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October 13, 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:

On behalf of the American Society of Addiction Medicine (ASAM), a national medical specialty society representing more than 7,000 physicians and associated health professionals who specialize in the prevention and treatment of addiction, thank you for the opportunity to provide comments on the Department of Health and Human Services (HHS), 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"). The 2023 Proposed Rule sets an important benchmark in the provision of care for people with substance use disorders. As people across the United States continue to experience the crushing toll of the addiction and overdose crisis through the loss of family members, friends, and loved ones, ASAM 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 stated 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 that disparately limit access to MH/SUD services.

To realize the promise of the 2023 Proposed Rule's many strong provisions, however, the Department should eliminate the proposed exceptions relating to "independent professional medical or clinical standards" and "fraud, waste, and abuse." To be clear, ASAM supports requirements for plans/issuers to follow independent professional medical/clinical standards (generally accepted standards of care), and it is critical to combat fraud, waste and abuse to safeguard the health and well-being of consumers. However, as proposed, the 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, the proposed exceptions are not firmly based in MHPAEA's statutory text, and the underlying legitimate issues are most appropriately and effectively addressed within the existing (and proposed) NQTL rules.

In addition, as you consider ASAM's comments to improve the 2023 Proposed Rule, ASAM urges you to take additional steps to hold plans and issuers accountable. These additional steps include (1) seeking an amendment to the Employee Retirement Income Security Act (ERISA) to allow DOL to assess civil monetary penalties against covered health insurance issuers, plan sponsors, and plan administrators for violations of federal parity law; (2) using existing authority to prohibit plans and issuers from imposing NQTL limitations when they cannot affirmatively demonstrate that the NQTLs for MH/SUD care are no more restrictive as written or in operation when compared to M/S benefits; (3) using existing authority to levy taxes on any failure to meet group health plan requirements under <u>26 U.S. Code § 4980D</u>; and (4) further enforcing parity protections in all Medicaid managed care, the Children's Health Insurance Program (CHIP), and Alternative Benefit Plans (ABPs), as well as working with state Medicaid agencies to help ensure compliance and accountability.

ASAM's full comments are set forth below.

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)

ASAM 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 "<u>scope or duration of</u> <u>treatment</u>." 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.

While plans and issuers may argue that treatment limitations that place a greater burden on access to MH/SUD care are nonetheless compliant with the existing rules, 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 have lost sight of an obvious, fundamental premise of MHPAEA: the degree to which a "treatment limitation," in fact, limits access to MH or SUD treatment. ASAM strongly supports 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 is to describe only the limitations placed upon benefits – not to compare the 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, to clarify that "benefit classification group" will continue to be how MHPAEA compliance is evaluated.

Examples of potentially discriminatory payer practices reported by ASAM members are described herein in bold; they include low reimbursement that do not cover operational costs, burdensome network admission standards/processes, and burdensome prior authorization, step-therapy, or medical necessity reviews.

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

ASAM 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, ASAM agrees 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, then plans/issuers may not apply the NQTL to MH/SUD benefits within a classification of care, then a plan/issuer must 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.

Reported examples of harms due to commonly applied treatment limitations (e.g., prior authorization, concurrent review, retrospective review) on MH/SUD benefits that are potentially more restrictive than what happens on the M/S side include:

- increased fatal overdose, withdrawal, and suicide risks for patients with SUD, as well as increased risk of incarceration and return to use of unregulated drugs, due to time-consuming prior authorizations on addiction medications or payer requirements for stable patients to transition from their injectable buprenorphine back to sublingual buprenorphine;
- increased risk of contracting hepatitis or HIV due to delays in, or denials of, patient access to addiction medications;
- increased out-of-pocket costs for patients with SUD due to quantity and dosing limitations on addiction medications (resulting in some patients committing crimes to pay for out-ofpocket costs for their addiction medications);
- increased risks to patient health when coverage for branded MH medication coverage is conditioned on patients first "failing" on at least two generic options;
- increased travel times for patients needing injectable addiction medication because of burdensome prior authorizations for these medications (and related logistics/care coordination); the associated level of administrative burden imposed by some payers dissuades more medical practices from delivering this type of therapy; there are reports of patients needing to drive up to 4 hours to receive their monthly injections of addiction medication from a provider who is willing to hire the administrative staff necessary to manage the administrative burden imposed by some payers for covering these types of medications;
- wasting of valuable clinician and clinic staff time/causing clinician burnout due to (a) prior authorizations on addiction medications; (b) routine denials of residential levels of addiction care, and (c) burdensome documentation requirements for billing case management services for patients with SUD.

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

ASAM 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 is deeply flawed and may 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 providers under the existing regulations indicates that some 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 disorders in the interim final regulations.

The Departments also confirmed that a panel of experts convened by 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.

