/S benefits in the same classification. This new requirement and accompanying tests go beyond what is required by the CAA, which focuses on improved NQTL documentation. We are concerned that this requirement could effectively eliminate common, reasonable medical management programs that are essential to improve patient outcomes, ensure patient safety, and make care and coverage more affordable. Coalition members recommend that this provision be removed from the regulation and that the Tri-Agencies instead focus on providing clear, workable guidance implementing the NQTL comparative analyses provisions, as required by the CAA.

- **Mandated outcomes data and "material" differences:** The Tri-Agencies propose to require that plans and issuers collect and evaluate outcomes data in a manner reasonably designed to assess the impact of an NQTL on access to MH/SUD benefits. If the relevant data shows "material" differences in access to MH/SUD benefits when compared to M/S benefits, that would be a "strong indicator" of noncompliance, and the Tri-Agencies propose to require plans and issuers to take reasonable action to address that difference (and document the steps taken). In addition, for the network composition NQTL, the Tri-Agencies have proposed that a plan or issuer is per se noncompliant if the data shows a material difference. The Coalition has several concerns with this provision:

    - The Proposed Rule presumes that material differences in outcomes data reflect compliance violations but does not presume compliance if these differences are not present. This "one way" use of outcomes data is inconsistent with the Tri-Agencies' reliance on this information to determine compliance. To address this, we recommend that compliance be presumed if there is a lack of material differences in outcomes data.

- The Coalition also recommends that the Tri-Agencies codify an exhaustive list of outcomes data required to be evaluated and define "material."

- Finally, the Coalition recommends that the Tri-Agencies not finalize the rule that a material difference constitutes a per se violation for the network composition NQTL. The Coalition is concerned that this proposed network composition NQTL standard would force plans to accept lesser credentialed providers into their networks, which would compromise outcomes and patient safety. In addition, there are many reasons why a plan or issuer may not meet network standards; many of which are outside the control of the plan or issuer.

- **Exceptions to components of the NQTL Test:** The Tri-Agencies have proposed two exceptions from certain elements of the NQTL test for (1) independent professional medical or clinical standards, and (2) standards to detect or prevent and prove fraud, waste, and abuse. The Coalition strongly supports the retention of these exceptions in the final regulations. We also believe more specificity is needed, including in describing which independent and clinical standards are acceptable. This would help promote consistent enforcement and support the Tri-Agencies' efforts to ensure compliance with the parity requirements.

- **Fiduciary certification:** The DOL would require ERISA plans to include a certification by one or more named fiduciaries who reviewed the comparative analysis, to indicate in the analysis whether they found it to be compliant with the Proposed Rule's requirements. The proposed regulations, if finalized, will make the NQTL analysis so complicated that it will be difficult, if not impossible, for plan sponsors to understand if compliance with the NQTL analysis has been met, let alone certify they are compliant. In addition, under ERISA, fiduciaries are expected to hire and rely on experts in areas where additional specialized expertise is required. However, this proposal undercuts that fundamental principal by requiring plan fiduciaries themselves to have the requisite MHPAEA NQTL expertise and make certifications on NQTL compliance. The Coalition asks the DOL to not finalize the fiduciary certification requirement. Congress did not include this requirement in the CAA. Additionally, the Coalition notes this requirement diverges from disclosure requirements under other relevant statutory schemes.

- **Meaningful benefits:** The Tri-Agencies propose to mandate plans and issuers to provide "meaningful benefits" for the treatment of a particular MH/SUD condition in each classification (if the condition is covered in any classification), which would be determined by comparing this coverage to the benefits offered for M/S conditions in the same classification. If this requirement is adopted, the Coalition urges the Tri-Agencies to recognize that a plan or issuer has satisfied the standard if the plan or issuer provides at least one primary treatment for the MH/SUD condition or disorder in a classification, based on clinical standards.

- **The need for additional procedural review:** The Tri-Agencies do not address what procedural protections plans and issuers are provided prior to receipt of a final

determination of noncompliance, as related to the NQTL comparative analysis. Due to the importance of compliance and the severe consequences for noncompliance, the Coalition recommends that plans and issuers be provided an additional level of review to ensure they receive fair process. These reviews should be coordinated between DOL and HHS, with uniform information shared with state regulators, in order to ensure consistency in approach.

- **The applicability date:** The Coalition advocates for a later applicability date for the provisions in the Final Rule. Specifically, the Coalition recommends that the Tri-Agencies provide for at least a one-year delay after the effective date of the Final Rule. Due to the complexity of the new rules, we recommend that the Tri-Agencies apply a reasonable, good faith compliance standard for the first year after the applicability date in the Final Rule. In addition, if the "substantially all/predominant" test is finalized, the Coalition recommends that this rule be effective no sooner than two years after the effective date of the Final Rule. Due to the lengthy rulemaking process, the Final Rule would likely be published in 2024. These recommendations would allow plans and issuers adequate time to implement the major expansions of MHPAEA and CAA requirements included in the Proposed Rule.

