

October 17, 2023

The Honorable Xavier Becerra Secretary U.S. Department of Health and Human Services 200 Independence Avenue, SW Washington, DC 20201

The Honorable Lisa M. Gomez Assistant Secretary Employee Benefits Security Administration U.S. Department of Labor 200 Constitution Avenue, NW Washington, DC 20002

The Honorable Douglas W. O'Donnell Deputy Commissioner for Services and Enforcement Internal Revenue Service U.S. Department of the Treasury 1111 Constitution Avenue, NW Washington, DC 20224

Re: 0938-AU93 1210-AC11

1545-BQ29

Requirements Related to the Mental Health Parity and Addiction Equity Act

Dear Secretary Becerra, Assistant Secretary Gomez, and Deputy Commissioner O'Donnell;

The Mental Health Liaison Group (MHLG) – a coalition of national organizations representing consumers, family members, mental health and substance use disorder providers, advocates, and other stakeholders – appreciates the opportunity to comment on the Department of Health and Human Services, Employee Benefits Security Administration, and the Internal Revenue Service's (the "Departments") proposed rule, Requirements Related to the Mental Health Parity and Addiction Equity Act (hereinafter "2023 Proposed Rule").

MHLG strongly supports the 2023 Proposed Rule's overarching goal to increase access to mental health and substance use disorder (MH/SUD) treatment by addressing treatment limitations that place a greater burden on participants/beneficiaries' access to MH/SUD treatment than to medical/surgical (M/S) treatment. We are especially supportive of the statement of the purpose of the regulations and law and the corresponding requirement



that plans analyze the impact of a nonquantitative treatment limitation (NQTL) on access to MH/SUD services as part of the comparative analysis. We further support the data collection and reporting requirements of the rule, especially with respect to the comparative analyses of NQTLs and network composition, as such requirements are essential to ensure compliance with the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) given the longstanding history of practices to disparately limit access to MH/SUD services.

To fully realize the promise of the 2023 Proposed Rule's many extraordinarily strong provisions, however, the Departments must eliminate the proposed exceptions relating to "independent professional medical or clinical standards" and "fraud, waste, and abuse." To be clear, we strongly support requirements for plans/issuers to follow independent professional medical/clinical standards (generally accepted standards of care) and believe it is critical to combat fraud, waste and abuse to safeguard the health and well-being of consumers. However, as structured, the proposed exceptions threaten to swallow significant parts of the 2023 Proposed Rule, potentially making its promise of increased access to MH/SUD services by combatting discriminatory treatment limitations illusory. Furthermore, we believe that these exceptions are not firmly based in MHPAEA's statutory text and that the underlying legitimate issues are most appropriately and effectively addressed within the existing (and proposed) NQTL rules.

Our full comments are as follows.

29 CFR § 2590.712, 45 CFR § 146.136, AND 26 CFR § 54.9812-1 - PARITY IN MENTAL HEALTH AND SUBSTANCE USE DISORDER BENEFITS

Purpose -(a)(1)

MHLG strongly supports the purpose of the 2023 Proposed Rule. If the problematic proposed exceptions to core requirements of the 2023 Proposed Rules are eliminated, the Proposed Rule would significantly strengthen implementation of MHPAEA. When MHPAEA was enacted 15 years ago, the intent was to prohibit discriminatory treatment limitations that limit the "scope or duration of treatment." However, the current regulations have been insufficient to hold plans and issuers accountable for treatment limitations, including NQTLs, that place a greater burden on access (and, therefore, are more restrictive) to MH/SUD treatment as compared to M/S benefits.

We have seen how plans and issuers have engaged in elaborate, post-hoc rationalizations for why treatment limitations that place a greater burden on access to MH/SUD care are nonetheless compliant with the existing rules. While these rationalizations have never been convincing and state and federal regulators are increasingly holding plans and issuers accountable, the current regulations have not adequately placed the emphasis on the



disparate burden that treatment limitations frequently place on plan members' access to MH/SUD treatment as compared to M/S treatment. Instead, too often, plans and issuers (as well as many regulators) have lost sight of an obvious, fundamental question under MHPAEA: the degree to which a "treatment limitation," in fact, limits access to MH or SUD treatment. We strongly support the Departments anchoring MHPAEA, including its implementing regulations, to whether plans/issuers' treatment limitations disparately limit access to MH/SUD treatment.

In addition, we urge the Department to make an important technical correction in the next-to-last sentence in (a)(1), which states: "...than they impose on access to generally comparable medical/surgical benefits." This language should be revised to state "...than they impose on access to medical/surgical benefits in the same benefit classification group." Evaluation of plans/issuers' MHPAEA compliance is always bounded by the relevant benefit classification group. Introduction of the phrase "generally comparable medical/surgical benefits" in (a)(1) to describe types of benefits under a plan could lead to uncertainty and confusion, because the term "comparable" used in the current rule and the offered examples to describe only the limitations placed upon benefits – not to compare the benefits themselves. Additionally, attempting to identify "generally comparable" MH/SUD and M/S benefits (other than through benefit classification groups) is fraught with difficulty, which is why it has previously been rejected. We urge the Departments to remove the words "generally comparable" in this instance, in order to clarify that "benefit classification group" will continue to how MHPAEA compliance is evaluated.