ASAM urges 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 (as

well as fraud, waste and abuse 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 one were to believe that an "independent professional medical or clinical standards" exception were theoretically appropriate or workable, ASAM has 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)(ii)(B), and (c)(4)(iv)(D). If the Departments permit this to occur, then 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 MH/SUD care. In fact, the exception could 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, ASAM urges 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 are adopting 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</u> <u>Mexico</u>. We support the following version of these 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.

ASAM notes 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 companies), "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 payers/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. For example, in the case of medical necessity, utilization management, and appeals decisions concerning service type, service, intensity, level of care, continued stay, and transfer for SUD, a key nonprofit criterion is <u>The American Society of Addiction Medicine (ASAM) Criteria</u>, which has been converted into a structured, interactive tool, called <u>The ASAM Criteria Navigator</u>, for medical review processes for patients with SUDs.

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 can be subjected to rigorous peer review, validation studies in real-world clinical settings and reviewed in professional and scholarly journals.

In fact, as early as 1997, <u>research published in the American Journal of Psychiatry</u>, the official, peerreviewed 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.
- **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. In the case of SUD care, 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*, as well as the average length of stay/treatment units and denial rates by each of these levels of care.

• Prohibit plans/issuers from withholding their criteria/guidelines for MHPAEA review. We have heard 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 <u>2023 MHPAEA Report to Congress</u> 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, the Departments can advance this important issue without allowing plans/issuers to continue practices that will inhibit access.

Reported examples of plans limiting/denying services that are medically necessary in a manner that are not consistent with generally accepted standards of care include:

- limiting dosing amounts of buprenorphine for opioid use disorder treatment, which are not consistent with <u>current studies and guidelines in the era of high-potency synthetic opioids</u>, particularly among the pregnant patient population (which leads to some patients bearing out-of-pocket payment for buprenorphine dosages above 24mg/day or experiencing insufficient craving coverage and return to use);
- capping the number of months that a patient is covered for injectable buprenorphine (resulting in a return to use while on sublingual buprenorphine);
- denying payment for counseling services for trauma survivors (which leads to return to use);
- denying/delaying coverage for psychiatric medications when prescribed by an SUD provider who is also starting the patient on an addiction medication;
- requiring patients to return to use of unregulated drugs before meeting criteria for admission to any residential treatment (exposing patients with severe SUD histories to unnecessary risk);
- denying residential placement for long term stability because the child has not first tried IOP or PHP, notwithstanding that a child or adolescent may have been hospitalized four or more times in the last few months and even when the child may be continuously running away from home and engaging in self-harm, suicide attempts, or substance use, and it is clearly not safe for the child to spend nights at home while attending daytime-only programming; and
- denying care for 17-year-old adolescents, because they are too close to turning 18 and would have to terminate the program once they turn 18; as a result, for the remainder of their 17th year (could be 6 months or more), they remain untreated and at risk.

"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. ASAM strongly supports efforts to ensure that individuals needing MH/SUD care receive 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, health plans may seek to exploit claims of "fraud, waste, and abuse" to deny or otherwise limit access to medically necessary care. Plans/issuers may switch 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, ASAM does 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. The Departments have not 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.

Reported examples of how health plans exploit ambiguities to limit access to MH/SUD treatment or how they use claims of "fraud, waste, and abuse" to deny care or put burdensome requirements on providers that result in providers not wanting to participate in plan networks or take insurance include:

- denying reimbursement for MH/SUD treatment if care is not being delivered at a preidentified subset of medical facilities; and
- requiring excessive paperwork to 'show medical necessity' in the name of preventing 'fraud, waste, and abuse,' which can be too cumbersome for the average private practitioner to participate in their networks with federal privacy laws, meaningful use, and other IT requirements for electronic records (and each network having their own version of these), providers must either hire mid-level support staff to assist or limit the number of networks in which they participate.

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

ASAM supports 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 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." If the Departments identified "scope of covered services" as an NQTL, then they would remove any doubt 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.

Reported examples of fundamental services that are not covered for SUD benefits include counseling services (in conjunction with addiction medications); case management services in the context of outpatient care, and injectable buprenorphine. In addition, while standard treatment (i.e., brief counseling, often over a 1-800 telephone Quitline) and pharmacotherapy (often over-the-counter with no professional input or guidance from a prescriber) for tobacco use disorder (TUD) has been quite successful, those who have some of the most persistently high prevalence rates of cigarette smoking and vaping have been persons with mental illnesses or persons with SUD other than tobacco. Brief counseling and nicotine replacement therapy is often not enough intensity of service to assist these individuals to enter and sustain tobacco remission and recovery. With SUDs other than TUD, when the intensity of service has not resolved the condition adequately, the patient is referred to a higher level of care. This is not the case for TUD, which is treated differently than other SUDs by many health plans today. ASAM Level 2 and Level 3 care should be available for patients with TUD and covered when medically necessary. Utilization management for application of benefits to persons being treated for TUD should meet MHPAEA requirements.