The Coalition has carefully reviewed the Proposed Rule and prioritized its comments to address the proposals that cause the greatest concern. We also provide constructive, detailed comments on several other provisions to support compliance and implementation of MHPAEA and to make the rules better and more workable. There are a few provisions for which the Coalition is asking the Tri-Agencies to not finalize the proposal primarily because of the unintended consequences to enrollees. A number of our key concerns relate to provisions that are unrelated to implementing the NQTL standards and processes as codified by the CAA. As the Tri-Agencies are aware, the CAA amends MHPAEA to create specific new documentation standards for NQTLs. In adopting these provisions, Congress codified the NQTL standards and the process for demonstrating NQTL parity compliance reflected in existing regulations. For example, the CAA does not include the substantially all/predominant test or the fiduciary certification. Coalition members requested, and support, the issuance of additional regulatory guidance implementing the CAA documentation standards. Clear guidance implementing the existing NQTL rules will allow plans and issuers to more readily demonstrate compliance with MHPAEA. But we respectfully suggest that certain new requirements unrelated to CAA implementation, as noted in our comments, be removed and that the Proposed Rule keep a tight focus on clarifying the NQTL requirement codified in the CAA.

* * *

We appreciate your consideration of our comments and look forward to continuing to work collaboratively with the Tri-Agencies to support individuals' access to MH/SUD services consistent with the parity requirements. Please do not hesitate to reach out to Lisa Campbell (lcampbell@groom.com) or Michael Kreps (mkreps@groom.com) with questions at any time.

Sincerely,

American Benefits Council
Anthem, Inc.
Association for Behavioral Health and Wellness
AHIP
Blue Cross Blue Shield Association
Business Group on Health
College and University Professional Association for Human Resources
National Coordinating Committee for Multiemployer Plans
The ERISA Industry Committee
The Council of Insurance Agents & Brokers
U.S. Chamber of Commerce

Enclosure

Enclosure

Coalition – Detailed Comments on MHPAEA Proposed Rule

I. List of NQTLs

The Tri-Agencies have proposed to alter the definition of a "treatment limitation" to include a list of examples of NQTLs and have also indicated that there are additional NQTLs not specified in the regulation. The Tri-Agencies state that even if an NQTL is not included on the list, a plan or issuer still must satisfy the standards and framework outlined in the Proposed Rule. Examples of additional NQTLs not listed in the regulation (but listed in the preamble) include: concurrent care review; billing restrictions, such as a requirement for a licensed provider to bill through or under the supervision of another type of licensed provider; retrospective review; treatment plan requirements; refusal to cover treatment until completion of a comprehensive assessment by specific providers; outlier management; and limitations based on expectation of improvement, likelihood of progress, or demonstration of progress.

The Coalition recommends that the Tri-Agencies provide a defined list of NQTLs that plans and issuers would be required to provide an NQTL analysis for upon an initial request from the relevant Secretary for a comparative analysis.

The Coalition is concerned that the Tri-Agencies' proposed, open-ended (and, therefore, overly broad) definition of "treatment limitation" will increase uncertainty in determining which common plan practices could constitute an NQTL. Under the Proposed Rule, dozens of common plan operations could potentially be deemed an NQTL, necessitating additional comparative analyses. Due to the requirement that plans and issuers promptly respond to the DOL's or HHS' request for an NQTL comparative analysis or risk publication in the CAA's mandated Congressional Report, plans and issuers would be required to maintain dozens of detailed NQTLs in order to maintain compliance in the event DOL or HHS might possibly consider a plan operation to be an NQTL.

The Tri-Agencies should not leave the list of NQTLs indefinite. Stakeholders need to know what is subject to the comparative analysis requirement as an NQTL by DOL and HHS, and what tools are simply considered a managed care activity. For example, some case management programs are voluntary and provide additional benefits to members, but in some cases the DOL has determined they are NQTLs. Creating a list would also promote widespread MHPAEA compliance, which is a mutual goal of the Tri-Agencies and the Coalition. Lack of specificity could quickly lead to regional enforcement distinctions (which we have already been seeing in CAA MHPAEA enforcement), generating significant compliance challenges for plans and issuers who would be unable to anticipate when a plan provision could be construed as an NQTL.

The Coalition proposes that the Tri-Agencies use the list of NQTLs in the regulation (including the preamble) for which plans and issuers should be prepared to provide a comparative analysis upon request. Under our proposal, the Tri-Agencies could update this list

over time if they identify new NQTLs. The Coalition does not believe that this would limit DOL or HHS from requesting an analysis for an NQTL that is not on the list. We only propose that the timeframe to supply an analysis for an NQTL not included on this list would be extended to permit plans and issuers sufficient time to conduct an analysis when requested to do so. This process would allow DOL or HHS to request an NQTL analysis for any provision of concern and give a plan or issuer reasonable time to develop an NQTL analysis if the plan or issuer in good faith did not believe a plan provision was an NQTL. Furthermore, for any NQTLs not listed in the MHPAEA regulations as an NQTL, the provision could state that the Tri-Agencies would work with the plan or issuer to determine whether a certain plan activity is considered an NQTL, and if the Tri-Agencies determine it is an NQTL, the timeframe to supply an analysis would be extended to permit plans and issuers sufficient time to conduct an analysis when requested to do so.