Substantially All / Predominant Test for NQTLs - (c)(4)(i)

MHLG strongly supports applying the substantially all / predominant test to NQTLs. The statutory language of MHPAEA is unambiguous in its requirement that treatment limitations applicable to MH/SUD benefits must be "no more restrictive than the predominant treatment limitations applied to substantially all medical and surgical benefits..." This test already applies to financial requirements and quantitative treatment limitations, and it should apply to NQTLs as well, which are also a "treatment limitation" under MHPAEA. Thus, we agree with the 2023 Proposed Rule's requirement that, if an NQTL is not applied to "substantially all" (i.e., two-thirds under the longstanding regulations) M/S benefits within a classification of care, plans/issuers may not apply the NQTL to MH/SUD benefits within that classification. If a plan/issuer does apply an NQTL to "substantially all" M/S benefits within a classification of care, a plan/issuer must then show that the NQTL applied to MH/SUD benefits within that classification is no more restrictive than the predominant variation applied to M/S benefits within the classification.

We note that the application of this test for financial requirements and quantitative treatment limitations has resulted in substantial compliance. This is because a calculation is conducted to determine whether plans' application of a financial requirement or



quantitative treatment limitation meet the substantially all / predominant test. Applying this same test to NQTLs will likely result in similar improvements in MHPAEA compliance and increase participants/beneficiaries' access to MH/SUD care.

"Independent Professional Medical or Clinical Standards" Exception to NQTL Requirements – (c)(4)(i)(E), (c)(4)(i)(B), (c)(4)(iv)(D), and (c)(4)(v)(A)

MHLG supports the Departments' desire to incentivize plans/issuers to follow "independent professional medical or clinical standards (consistent with generally accepted standards of care)" when imposing NQTLs. All plans/issuers should be following these standards and adherence to clinical standards is often identified as a factor or evidentiary standard in NQTL analyses.

However, we urge the Departments to remove the exception, which we believe is deeply flawed and will be exploited by plans/issuers to limit access to needed MH/SUD services. While we appreciate the Departments' statement in the preamble that this exception (along with the "fraud, waste, and abuse" exception) is meant to be "narrow," the experience of individuals, families, and providers under the existing regulations indicates that plans/issuers will adopt and implement significant benefit exclusions and administrative barriers based on either exception.

We remind the Departments that they included a "clinically appropriate standards of care" exception to MHPAEA's NQTL requirements in their 2010 interim final regulations. Importantly, in the final regulations, the Departments removed this exception. The Departments wrote:

[C]ommenters raised concerns that this exception could be subject to abuse and recommended the Departments set clear standards for what constitutes a "recognized clinically appropriate standard of care." For example, commenters suggested a recognized clinically appropriate standard of care must reflect input from multiple stakeholders and experts; be accepted by multiple nationally recognized provider, consumer, or accrediting organizations; be based on independent scientific evidence; and not be developed solely by a plan or issuer. Additionally, since publication of the interim final regulations, some plans and issuers may have attempted to invoke the exception to justify applying an NQTL to all mental health or substance use disorder benefits in a classification, while only applying the NQTL to a limited number of medical/surgical benefits in the same classification. These plans and issuers generally argue that fundamental differences in treatment of mental health and substance use disorders and medical/surgical conditions, justify applying stricter NQTLs to mental health



or substance use disorder benefits than to medical/surgical benefits under the exception in the interim final regulations.

The Departments also confirmed that a panel of experts convened by the U.S. Department of Health and Human Services (HHS) could not identify situations supporting the clinically appropriate standard of care exception, noting that:

HHS convened a technical expert panel on March 3, 2011 to provide input on the use of NQTLs for mental health and substance use disorder benefits. The panel was comprised of individuals with clinical expertise in mental health and substance use disorder treatment as well as general medical treatment. These experts were unable to identify situations for which the clinically appropriate standard of care exception was warranted—in part because of the flexibility inherent in the NQTL standard itself.

We urge the Departments not to revisit this flawed standard. In 2013, the Departments correctly determined that, rather than operating as an exception, clinical appropriateness was most properly placed squarely within the framework of the regulations' NQTL requirements. Furthermore, we believe that such an exception lacks a firm basis in MHPAEA's statutory text, which requires that treatment limitations applicable to MH/SUD benefits be no more restrictive than the predominant treatment limitations applied to substantially all M/S benefits and includes no exceptions to this standard. We also note that the Consolidated Appropriations Act, 2021's (CAA, 2021) amendments to MHPAEA adopted the NQTL regulatory framework in statute without any exceptions to the framework.

Additionally, we believe the "independent professional medical or clinical standards" exception is likely unworkable. For example, if a plan/issuer claimed that independent professional medical or clinical standards justified the imposition of prior authorization or retrospective review under the "design and application" test ((c)(4)(ii)), how would the substantially all/predominant test ((c)(4)(i)) be applied to the prior authorization or retrospective review NQTL? Also, how would outcome data collection and analysis requirements ((c)(4)(iv)) assess an NQTL's impact on access if a plan/issuer could just claim that some undetermined part of the decreased access was due to following purported "independent professional medical or clinical standards"? This exception also relieves a plan/issuer from having to comply with any outcomes data collection or evaluation to demonstrate that the NQTL complies with in operation comparability and no more stringency under the design and application requirements of (c)(4)(ii). This exception would result in the 2023 Proposed Rule actually weakening the existing regulations.

Even if we believed that an "independent professional medical or clinical standards" exception were theoretically appropriate or workable, which we do not, we have deep



concerns that this term's current ambiguity and lack of definition will allow the exception to swallow the proposed strengthened NQTL requirements in paragraphs (c)(4)(i)(E), (c)(4)(i)(B), and (c)(4)(i)(D). If the Departments permit this to occur, the Departments' fundamental objective in putting forward the 2023 Proposed Rule will be severely undermined, and individuals will still be subjected to discriminatory treatment limitations that restrict access to care. In fact, we fear that the exception would even result in the 2023 Proposed Rule weakening the existing regulations.