II. The "No More Restrictive" Requirement and Accompanying Tests for NQTLs Applied to MH/SUD Benefits

The Tri-Agencies propose that plans and issuers must demonstrate that NQTLs applied to MH/SUD benefits are applied to at least two-thirds of the M/S benefits in the same classification. This proposal would require plans and issuers to determine the following information: (1) the share of plan payments for M/S benefits covered by an NQTL in a classification; (2) whether the NQTL applies to at least two-thirds of the M/S benefits in this classification; (3) the predominant variation of the NQTL applied to M/S benefits in this classification; and (4) whether the NQTL, as applied to the MH/SUD benefits in this classification, is more restrictive than the predominant variation of the NQTL that is applied to at least two-thirds of the M/S benefits.

A. *In the Final Rule, the Coalition recommends the Tri-Agencies not finalize the application of the "substantially all/predominant" test to NQTLs. The Coalition urges the Tri-Agencies to alternatively focus on providing clear, workable guidance to implement the NQTL requirements under the CAA.*

The Tri-Agencies' proposal constitutes a substantial revision of the NQTL rule and would, for the first time, require plans and issuers to apply the substantially all/predominant test to NQTLs. This proposal is entirely unexpected given that the Tri-Agencies are not mandated by Congress to apply this test to NQTLs. The CAA, which codified the Tri-Agencies' NQTL analysis "process-based" test, does not mandate application of this substantially all/predominant test to NQTLs in its requirement for the Tri-Agencies to issue NQTL-related guidance.[1] *See, e.g.,* IRC §§ 9812(a)(6), (7), (8); ERISA §§ 712)(6), (7), (8); PHSA §§ 2726(6), (7), (8).

[1] First, the CAA directs the Tri-Agencies to issue guidance to plans and issuers to assist plans and issuers in satisfying the requirements of the CAA, *see* CAA section 203, (a)(2) [amending ERISA § 712(a) to add new paragraph (7)], (a)(3) [amending Internal Revenue Code § 9812(a) to add new paragraph (7)], and section 203(b); Second, the CAA directs the Tri-Agencies to issue a Compliance Program Guidance Document, *see* CAA section 203, (a)(1) [amending PHSA § 2726(a) to add (8)(C)(i)], (a)(2) [amending ERISA § 712(a) to add (6)(A) – (D) and (8)(C)(i)], (a)(3) [amending Internal Revenue Code § 9812(a) to add (6)(A) –(D) and (8)(C)(i)], and section 203(b); and Third, the CAA directs the Tri-Agencies to issue finalized versions of any draft or interim guidance and regulations relating to mental health parity, *see* CAA section 203, (a)(1) [amending PHSA § 2726(a) to add

Moreover, the effect of the substantially all/predominant test in certain instances would prohibit common medical management techniques, even when offered in parity under the current NQTL rule, which would undermine effective, safe patient care. Medical management tools are not applied to restrict *access* to care. Rather these tools are used to confirm that care is medically necessary and covered under the terms of the plan. Some uses of medical management include:

- providing for the safety of participants and beneficiaries;
- confirming that services are medically necessary;
- preventing unexpected out-of-pocket costs for consumers due to a denial of payment for non-covered or not medically necessary services;
- confirming the level of care is appropriate; and
- deterring fraud, waste, and abuse.

As noted above, the current NQTL rule is all that is required by the CAA; the CAA specifically preserves the NQTL process-based test, recognizing that NQTLs are non-quantitative by definition. Medical management techniques (e.g., prior authorization), which Congress specifically and intentionally allowed for when enacting MHPAEA, are crucial for plans and issuers to improve Americans' health outcomes, reduce waste, and ensure that patients are provided medically necessary care. *See* Code § 9812(b)(2); ERISA § 712(b)(2); PHSA § 2726(b)(2) ("Nothing in this section shall be construed . . . in the case of a group health plan (or health insurance coverage offered in connection with such a plan) that provides mental health or substance use disorder benefits, as affecting the terms and conditions of the plan or coverage relating to such benefits under the plan or coverage, except as provided in subsection (a).").

For example, most plans and issuers do not apply prior authorization on two-thirds of benefits in the outpatient M/S classification. There are hundreds of outpatient M/S services, and far fewer outpatient MH/SUD services. Because the denominator for M/S outpatient services is so large, plans and issuers do not apply prior authorization on two-thirds of benefits in the outpatient M/S classification. Therefore, under the Proposed Rule, it is unlikely plans and issuers would be permitted to apply prior authorization on *any* MH/SUD benefits in the outpatient MH/SUD classification – even if application of the utilization management tool is the result of comparable application of an identical process and factors for both M/S and MH/SUD services. Prohibiting utilization management tools could have particularly negative impacts on patients receiving MH/SUD treatment because these tools are used to ensure that a service will be covered under the plan and that patients receive the right care at the right time. These approaches also help health plans make health coverage more available by making coverage more affordable, which remains a critical national goal.

---

(8)(C)(ii)], (a)(2) [amending ERISA § 712(a) to add (8)(C)(ii)], (a)(3) [amending Internal Revenue Code § 9812(a) to add (8)(C)(ii)], and section 203(b).

Similarly, most plans and issuers do not apply concurrent review on two-thirds of benefits in the inpatient M/S classification, due in part to the bundled payment structure for M/S inpatient care. For example, many M/S inpatient services are reimbursed one payment amount regardless of the length of stay (e.g., often times based on CMS' diagnosis-related group ("DRG") payment methodology). These M/S inpatient services are able to be reimbursed this way because such treatment includes a standard set of services and a standard length of stay without signification variation. However, this is generally not the case for inpatient MH/SUD treatment, as the treatment and length of stay can vary considerably based on the provider and the individual patient and his or her response to treatment. Concurrent review allows plans and issuers to periodically review the level of care to confirm the services are effective for the patient and the level of care is medically necessary and appropriate. The Proposed Rule would likely prohibit plans and issuers from applying concurrent review on benefits in the inpatient MH/SUD classification.

Lastly, under a similar analysis, plans and issuers could effectively be prevented from applying prior authorization and step therapy provisions for prescription drug benefits available via a plan's formulary. This is because there are hundreds of M/S prescription drugs, and far fewer MH/SUD prescription drugs. Plans apply prior authorization and step therapy for important safety and affordability reasons. The application of the substantially all/predominant test to prescription drug management NQTLs will, therefore, likely have a negative impact on the safety of participants and beneficiaries as it relates to prescription drugs, as well as the Administration's efforts to reign in the cost of healthcare and rising premiums for consumers.

For all these reasons, finalization of this requirement could lead to unintended and detrimental consequences. In addition, in order to comply and still maintain reasonable medical management on some MH/SUD services, plans and issuers could be compelled to subject *more* M/S services to NQTLs to both satisfy the parity standard and ensure their beneficiaries and participants continue to receive appropriate and medically necessary MH/SUD services. That could also result in coverage becoming less affordable for participants and beneficiaries. Such a result does not further the Tri-Agencies' and plans' and issuers' shared goal of expanding Americans' access to healthcare benefits by making care more affordable to lower- and middle-class individuals and their employers. To avoid these consequences, the Coalition recommends the Tri-Agencies not finalize the application of the substantially all/predominant test to NQTLs. We advocate for the Tri-Agencies to instead provide clear and workable guidance to plans and issuers to better match the Tri-Agencies' expectations for NQTL compliance, as provided for under the CAA.

B. ***If the Tri-Agencies retain the proposal, the Coalition recommends that the Tri-Agencies clarify how the "predominant" rule would work in practice, by defining the term "variation" of an NQTL in all of the different NQTLs.***

We recommend the Tri-Agencies provide additional clarification for key terms to enable plans and issuers to appropriately apply the test to NQTLs, should the Final Rule include this requirement. The Proposed Rule defines "predominant" as the most common or frequent

variation of an NQTL. However, the Tri-Agencies do not further define what they intend by the term "variation."

For example, we do not think the Tri-Agencies should consider a per diem versus a diagnosis-related group ("DRG") payment methodology a "variation" of the provider reimbursement NQTL. As noted above, a per diem type of reimbursement is generally not the most common type of reimbursement for M/S services in the inpatient classification and, therefore, plans and issuers would no longer be permitted to reimburse MH/SUD services on a per diem basis. Similarly, plans and issuers do not have sufficient guidance from the Tri-Agencies to determine whether negotiating payment rates above the base fee schedule versus simply offering the base fee schedule constitutes a "variation" of the provider reimbursement NQTL. It is unclear whether some of these practices represent a single NQTL with multiple variations, or several single NQTLs without any variations.

III. Outcomes Data and "Material" Difference

The Tri-Agencies propose that when plans and issuers design and apply an NQTL, they must collect and evaluate relevant data in a manner reasonably designed to evaluate the impact of the NQTL on access to MH/SUD benefits and M/S benefits. Additionally, plans and issuers would be obligated to consider the impact as part of the plan's or issuer's analysis of whether such NQTL is compliant, in operation. Under the Proposed Rule, relevant data includes both the number and percentage of claims denials as well as other data, relevant to the NQTL, that is required by State law or private accreditation standards. For network composition NQTLs, the proposal provides that such data would include: in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (including as compared to billed charges).

Under the Proposed Rule, if the relevant data evaluated reveals "material differences" in access to MH/SUD benefits as compared to M/S benefits, the differences would be considered a strong indicator that the plan or issuer is not in compliance. In such instances, the plan or issuer (1) must take reasonable action to address the material differences in access as necessary to ensure compliance, in operation; and (2) must document the action that has been or is being taken by the plan or issuer to mitigate any material differences in access to MH/SUD benefits as compared to M/S benefits.

The Proposed Rule would create a special rule for NQTLs related to network composition. Specifically, when designing and applying one or more NQTLs related to network composition, a plan or issuer will be *out of compliance* if the relevant data shows material differences in access to in-network MH/SUD disorder benefits as compared to in-network M/S benefits in a classification.

A. *The Coalition recommends that the Tri-Agencies provide an exhaustive list of outcomes data that plans and issuers are required to collect and analyze for a comparative analysis.*

The Coalition supports a uniform set of outcomes data for the NQTLs so that plans and issuers understand what data must be collected and analyzed for NQTL comparative analyses. The Coalition is concerned that requiring plans and issuers to collect and evaluate "any other relevant data" and leaving the required outcomes data undefined would require plans and issuers to maintain all possible outcomes data. To that end, the Coalition recommends adopting a discrete list of outcomes data, from an exhaustive list of all NQTLs, that plans and issuers are required to collect and evaluate. Similar to how the Coalition envisions the list of NQTLs, if the Tri-Agencies want to request additional data through the course of an NQTL comparative analysis review, the Tri-Agencies should provide additional time for an entity to respond to the request. We include one option of a list of outcomes data for NQTLs in the table below.