To incentivize plans/issuers to apply clinical standards that adhere to independent professional medical or clinical standards, we urge the Departments to require plans to document in their NQTL analyses how their clinical standards and practices deviate from independent professional medical or clinical standards as described below. To make such analyses meaningful, the Departments should adopt a definition of "independent professional medical or clinical standards" that is tied to criteria/guidelines developed by the relevant nonprofit clinical specialty associations.

An increasing number of states have adopted a strong definition of "generally accepted standards of care" for MH/SUDs. Strong definitions have been enacted in <u>Illinois</u>, <u>California</u>, <u>Georgia</u>, and <u>New Mexico</u>. We support the following version of these states' definitions for "independent professional medical or clinical standards," which we view as synonymous with "generally accepted standards of care":

"Independent professional medical or clinical standards" mean standards of care and clinical practice that are generally recognized by health care providers practicing in relevant clinical specialties such as psychiatry, psychology, clinical sociology, social work, addiction medicine and counseling, and behavioral health treatment. Valid, evidence-based sources reflecting independent professional medical or clinical standards are peer-reviewed scientific studies and medical literature, recommendations of federal government agencies, drug labeling approved by the United States Food and Drug Administration, and recommendations of nonprofit health care provider professional associations and specialty societies, including, but not limited to, patient placement criteria and clinical practice guidelines.

We note that the Departments' example framing in the preamble of "independent professional medical or clinical standards" – that these standards "must be independent, peer-reviewed, or unaffiliated with plans and issuers" – is far too weak. Such a framing could allow for nontransparent, proprietary criteria created and licensed by for-profit publishers to establish "the independent professional medical or clinical standards." It would likely be argued that such criteria are developed "independently" (even if they are infected by financial self-interest of the publishers seeking continued licensing agreements with managed care organizations), "peer-reviewed" (even if the reviewers are unidentified and cannot be publicly vetted for their purported expertise or potential conflicts of



interest), and "unaffiliated with plans and issuers" (even if these companies communicate with payors/licensees about desired changes to their criteria). Thus, we believe any such requirements must be much stronger as outlined above.

In using these standards to assess criteria/guidelines and medical necessity determinations in connection with an NQTL analysis, it is essential that the Departments tie a strong definition of "independent professional medical or clinical standards" (as we have suggested above) to criteria/guidelines from the relevant nonprofit clinical specialty associations. Key nonprofit criteria include The American Society of Addiction Medicine (ASAM) Criteria and American Association of Community Psychiatry's Level of Care Utilization System and the Child and Adolescent Level of Care Utilization System, and the American Academy of Child and Adolescent Psychiatry's Early Childhood Service Intensity Instrument and Child and Adolescent Service Intensity Instrument.

Tying this definition to nonprofit clinical specialty association guidelines and criteria is essential because they are:

- **Fully transparent and accessible.** Consumers, providers, and other stakeholders can readily access the criteria being used to determine whether specific MH/SUD services are, in fact, appropriate to meet individual patient needs.
- Developed through a consensus process that protects against conflicts of interest. The authors and reviewers of nonprofit criteria are publicly identified. Credentials, expertise, and potential conflicts of interests can be evaluated by the public.
- **Externally validated.** Nonprofit clinical criteria are subject to rigorous peer review, validation studies in real-world clinical settings, and are reviewed in professional and scholarly journals.

In fact, as early as 1997, <u>research published in the American Journal of Psychiatry</u>, the official, peer-reviewed journal of the American Psychiatric Association, sounded warning bells, concluding that: "Our findings underscore the necessity of determining the validity of all criteria used to assess the appropriateness of medical care. Wide acceptance of an instrument is clearly not sufficient to justify its use. The need for validation studies is particularly great when proprietary criteria are not available for public scrutiny."

Once a strong definition is in place that is tied to nonprofit clinical professional association criteria/guidelines, we urge the Departments to put in place the following requirements:

• Evaluate divergence from "independent professional medical or clinical standards." The Departments should require plans/issuers to analyze how any MH or SUD criteria/guidelines they use diverge from "independent professional medical or clinical standards." Such an analysis would also be done for M/S benefits within



the classification of care and would be subject to the NQTL comparability and stringency test. Given the Departments have previously found that plans/issuers have simply issued conclusory or generalized statements of compliance, it would be critically important for the Departments to analyze criteria/guidelines that plans use to ensure the accuracy of plans' conclusions. Further, the Departments should utilize groundbreaking work done by the New York State Office of Mental Health (NYS OMH), which evaluated mental health plans' medical necessity criteria against "Guiding Principles" that represent generally accepted standards of care. In its reviews of 69 health plans' criteria, NYS OMH found that all plans' clinical criteria were deficient. If plans exclusively utilize and adhere to specified nonprofit clinical specialty association criteria/guidelines, the Department could follow NYS OMH's example by permitting plans/issuers not to conduct such an evaluation for these specified nonprofit criteria/guidelines.

- Require specific data reporting for the medical necessity/appropriateness. The special rule should require specific data collection and analysis requirements relating to medical necessity/appropriateness. Such data should include the number of authorizations issued for participants/beneficiaries by each of the levels (and sub-levels) of care described in The ASAM Criteria and the age-specific LOCUS family of criteria.
- Prohibit plans/issuers from withholding their criteria/guidelines for MHPAEA review. We have heard disturbing reports that plans/issuers do not make the criteria/guidelines they use available for MHPAEA compliance reviews. Where an NQTL relies on such criteria/guidelines that are not made available to regulators, it would be impossible to determine the NQTL's MHPAEA compliance. The Departments noted in their 2023 MHPAEA Report to Congress that plans/issuers did not provide external guidelines they claimed to use as evidentiary standards. The Departments should explicitly require that plans/issuers make available any criteria/guidelines they use to federal and any applicable State authorities (as well as to participants/beneficiaries), without any exceptions for purported "proprietary" or "confidential" criteria/guidelines.