As noted in the chart below, the Coalition would recommend that any definition of "relevant data" for network composition standards *not* include comparing provider reimbursement rates to billed charges. Billed charges are an arbitrary amount determined by an individual provider and not necessarily tied to any independent standard or benchmark of what is a reasonable charge for a particular service. Rather, the Coalition would recommend a comparison to Medicare reimbursement rates. Medicare rates (unlike billed charges) are an unbiased, third-party measurement beyond the control of plans and issuers, and, as such, should be viewed as a reliable measurement source by the Tri-Agencies.

If the Tri-Agencies require comparison of reimbursement rates between MH/SUD and M/S providers (as opposed to a comparison of reimbursed rates and billed charges, for instance), those comparisons should account for the differences in education and licensure requirements and the expenses necessary to operate a practice. Operating costs, for instance, for a MH/SUD inpatient facility and a M/S inpatient facility vary widely, as M/S facilities often have higher staffing requirements and much more expensive equipment, among other factors. Also, as noted above, the proposed comparability standard for provider reimbursement would further complicate the evaluation of bundled payments or other innovative, non-fee-for-service payment arrangements.

Exhaustive List of Required Outcomes Data
Prior Authorization
• Number of MH/SUD claims denials (separated by outpatient and inpatient) • Number of M/S claims denials (separated by outpatient and inpatient) • Number of MH/SUD claims (separated by outpatient and inpatient) • Number of M/S claims (separated by outpatient and inpatient) • Percentage of MH/SUD claims denials (separated by outpatient and inpatient) • Percentage of M/S claims denials (separated by outpatient and inpatient)
Concurrent Review
• Number of MH/SUD claims denials (separated by outpatient and inpatient) • Number of M/S claims denials (separated by outpatient and inpatient) • Number of MH/SUD claims (separated by outpatient and inpatient)

- Number of M/S claims (separated by outpatient and inpatient)
- Percentage of MH/SUD claims denials (separated by outpatient and inpatient)
- Percentage of M/S claims denials (separated by outpatient and inpatient)

Fail First/Step Therapy

- Number of MH/SUD claims denials (separated by outpatient and inpatient)
- Number of M/S claims denials (separated by outpatient and inpatient)
- Number of MH/SUD claims (separated by outpatient and inpatient)
- Number of M/S claims (separated by outpatient and inpatient)
- Percentage of MH/SUD claims denials (separated by outpatient and inpatient)
- Percentage of M/S claims denials (separated by outpatient and inpatient)

Prescription Drugs – Prior Authorization[2]

- Number of MH/SUD drugs subject to prior authorization
- Number of M/S drugs subject to prior authorization
- Percentage of MH/SUD drugs subject to prior authorization
- Percentage of M/S drugs subject to prior authorization

Prescription Drugs – Step Therapy[3]

- Number of MH/SUD drugs subject to step therapy
- Number of M/S drugs subject to step therapy
- Percentage of MH/SUD drugs subject to step therapy
- Percentage of M/S drugs subject to step therapy

Network Adequacy

Time and Distance Standards

- The percentage of participants, beneficiaries, and enrollees who can access, within a specified time and distance by county-type designation, one (or more) in-network providers within MH/SUD provider categories
- The percentage of participants, beneficiaries, and enrollees who can access, within a specified time and distance by county-type designation, one (or more) in-network providers within M/S provider categories
- The percentage of participants, beneficiaries, and enrollees who can access in-network providers within MH/SUD provider categories as measured by including in-network providers available to those participants, beneficiaries, and enrollees through virtual or

[2] For prescription drug outcomes data, the Coalition would recommend that any definition of "relevant data" for prior authorization *not* include the number and percentage of claims denials, and instead use the number and percentage of drugs subject to prior authorization. This is because, due to pharmacy processes, claims denial data includes denials for a number of reasons unrelated to prior authorization, such as because the enrollee failed to retrieve the prescription from the pharmacy, administrative reasons (such as duplicate claim), and clinical and safety concerns (such as drug interactions and refill too soon).

[3] *Id*. The same reasoning applies to "relevant data" for step therapy.

telehealth platforms • The percentage of participants, beneficiaries, and enrollees who can access in-network providers within M/S provider categories as measured by including in-network providers available to those participants, beneficiaries, and enrollees through virtual or telehealth platforms
Provider Reimbursement
• In-network rate and Medicare rate for inpatient MH/SUD and M/S benefits, outpatient office visit MH/SUD and M/S benefits, and all other outpatient MH/SUD and M/S benefits • Allowed amounts for CPT codes 99213 and 99214 as well as CPT code 90834 for specific types of MH/SUD and M/S providers

B. *The Coalition recommends that the Tri-Agencies make the "material difference" rule apply evenly, and define the term "material."*

The Coalition is concerned that the "material difference" standard in the Proposed Rule is uneven. That is, if there are material differences, then the plan or issuer has a burden of proving compliance, but if the differences are immaterial, the Tri-Agencies will not presume compliance and will not rely on the data to demonstrate compliance. The Coalition recommends that the standard apply evenly, such that if there are no material differences in outcomes data, there is a presumption that the plan or issuer is in compliance with the NQTL requirements.

In addition, the Tri-Agencies should define "material" differences. If the Tri-Agencies do not define what they believe is "material," compliance will be unclear, and the regulated community will learn this definition through enforcement actions, which may result in different interpretations between the DOL and HHS.