By removing the "independent professional medical or clinical standards" exception, creating a strong definition for this term that is tied to nonprofit professional association criteria/guidelines, and putting in place the above requirements, we believe that the Departments can advance this important issue without allowing plans/issuers to continue practices that will inhibit access.

"Fraud, Waste, and Abuse" Exception to NQTL Requirements – (c)(4)(i)(E), (c)(4)(ii)(B), and (c)(4)(v)(B)

There is no place for fraud, waste, and abuse in MH/SUD services, just as there is no place for fraud, waste, and abuse in M/S services. MHLG strongly supports efforts to ensure that



individuals needing MH/SUD care receive the most clinically appropriate care, which is why it is so important for both providers and payers to follow independent professional medical or clinical standards / generally accepted standards of care. Unfortunately, we know that many health plans have sought to exploit claims of "fraud, waste, and abuse" to deny or otherwise limit access to medically necessary care. Some stakeholders report that plans/issuers have switched to routinely conducting mundane audits under the auspices of fraud and abuse investigation units, even though there is no evidence of fraud or abuse. Therefore, we do not support the Departments' attempts to create a "fraud, waste, and abuse" exception to the NQTL requirements in paragraphs (c)(4)(i)(E) and (c)(4)(ii)(B). While we support plans/issuers' legitimate efforts to combat, prevent and detect fraud, waste, and abuse, the Departments' proposed exception (like the independent professional medical or clinical standards exception) has the potential to swallow the proposed stronger NQTL requirements.

To combat fraud, waste, and abuse, plans/issuers should incorporate "fraud, waste, and abuse" as a factor for relevant NQTLs, which are subject to MHPAEA's comparability and stringency tests for MH/SUD and M/S. This is the most transparent way to ensure the plans are not inappropriately limiting MH/SUD treatment under the guise of efforts to combat "fraud, waste, and abuse." Locating "fraud, waste, and abuse" within the existing and proposed NQTL requirements also has the advantage of being well-grounded in MHPAEA's statutory text. In contrast, there is no "fraud, waste, and abuse" exception in MHPAEA's statutory text that would allow plans/issuers to avoid MHPAEA's NQTL requirements, which the CAA, 2021 incorporated into the MHPAEA statute.

As we described above for the "independent professional medical or clinical standards" exception, we also believe this exception is broadly unworkable. For instance, it is unclear how plans/issuers that use "fraud, waste, and abuse" as a factor in designing and applying an NQTL would perform the more restrictive (substantially all/predominant) test. We do not believe the Departments have articulated the analysis clearly, even though the preamble explains that the exception must be separately tested under and satisfy each of the applicable analyses for the NQTL to be applied.

Meaningful Benefits of Treatment of a Mental Health Condition or Substance Use Disorder -(c)(2)(ii)(A)

We support the provision requiring that if any MH or SUD benefits are provided in any classification of care, both MH and SUD benefits must be provided in all classifications of care and the scope of covered MH and SUD benefits in each classification must be "meaningful." Though plans/issuers are already required to provide MH/SUD benefits in all classifications if they provide MH or SUD services in any classification, there has been a lack of clarity on the breadth of MH and SUD services that must be covered. The proposed clarification, therefore, is a very important addition. However, the lack of definition of the



term "meaningful" will likely result in significant future disagreement about whether covered benefits are, in fact, "meaningful."

Without a definition, plans/issuers will likely interpret such a requirement narrowly, resulting in plan members having no greater access to care and being forced to assert rights through the appeals process and/or litigation. We recommend that "meaningful" coverage be defined as the full continuum of services that are consistent with independent professional medical or clinical standards (or, equivalently, the term "generally accepted standards of care"), as defined in the recommended definition above. Plan members should have access to the full continuum of MH and SUD services when comprehensive M/S services are routinely covered.

Additionally, to further ensure equitable access to MH/SUD care, we urge the Departments to identify "scope of covered services" as an NQTL in the non-exhaustive NQTL list. Every plan/issuer limits the scope of covered MH/SUD services, and any limitation on covered services meets MHPAEA's statutory definition of "treatment limitation" and the current regulations definition of NQTL ("nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under a plan or coverage"). Given this, every plan/issuer should already be conducting NQTL analyses for "scope of covered services," yet we are aware of none that do so. If the Departments identified "scope of covered services" as an NQTL, they would remove any ambiguity that a plan/issue must identify, for any excluded service, the "factor" and "evidentiary standard" that the plan/issuer used for M/S exclusions within the classification of care and determine whether the MH/SUD exclusion met the NQTL comparability and stringency test. A "scope of covered services" NQTL should also be subject to the 2023 Proposed Rule's requirements relating to outcomes data and actions to address access disparities.

Our organizations have seen firsthand how plans/issuers have failed to provide meaningful benefits in each classification of care. For example, plans/issuers routinely fail to cover MH/SUD emergency ("crisis") services, including both mobile crisis response teams and crisis stabilization services. This failure harms participants/beneficiaries needing such services, leaves our crisis response system underdeveloped, and shifts costs to public sector programs, including Medicaid and social services. Other examples include plans/issuers' failure to cover Coordinated Specialty Care, the evidence-based intervention for individuals experiencing early psychosis, and methadone in opioid treatment programs.

Prohibition on Discriminatory Factors and Evidentiary Standards - (c)(4)(ii)(B)

MHLG strongly supports this provision, which prohibits a plan/issuer from relying on any factor or evidentiary standard if it discriminates against MH/SUD benefits. This self-evident provision is necessary to ensure that plans/issuers, in designing and applying any NQTL, do not simply attempt to launder their discriminatory intent by relying on a factor or



evidentiary standard that itself is discriminatory. This can occur when plans/issuers rely on and perpetuate historic data or discriminatory structures as the basis for how they have designed and applied an NQTL or apply metrics that have not been subject to MHPAEA. For example, plans commonly justify discriminatory reimbursement rates by citing the Medicare Fee Schedule.

Of course, Medicare is not subject to MHPAEA and has long undervalued MH/SUD services. The Centers for Medicare & Medicaid Services (CMS) has recognized this <u>undervaluation</u> in recently proposed updates to the reimbursement rate for psychotherapy in the Medicare Physician Fee Schedule (PFS), but they acknowledge that they still need to develop systemic solutions to longstanding process limitations. In the meantime, MH and SUD clinicians account for <u>almost half</u> of the total providers who opt out of Medicare, with <u>low reimbursement rates</u> cited as a key factor affecting provider willingness to accept insurance and join networks. In (c)(4)(ii)(B), the Departments have put forward strong language prohibiting discriminatory factors and evidentiary standards. We believe that the provisions of this prohibition capture the Medicare Fee Schedule, which is not subject to MHPAEA and which CMS itself recognizes undervalues MH/SUD services. Given the frequency with which the Medicare Fee Schedule is used by plans/issuers to claim MHPAEA compliance, we urge the Departments to make clear that plans/issuers may not establish compliance by relying on the Medicare Fee Schedule.

Required Use of Outcomes Data & Actions to Address Material Differences in Access – (c)(4)(iv)(A-B)

MHLG strongly supports the provision to require a plan/issuer to collect and evaluate relevant data to assess the impact of the NQTL on MH/SUD and M/S benefits and to tie the "type, form, and manner of collection and evaluation" of data to guidance that can be periodically updated. The collection of data using standardized definitions and methodologies is critical to assessing an NQTL's impact on access to MH/SUD and M/S care. A core failing of the existing MHPAEA regulations is that an NQTL's impact on access to MH/SUD as compared to M/S treatment is rarely appropriately measured and analyzed. Instead, plans/issuers rely on process-related justifications and arguments to inappropriately justify disparate access to treatment. By requiring plans/issuers to collect and assess outcomes data and to address disparities in access, the Departments are appropriately bringing the focus of NQTL analyses back to the fundamental purpose of MHPAEA – addressing disparities in access to MH/SUD care.

We urge the Departments to clarify that outcome data must be separately reported for MH and SUD services to conform to the statutory standard. Experience has also demonstrated that a plan/issuer's performance for one set of benefits (either MH or SUD) does not necessarily reflect performance for the other set of benefits.



We also strongly support the requirement that plans/issuers must take "reasonable action" to address differences in access shown by this data. However, we are concerned that the proposed action would only be necessary when such differences are "material," a term that is not defined. We note that MHPAEA's statutory "no more restrictive" standard does not require a "material difference" and would, therefore, establish a weaker standard than the statute. Consistent with the statute's "no more restrictive" standard, we urge the Departments to require plans to take action whenever the data shows *any* difference in access. If the Departments do not alter the "material differences" standard, we urge the Departments to narrowly define the meaning of this term, adopting a low threshold and one that would not require consumers to employ expert statisticians to make use of this important test. Without a definition, plans/issuers will be left to determine whether the differences in access shown by the data are "meaningful." Such a situation will make it extraordinarily difficult for the Departments or any applicable State authority to hold plans accountable.

Special Rule for NQTLs Related to Network Composition - (c)(4)(iv)(C)

MHLG believes that inadequate networks are one of the most significant barriers to individuals accessing needed MH/SUD care. Thus, we strongly support the new proposed rules relating to "network composition," which would address many of these access issues. The special rule relating to network composition NQTLs is particularly powerful because a plan/issuer would fail to meet the requirements of (c)(4)(i) and (c)(4)(ii) "if the relevant data show material differences in access to in-network mental health and substance use disorder benefits as compared to in-network medical/surgical benefits in a classification." This strong requirement should be maintained.

Effect of Final Determination of Noncompliance – (c)(4)(vii)

MHLG strongly supports the provision that gives the Secretaries the ability to direct that a plan/issuer not impose an NQTL after a final determination of noncompliance and urge the Departments to change the "may" to a "shall" to indicate that the plan will not be permitted to apply a non-compliant NQTL. This standard is consistent with (c)(4), which makes clear that a plan that fails to meet any of the NQTL standards cannot impose the limitation and the current (h), which bars the sale of any plan that does not comply with the NQTL standards. We strongly urge the Departments to clarify that, if a plan/issuer cannot demonstrate that an NQTL is compliant, it should not be allowed to be imposed. Otherwise, the Departments are allowing participants/beneficiaries to be subject to noncompliant treatment limitations. The result will inevitably be individuals who are wrongly denied access to needed MH/SUD services, placing the health, well-being, and potentially lives of these individuals at risk. Furthermore, we urge the Departments to add provisions that, if a plan/issuer does not comply, the Departments will work with the Internal Revenue Service to assess penalties allowed by MHPAEA.



Additionally, this power should clearly be available, not just to Secretaries of the relevant federal regulator, but to any applicable State authority as well, as set out in the HHS proposed section 146.137(e)(1). State insurance departments have primary enforcement authority for state-regulated fully insured plans and have played a leading role enforcing MHPAEA, particularly given the federal Departments' inadequate resources that allow them to review only a small fraction of overall plans/issuers. Applicable State authorities should clearly have authority to make such a determination under the 2023 Proposed Rule.