If the proposal is adopted, the Coalition recommends that the Tri-Agencies adopt a definition of "material difference" that is based on the following principles:

- **Acceptable Level of Difference**: MH/SUD benefits are equally as important as M/S benefits, and it is entirely appropriate for participants to have equal access to both types of benefits. But it is also important to recognize that there are inherent differences between the nature of the care and the number and types of services provided under these benefit types, including the different providers that provide such services. Despite diligent effort on the part of plans and issuers, these differences may inevitably lead to small variations in outcomes in the metrics described in the Proposed Rule. These minor differences do not indicate a bias. Instead, they may reflect the practical impossibility of treating different things exactly the same.

- **Participant Behavior:** Even if it were possible to structure and administer a plan or coverage such that the accessibility of MH/SUD benefits was identical to the accessibility

of M/S benefits, the probability of a claim being denied would only be the same between the benefit types if participants behaved exactly the same with respect to those benefit types. This is unlikely to be the case. A plan or issuer with a fair and unbiased process in place may deny materially more claims on one side or the other merely because more participants submit claims for non-covered services of that type. This could happen if it were more difficult for participants to distinguish between covered and non-covered services under one benefit type, or if there were greater demand for one type of non-covered service. The definition should contain an allowance to account for the fact that accessibility is only one driver of claims denial experience, and there may be other drivers that are not connected to accessibility.

- **Credibility**: In general, the more data that is included in a statistical analysis, the more likely it is that the statistical measurements are close to the underlying probabilities. If you flip a coin a thousand times you are far more likely to observe a distribution of heads or tails that is close to fifty-fifty than if you only flip it one hundred times. In other words, the more data observations you have, the more confident you can be that those observations are consistent with the underlying probabilities. Claims for benefits are dramatically more complex than flipping coins because there are countless facts and circumstances that distinguish each individual claim process from the others, but the basic principle that larger data analyses are more credible than smaller data analyses remains valid. The definition should recognize the relationship between data size and data credibility, for example, to ensure that plans with relatively small amounts of claims data are not disadvantaged.

Finally, if the proposal is adopted, the Coalition recommends that the Tri-Agencies define what constitutes "reasonable action" that plans and issuers are required to take to address the material differences. This is especially important for NQTLs that are common plan structures, like network composition, and not necessarily benefit limitations.

C. *The Coalition recommends that the Tri-Agencies not adopt a special rule for NQTLs related to network composition.*

The Coalition agrees with the Tri-Agencies that access is important and stands ready to work with the Department to increase access to MH/SUD services. However, the Coalition believes that a material difference in network composition data should not constitute a per se failure to comply with MHPAEA. The Coalition is concerned that this proposed network composition NQTL standard would force plans to accept lesser credentialed providers into their networks, which would compromise outcomes and patient safety, and also would not adequately consider the role telehealth plays in expanding access to quality MH/SUD services, as discussed infra. There are many other reasons why a plan or issuer may not meet network standards; many of which are outside the control of the plan or issuer. For example, plans and issuers may be unable to fulfill the network standards due to a shortage of mental health providers or specialists generally and especially in rural regions. The Bureau of Health Workforce, Health Resources and Services Administration at HHS estimates that 164 million people in the United States are

living in "Mental Health Care Professional Shortage Areas," estimating that an additional 8,289 providers are needed to fill this gap nationwide.[4] This means that almost half of Americans reside in areas where patients are unable to access mental health services because of a shortage of mental health providers. In the Proposed Rule, the Tri-Agencies recognize that a provider shortage may be a factor in the inability of a plan or issuer to meet certain network standards. However, it's unclear what information a plan or issuer would need to provide to the Tri-Agencies to demonstrate a provider shortage and how the Tri-Agencies will consider this information, specifically as it relates to a plan or issuer avoiding a final determination of noncompliance. The proposed special rule also does not adequately account for the personal choices that some MH/SUD providers make to *not* participate in networks for various reasons.

Moreover, the COVID-19 pandemic represented a substantial shift toward telehealth in the way many Americans sought and received MH/SUD treatment. In addition to expanding the method by which a patient can receive treatment, telehealth allows plans and issuers to address regional provider shortages in ways that alleviate immediate demand while they continue working to grow local provider networks for in-person services. We recognize that telehealth-only MH/SUD treatment may not be appropriate for every patient's need, but telehealth can help increase access, fill gaps left by provider shortages, and is often preferred by some patients for its convenience. However, the Proposed Rule offers no substantive consideration of accounting for the ways in which telehealth has increased access to patient care for MH/SUD treatment and addressed longstanding provider shortages. If network adequacy is to be evaluated for parity, a concrete method to judge the access impacts of telehealth must be an included consideration. For example, some issuers have reported that more than 50% of their routine outpatient MH/SUD visits now occur through telehealth. While the distribution varies by plan or issuer, metrics around time and distance are much less relevant when such a substantial portion of MH/SUD care is delivered via telehealth. The changes plans and issuers made during and following the COVID-19 pandemic to meet the needs of the enrollees were so substantial that they render older studies – and old methods of measuring network access – obsolete.