For too long, there have been no meaningful consequences when plans/issuers have violated MHPAEA. Through widespread inaction and the lack of meaningful consequences for violations of MHPAEA's requirements, state and federal regulators have prioritized plans/issuers' interests and profits over the ability of individuals to receive needed MH/SUD care. It is now finally time to put teeth into the rules and prohibit plans/issuers from imposing treatment limitations that are not in compliance with MHPAEA. After nearly 15 years since enactment of MHPAEA, barring the application of non-compliant NQTLs is the only way to incentivize plans to more carefully evaluate NQTLs as they design and apply plan benefits and during the comparative analysis.

Examples Relating to Prohibited Exclusions of Autism and Eating Disorder Coverage – (c)(2)(ii)(C)

MHLG strongly supports the addition of new examples in the 2023 Proposed Rule, which would make clear that exclusions of key services for autism spectrum disorder and eating disorders violate MHPAEA. While the Departments have already been taking enforcement action against plans/issuers' discriminatory exclusions of autism and eating disorder services, these examples will remove any remaining ambiguity that these exclusions are inconsistent with MHPAEA's requirements.

Meaning of Terms - (a)(2)

MHLG supports the new and revised definitions in (a)(2) of the 2023 Proposed Rule. These changes significantly improve clarity and will increase access to care. The proposed changes to definitions of "mental health benefits" and "substance use disorder benefits" would ensure that the placement of benefits is consistent with "generally recognized independent standards," which are tied to the Diagnostic and Statistical Manual of Mental Disorders (DSM) and the mental, behavioral and neurodevelopmental disorders chapter of the International Classifications of Disease (ICD). The 2023 Proposed Rule would also ensure that any state laws that define MH/SUDs in a manner that conflict with "generally recognized independent standards" do not reduce plan members' protections under MHPAEA. This has particularly been an issue where autism spectrum disorder (ASD) benefits have been defined as M/S benefits, even though this is contrary to generally



recognized independent standards as reflected by the DSM and ICD. Where this has occurred, individuals with ASD have been denied MHPAEA protections.

We also strongly support the Departments' proposed definitions for key terms relating to NQTLs – "evidentiary standards," "factors," "processes," and "strategies." The lack of definitions for these terms, which are foundational to MHPAEA's NQTL requirements, has hindered efforts to hold health plans accountable on discriminatory NQTLs due to frequent disagreements about their meaning.

Non-Exhaustive List of NQTLs - (c)(4)(iii)

MHLG supports the revisions to the list of NQTLs, including relating to "network composition," and the clarification that this list is "non-exhaustive." While this is consistent with the Departments' current interpretation, specifying it in rule can remove any potential ambiguity. As referenced above, we urge the Departments to add "scope of covered services" as an identified NQTL.

Provisions of Other Law - (d)(3)

MHLG urges the Departments to add the following sentence, with any adjustment for code-specific terms to make clear that no part of the comparative analyses or other application information required by 29 CFR § 2590.712-1 / 45 CFR § 146.137 / 26 CFR § 54.9812-2 may be withheld: "All requested plan information shall be made available to claimant and may not be withheld as proprietary or commercially protected information." Plans/issuers frequently do not provide required requested information, and it is important that their obligations be made as explicit as possible wherever they appear to make it more difficult for plans/issuers to falsely claim that such exceptions exist.

29 CFR § 2590.712-1, 45 CFR § 146.137, AND 26 CFR § 54.9812-2 – NONQUANTITATIVE TREATMENT LIMITATION COMPARATIVE ANALYSIS REQUIREMENTS

MHLG strongly supports the addition of new requirements relating to plans/issuers' NQTL comparative analyses that they are required to conduct under amendments to MHPAEA enacted as part of the CAA, 2021. These detailed requirements are necessary to ensure there is clarity on what plans/issuers' analyses must contain and to hold plans accountable for following these requirements.

We also appreciate language relating to providing participants/beneficiaries with information summarizing changes the plan/issuer "has made as part of its corrective action plan following the initial determination of noncompliance, including an explanation of any opportunity for a participant or beneficiary to have a claim for benefits reprocessed." The



framing of the notice as an "opportunity" for a participant/beneficiary to have a claim for benefits reprocessed is misguided and places the burden on participants/beneficiaries in an inappropriate manner. The participant/beneficiary is not well placed to know they may have been impacted by noncompliant NQTL and to navigate a likely complicated path (that the proposal leaves unidentified) to pursue remedies. Instead, we strongly urge the Departments to place an affirmative obligation on plans/issuers, as part of the corrective action plan, to identify affected participants/beneficiaries, reprocess any claims, notify those who they determine have been impacted by the non-compliant NQTL. We commend the Departments for appropriately shifting the burden away from consumers throughout this proposed rule, and we urge a consistent approach here.

Finally, in (b), we urge the Departments to explicitly reference "any applicable State authority" to ensure clarity that plans' comparative analysis must be made available to state regulators upon request. The relevant sentence should read: "Each comparative analysis must comply with the content requirements of paragraph (c) of this section and be made available to the Secretary (or to any applicable State authority), upon request, in the manner required by paragraphs (d) and (e) of this section." While this statutory requirement is referenced in (e), some insurers have refused to provide required parity compliance analysis to the applicable State authority upon request if the relevant Secretary has not also requested the analysis. This change will help prevent such false claims by preventing selective citation of the proposed regulations.

45 CFR § 146.180 - TREATMENT OF NON-FEDERAL GOVERNMENT PLANS

MHLG supports the language implementing the elimination of self-funded non-federal government plans' ability to opt out of MHPAEA. Hundreds of thousands of public employees and their family members have for too long been denied critical MHPAEA protections as their public-sector employer affirmatively opted-in to discriminating against individuals needing MH/SUD services.