IV. The Exceptions for Independent Professional Medical or Clinical Standards to Detect or Prevent and Prove Fraud, Waste, and Abuse

The Proposed Rule provides exceptions from certain elements of the NQTL test for (1) independent professional medical or clinical standards and (2) standards to detect or prevent and prove fraud, waste, and abuse. Specifically, NQTLs that are consistent with independent professional medical or clinical standards may be excepted from the "no more restrictive" requirement. The NQTLs that fall within this exception may also be deemed to comply with the "nondiscrimination" requirement and may be excepted from the "relevant data" requirements. Additionally, NQTLs that are consistent with standards related to fraud, waste, and abuse may be excepted from the "no more restrictive" requirement and may be deemed to comply with the "nondiscrimination" requirement.

---

[4] *See* Health Resources and Services Administration's ("HRSA") Healthcare Shortage Workforce Areas at https://data.hrsa.gov/topics/health-workforce/shortage-areas (last visited September 19, 2023).

The Coalition strongly supports the inclusion of these exceptions in the final regulations and recommends that the Tri-Agencies adopt definitions of "independent professional medical or clinical standards" and "standards to detect or prevent fraud, waste, and abuse."

As noted above, the Coalition strongly opposes the application of the substantially all/predominant test to NQTLs. However, regardless if the substantially all/predominant test is finalized, the Coalition strongly supports the Tri-Agencies' proposal to create exceptions from the applicable NQTL requirements. Clear definitions and guidelines are needed to enable plans and issuers to rely on these exceptions. Without clarification, stakeholders remain subject to the risk of enforcement for their good faith interpretations of what standards or practices these exemptions could encompass.

The Coalition recommends the Tri-Agencies take the following actions in the Final Rule to provide stakeholders the needed certainty to depend on these exceptions. First, the Coalition recommends the Tri-Agencies create a definition for "independent professional medical or clinical standards" constituting an exception that includes the following specific examples of acceptable independent standards:

- Professional standards of safety and effectiveness recognized in the U.S. for diagnosis, care, or treatment, including third-party criteria such as InterQual Behavioral Health Criteria; Milliman Care Guidelines; American Society of Addiction Medicine ("ASAM") Criteria; Level of Care Utilization System ("LOCUS") guidelines; Child and Adolescent Level of Care/Service Intensity Utilization System ("CALOCUS-CASII") guidelines; and Medicare National and Local Coverage Determination guidelines

- Peer-reviewed scientific studies and medical literature, from which a higher level of evidence and study quality is more strongly considered in determinations

- Independent experts in the field

- Nationally recognized drug compendia resources such as Facts & Comparisons®, DRUGDEX®, and The National Comprehensive Cancer Network® ("NCCN"®) Guidelines

- Medical association publications, such as those from American Society of Addiction Medicine and American College of Obstetricians and Gynecologists

- Government-funded or independent entities that assess and report on clinical care decisions and technology such as the Agency for Healthcare Research and Quality ("AHRQ"), Hayes Technology Assessment, Cochrane Reviews, and National Institutes for Health and Care Excellence ("NICE")

- Published expert opinions, including in UpToDate

- Expert panels convened by accrediting organizations

These clinical standards are widely relied upon by plans and issuers. The Tri-Agencies' inclusion of these clinical standards as examples, as well as other standards the Tri-Agencies determine may be appropriate, would help promote uniform MHPAEA enforcement and compliance nationwide.

Second, the Coalition recommends that the Tri-Agencies establish a "standard" for the fraud, waste, and abuse exception. At the very least, the Tri-Agencies should provide an example of how plans and issuers would be able to utilize this exception. The Tri-Agencies should also explain the documentation a plan or issuer must provide to fit within the exception. If the Tri-Agencies anticipate requesting evidence from plans or issuers, the Final Rule should specifically list the required information to equip plans and issuers with the knowledge and tools to comply with MHPAEA.

V. Fiduciary Certification

For the first time, for plans subject to ERISA, the comparative analysis would be required to include a certification by one or more named fiduciaries who have reviewed the analysis, stating whether they found the comparative analysis to be in compliance with the content requirements of the Proposed Rule.

The Coalition recommends that the Tri-Agencies not adopt the fiduciary certification requirement.

By imposing the fiduciary certification requirement, the Tri-Agencies are going beyond what Congress intended in the CAA. In 2020, Congress passed the CAA and elected not to impose certification requirements. Congress knows how to impose such requirements – for example, Congress included a certification requirement for the prohibition of gag clauses in the CAA. However, Congress refrained from imposing a certification requirement for the NQTL comparative analysis. If Congress intended a certification requirement be imposed as part of the NQTL comparative analysis, they would have included such a requirement in the CAA.

In addition, the DOL deviates from their requirements under other statutory provisions. For example, under ERISA, plan sponsors are not subject to similar certifications in other areas where they receive disclosures in their capacity as plan fiduciaries, such as ERISA section 408(b)(2).

And significantly, the Proposed Rule, if finalized, will make the NQTL analysis so complicated that it will be difficult for plan sponsors to understand if compliance with the NQTL analysis has been met, let alone certify they are compliant. In addition, under ERISA, fiduciaries are obligated to hire experts in areas where expertise is required. Navigating the existing NQTL requirements is challenging, and the Proposed Rule indicates the Tri-Agencies' intent to make

profound changes in plans' duties. Fiduciaries would be hard-pressed to possess the requisite information to make such certifications on compliance.

VI. Provision of Meaningful Benefits

The Proposed Rule, if finalized, would obligate plans and issuers to provide "meaningful benefits" for the treatment of a particular MH/SUD condition in each classification, as determined in comparison to the benefits provided for M/S conditions in the classification. The Tri-Agencies included two key examples involving applied behavior analysis ("ABA") therapy and nutrition counseling to demonstrate how plans and issuers may comply.

If the Tri-Agencies retain the "meaningful benefits" proposal, the Coalition recommends that the Tri-Agencies find that a plan or issuer provides "meaningful benefits" for a MH/SUD condition in each classification if the plan or issuer provides at least one primary treatment for the condition or disorder in a classification.

MHPAEA is not a benefit mandate, and Congress did not mandate coverage for all MH/SUD treatment in all classifications when enacting MHPAEA. In the Final MHPAEA 2013 Rules, the Tri-Agencies explicitly explained that they "did not intend to impose a benefit mandate through the parity requirement that could require greater benefits for mental health conditions and substance use disorders." The Coalition is concerned that, without a clear and reasonable definition of "meaningful benefits," the term could be interpreted to require coverage of every possible prescribed treatment for a MH/SUD condition. Notably, plans and issuers are deliberate in the decision-making regarding the services that are covered (and not covered), and include medical providers in those discussions to determine what treatments are safe and effective for enrollees in their plans. This proposal is especially troubling for the Coalition in relation to the potential mandate of certain services, such as wilderness therapy, among other treatments, that raise significant quality and safety concerns.

If the Tri-Agencies decide to retain this proposal, the Coalition recommends that the Tri-Agencies adopt the standard that a plan or issuer will be deemed to satisfy the "meaningful benefits" requirement if the plan or issuer covers at least one primary treatment for a MH/SUD condition or disorder in a classification as determined by evidence-based clinical standards.

VII. The Need for Additional Procedural Review

The Tri-Agencies do not address in the Proposed Rule what procedural protections they intend to implement prior to issuing a final determination of noncompliance, as related to the NQTL comparative analysis.

The Coalition recommends that the Tri-Agencies provide some form of independent and coordinated review before a final determination of noncompliance may be issued.

In order to preserve plans' and issuers' procedural rights, the Tri-Agencies should provide them with the option to request a hearing to consider any concerns about findings of

noncompliance. The CAA provides for severe consequences if a final determination of noncompliance is issued. Notably, within seven days, the plan or issuer is required to notify participants and beneficiaries of its noncompliance with MHPAEA, and the DOL or HHS will identify the plan or issuer by name in its annual report to Congress.

The Coalition recommends the Tri-Agencies offer a DOL National Office review or an HHS Center for Consumer Information and Insurance Oversight ("CCIIO") Director review, and that the DOL and HHS coordinate on this review in order to ensure plans and issuers are treated consistently and with fairness. A DOL National Office review or CCIIO Director review would permit a plan or issuer to request a review of the Regional Office's or CCIIO contractor's findings before a final determination of noncompliance is issued, and, similarly, a final determination of noncompliance would not be issued until the review is completed. This review would include analysis of the plan's or issuer's submitted written materials, including supplementary materials, and a joint conference. After completion of the review process, the DOL National Office or CCIIO Director would issue a written determination of compliance or non-compliance within six months.

VIII. The Applicability Date and Good Faith Compliance Standard

The Tri-Agencies indicate that the Proposed Rule's provisions, if finalized, would become effective on the first day of the first plan year beginning on or after January 1, 2025.

The Coalition recommends that the Tri-Agencies provide for at least a one-year delay after the effective date of the Final Rule. We also recommend the Tri-Agencies apply a reasonable, good faith compliance standard for the first year after the Final Rule's provisions are effective. In addition, if the "substantially all/predominant" test is finalized, the Coalition recommends that this test be applicable no sooner than two years after the effective date of the Final Rule.

The Tri-Agencies should grant stakeholders adequate time to conform their practices to comply with the Final Rule. In particular, applying the "substantially all/predominant" test to NQTLs would create additional complexities that would require plans and issuers to consider how best to comply and continue to provide affordable and equitable access to MH/SUD services. The calculations required to perform this testing are complex and will take a significant amount of time to set up and perform. Plans' and issuers' systems are not currently designed to calculate the dollar amount of plan payments for NQTLs in all of their benefit classifications, nor are systems set up to provide outcomes data.

As a practical matter, the Tri-Agencies are unlikely to finalize the rule until sometime in 2024, given that public comments are due on October 17. The Tri-Agencies will need time to review and respond to the many public comments before finalizing the rule. A January 1, 2025 effective date would give plans and issuers less than a year to make significant changes to their plan designs, policies, and systems.

We recommend that the Tri-Agencies provide for at least a one-year applicability date delay after the rules are finalized to provide stakeholders the requisite time to establish and ensure their plans, policies, and systems will satisfy the new standards imposed under the Final Rule. Then, due to the complexity of the new rules, we ask that when the rules are first applicable, the Tri-Agencies apply a reasonable, good faith compliance standard for at least a year. In addition, if the "substantially all/predominant" test is finalized, the Coalition recommends an additional one-year transition period to come into compliance with the "substantially all/predominant" test (*i.e.*, two years to transition to full compliance with this test).