We urge the Department of Health and Human Services to prioritize robust MHPAEA compliance reviews of these plans as soon as their opt out is no longer valid. This is particularly important given that many of these public sector plans opted out of MHPAEA specifically because they wished to continue discriminatory treatment limitations on MH/SUD benefits. The Department should immediately request plans' NQTL compliance analyses to ensure they are taking the necessary steps to comply with MHPAEA.



OTHER ISSUES

Third-Party Administrators (TPAs)

The Departments have asked for feedback on how third-party administrators (TPAs) "could be further incentivized to facilitate compliance with MHPAEA." MHLG agrees with the Departments' concern about this issue. Though, rather than "incentivize" TPAs to comply with MHPAEA, we urge the Departments to use all possible avenues to hold both self-funded plan sponsors and TPAs accountable for MHPAEA compliance.

Recent <u>reports</u> have highlighted ongoing problems where TPAs, who are the experts in health plan design and administration and who make critical coverage decisions, refuse to provide essential information, including data, to the employer plan sponsor by claiming that such information is "proprietary" or has "commercial value." TPAs' refusal to provide information and data on plan design and access to benefits fundamentally inhibits MHPAEA compliance and cannot be allowed to stand. The Departments have repeatedly made clear that such plans/issuers must provide such information. In the 2015 MHPAEA <u>FAQ XXIX</u> (Q12), the Departments made clear that information relating to medical necessity criteria purported to be of "proprietary" or "commercial" value must be provided to plan members' upon request. The Departments have also reiterated that information related to MHPAEA compliance, including NQTL analyses, must be provided without restrictions upon request in the 2023 Proposed Rule's <u>preamble</u>.

Yet, we frequently see plans/issuers and their TPAs refusing to provide legally required information, without any apparent consequence. To address the ongoing problems with TPAs hindering compliance with MHPAEA, we urge the Departments in the 2023 Proposed Rule to require plan sponsors to insert MHPAEA compliance provisions into their contracts with TPAs. HHS utilized in a similar approach in 2001 when it required health care entities covered by HIPAA (mainly health care providers and health insurers) to include HIPAA-related provisions in their contracts with outside entities that handle patient information on behalf of covered entities. Without such "business associate agreements," HIPAA's privacy and security protections would have been undermined if businesses handling patient information for billing, accounting, legal, IT, or other purposes could simply ignore HIPAA. These agreements contractually obligate the outside entities to carry on the HIPAA obligations of the covered entities and help them with compliance. The Departments should do the same for MHPAEA by requiring a plan sponsor to enter into a contract with any TPA they hire that includes specific obligations whereby the TPAs must assist the plans in fulfilling their MHPAEA obligations to participants/beneficiaries and regulators.

Finally, we urge the U.S. Department of Labor (DOL) to use ERISA's strong protections to hold TPAs accountable as ERISA fiduciaries and co-fiduciaries. Under 29 U.S.C. 1132(a)(5), DOL may bring legal action against any fiduciaries that violate MHPAEA, including TPAs, as



incorporated into ERISA through 29 U.S.C. 1185a. Further, under 29 U.S.C. 1134, DOL is granted the power, "in order to determine whether any person has violated or is about to violate any provision of this subchapter," including MHPAEA, and to "make an investigation" and to "inspect such books and records and question such persons as he [the Secretary] may deem necessary to enable him [the Secretary] to determine the facts relative to such investigation." Thus, DOL may investigate TPAs for acts or practices that violate MHPAEA and can sue to enjoin such practices. Finally, DOL is authorized under 29 U.S.C. 1135 to "prescribe such regulations as he finds necessary or appropriate to carry out the provisions of this subchapter." We urge DOL to use its substantial authority and discretion to ensure that TPAs have adopted policies and procedures that are MHPAEA-compliant.

MH/SUD Emergency ("Crisis") Services

The Departments have requested feedback relating to MH/SUD crisis services under MHPAEA and the Affordable Care Act's (ACA) Essential Health Benefits (EHB) categories for non-grandfathered individual and small group coverage. Federal policymakers have dedicated enormous effort to standing up the 988 Suicide and Crisis Lifeline and expanding MH/SUD crisis services, which help people get the help they need and avoid needless, and often tragic, encounters with law enforcement. While every benchmark plan includes EMS and emergency transport services, very few include mental health crisis (i.e., emergency) response or crisis stabilization services. This failure to include MH/SUD crisis services under EHB means that many individuals do not have appropriate coverage of these services. A number of states, including California, Virginia, and Washington, have recently required health plans to cover MH/SUD crisis services. Washington has made clear that coverage of MH/SUD crisis services is necessary for health plans to comply with MHPAEA. HHS should include MH/SUD crisis services within the MH/SUD EHB category. Additionally, when finalizing this rule, MHLG encourages the Departments to make clear that, if a plan/issuer covers physical health emergency services (including EMS and emergency transport), it must cover comparable MH/SUD emergency/crisis services (including mobile crisis response) under the same standards (e.g., no prior authorization).

Provider Directory Requirements

The Departments have requested feedback on how to improve provider directories through rulemaking. MHLG urges the Departments to require periodic independent third-party testing of provider directories to assess the accuracy of information and that a sufficient percentage of providers are accepting new patients. HHS has already put forward strong proposed standards for Medicaid managed care and the Children's Health Insurance Program (CMS-2439-P), which establish maximum appointment wait time standards for routine outpatient MH/SUD services of 10 business days and require such independent secret shopper surveys. This proposed rule should be a model for the Departments in



individual and group plans. Additionally, plans/issuers should be required to identify providers who are available via telehealth. Finally, the Departments should ensure that participants/beneficiaries who cannot access in-network services on a timely basis can access out-of-network services, with their out-of-pocket costs no greater than the amounts that they would have paid for the same services received from an in-network provider.

Claims Procedure Requirements

The Departments have requested feedback on how the ACA and ERISA's existing claims procedure requirements can facilitate access to MH/SUD benefits. Most fundamentally, MHLG urges HHS and DOL to strengthen enforcement with existing claims procedure requirements, which in our experience are frequently not followed with little apparent consequence. To strengthen participants/beneficiaries' ability to challenge inappropriate denials of MH/SUD care, HHS and DOL should, at minimum, make clear that plans/issuers' NQTL compliance analysis must be made available upon request, with no restrictions for purported "proprietary" or "confidential" information. While we believe this is HHS and DOL's interpretation of existing law, making this explicit in the claims procedure requirements is important.

HHS and DOL should also require that, for any adverse benefit determination relating to MH/SUD, the adverse benefit determination and explanation of benefits should contain clear instructions on how to request and receive any NQTL compliance analysis(es) related to the determination. The requirements should include phone number, email, and address where such a request could be submitted, including on an expedited basis to enable the submission of meaningful urgent appeals and requests for expedited external reviews. MHLG also supports the Departments' suggestion that, should a plan/issuer deny authorization for a specific level of care, the plan/issuer must identify a lower level of care that it believes would be more appropriate, along with information related to the coverage of such service in the plan and the availability of network providers to deliver the lower level of service. We also support the Departments' suggestion that the plan/issuer provide an explanation of how a particular NQTL was applied to particular benefits.

Finally, HHS and DOL should put in place meaningful enforcement mechanisms to ensure that plans/issuers fulfill their obligation to provide participants/beneficiaries with legally required information, upon request. We believe meaningful consequences must include automatic reversal of any adverse benefit determination associated with the request. A potential mechanism is directing independent review organizations (IROs) to automatically reverse adverse benefit determinations when plans fail to provide claimants with any information requested during the internal and/or external appeals process. Otherwise, the claims' procedure requirements to provide information are toothless, and the external appeal process is a meaningless alternative to litigation.



HHS Must Propose and Finalize MHPAEA Rules for Medicaid

While MHLG appreciates the 2023 Proposed Rule, which affects individual and group health plans, it is imperative that HHS move quickly to propose and finalize rules for Medicaid managed care, the Children's Health Insurance Program (CHIP), and Alternative Benefit Plans (ABPs) without delay after the finalization of this proposed rule. The Administration must not allow a strong set of MHPAEA rules for individuals in individual and group plans, but a weaker set of rules for individuals in Medicaid managed care, CHIP, and ABPs. This is particularly critical given that these plans serve lower-income individuals and families who are disproportionately Black, Latino, Native American, and from other marginalized and underserved communities. Many of the entities that serve as Medicaid MCOs also operate in the state-regulated insurance markets and serve as TPAs for employer-sponsored plans. HHS must also finally hold state Medicaid agencies accountable for strong oversight, given most states' deeply inadequate MHPAEA enforcement efforts.

CONCLUSION

We have included numerous citations to supporting research, including direct links to the research. We direct the Departments to each of the materials we have cited and made available through active links, and we request that the full text of each of the studies and articles cited, along with the full text of our comment, be considered part of the formal administrative record for purposes of the Administrative Procedure Act. If the Departments are not planning to consider these materials part of the record as we have requested here, we ask that you notify us and provide us an opportunity to submit copies of the studies and articles into the record.

Thank you for the opportunity to comment on this important issue. If you have further questions, please contact David Lloyd, Chief Policy Officer of The Kennedy Forum, at david@thekennedyforum.org or Lauren Finke, Policy Director, at lauren@thekennedyforum.org.

Sincerely,

The Kennedy Forum
American Art Therapy Association
American Association for Marriage and Family Therapy
American Association for Psychoanalysis in Clinical Social Work
American Association of Child and Adolescent Psychiatry
American Association of Psychiatric Pharmacists
American Association on Health and Disability
American Counseling Association
American Foundation for Suicide Prevention



American Psychiatric Association

American Psychological Association Services

American Society of Addiction Medicine

Anxiety and Depression Association of America

Association for Ambulatory Behavioral Healthcare

Centerstone

Children and Adults with Attention-Deficit/Hyperactivity Disorder

Children's Hospital Association

Clinical Social Work Association

Crisis Residential Association

Crisis Text Line

Depression and Bipolar Support Alliance

Employee Assistance Professionals Association

Families USA

First Focus on Children

Global Alliance for Behavioral Health and Social Justice

Huntington's Disease Society of America

IC&RC

Inseparable

International OCD Foundation

International Society for Psychiatric Mental Health Nurses

Lakeshore Foundation

Legal Action Center

Maternal Mental Health Leadership Alliance

Meadows Mental Health Policy Institute

Mental Health America

NAADAC, the Association for Addiction Professionals

NAMI - National Alliance on Mental Illness

National Association for Behavioral Healthcare

National Association for Children's Behavioral Health

National Association for Rural Mental Health

National Association of County Behavioral Health and Developmental Disability Directors

National Association of School Psychologists

National Association of Social Workers

National Association of State Mental Health Program Directors

National Board for Certified Counselors (NBCC)

National Council for Mental Wellbeing

National Eating Disorders Association

National Federation of Families

National Register of Health Service Psychologists

NHMH - No Health without Mental Health

Policy Center for Maternal Mental Health



Postpartum Support International
Psychotherapy Action Network
REDC
RI International
SMART Recovery
The Jed Foundation
Tourette Association of America
Treatment Communities of America
Vibrant Emotional Health