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

ASAM 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 rely 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 Physician Fee Schedule (PFS). 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 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.

ASAM members report inadequate networks of practitioners able to provide psychotherapy and counseling services to patients with MH/SUD - ironically, leading to relatively easier access to innetwork psychiatrists and medications without behavioral interventions – due to low reimbursement rates for these non-physician practitioners.

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

ASAM 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. 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.

ASAM also strongly supports 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, then 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)

Inadequate networks are one of the most significant barriers to individuals accessing needed MH/SUD care. Thus, ASAM strongly supports 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 innetwork mental health and substance use disorder benefits as compared to in-network medical/surgical benefits in a classification." This strong requirement should be maintained.

Reported examples of how payer practices perpetuate inadequate networks for SUD case include:

ASAM physician members, who (1) are not psychiatrists, (2) are <u>addiction specialist physicians</u> (<u>ASPs</u>) and (3) provide medical services for pain, have reported that certain health plans impose limitations on their ability to be credentialed in their behavioral health network. This situation can result from the structure of payer networks where behavioral health services - as defined to include MH/SUD care - are in a different payment bucket than traditional medical health services. This process of "carving out" the management of the behavioral health benefit can lead to parallel management, with parallel credentialing processes. This can be true even when one payer enterprise has both behavioral health and medical health arms – i.e., they still may be largely managed in silos. One payer has indicated that "dual citizenship" is not permitted by the payer for these types of physicians, but the traditional medical side of the payer can provide a special "notation" for such physicians providing pain care services, permitting buprenorphine for opioid use disorder (OUD) service reimbursement under the traditional medical plan. ASAM asked this payer whether such a "notation" process is regularly advertised by the medical plan to these physicians, and whether it is limited to the provision of buprenorphine for OUD. No direct response has been received to date.

By way of background, credentialing and billing for specific services depends on which bucket an individual clinician will be utilizing. An ASAM member who is a psychiatrist and an ASP, may have less trouble gaining credentials to provide MH/SUD treatment services through the behavioral health network than an ASP who is not a psychiatrist. However, such a member may have more difficulty gaining credentials to participate in the medical network, because they are a psychiatrist. This is challenging when the ASP needs to bill CPT codes for medical services provided but cannot as they are considered "out of network" under a particular bucket.

A billing claim for any CPT/HCPCS code includes the service provided, to whom, by whom, for what diagnosis, where and when. A psychiatrist billing for an appendectomy under the behavioral health plan will not be paid, as the service does not match the provider, and is not a covered service by the behavioral health plan. At the same time, an OB/GYN who is an ASP, billing to treat SUD under the traditional medical plan, may also not be paid for analogous reasons. If an OB/GYN (who may or may not be board-certified in addiction medicine) attempts to bill under the behavioral health benefit, they may be told that OB/GYNs are covered under the medical (not behavioral health) plan. It has been reported that some primary care physicians who do office based opioid treatment (OBOT) do not advertise this fact as part of their normal, day practice. Rather, they may run a self-pay-only OBOT clinic (which can include some of their regular patients) on certain afternoons or evenings. Unfortunately, we do not have an "easy" system where any willing provider can deliver appropriate SUD care and be paid for it.

These kinds of issue are specific to physicians delivering MH/SUD care. By way of contrast, a licensed non-ASP, physician may cover a shift at the emergency department or urgent care and be reimbursed for those services under the medical plan, but the same is not so easy when it comes to that same physician covering a shift in an addiction treatment office or center. As noted above, some ASAM members are board certified in Pain Medicine and Addiction Medicine. In the case of these physicians, they may be considered in-network with all these payers' traditional medical plans for pain care services and do not have a problem getting reimbursed for M/S services but cannot get reimbursed for MH/SUD services under the behavioral health plan.

Ironically, it has also been reported that advanced practice clinicians (i.e., nurse practitioners and physician assistants) can more easily contract under both the medical and behavioral health plans. Speculation is that because they have less education, they are not expected to have a specialty, and, therefore, are excluded from insurer credentialling practices that require a physician to pick a specialty. At the same time, we have heard that some commercial health plans may allow ASPs to contract under the behavioral health benefit but exclude non-ASP physicians (other than psychiatrists) from doing so, while allowing payment to mid-level practitioners for providing these services.

One ASAM member has reported that they had a discussion with a psychiatrist medical director within a Medicaid behavioral health plan in Florida who would not cover any physician providing SUD care except board-certified psychiatrists. After some discussion, the medical director allowed primary boarded *primary care* physicians who had a subspeciality certification in addiction medicine to bill the behavioral health plan for addiction services. At the same time, this medical director would <u>not</u> allow credentialling for ASPs who were part of other primary specialties. Notably, the member reported that this plan did allow for physician assistants and other mid-level provider to be credentialled and contracted to do SUD care.

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

ASAM 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 urges 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 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 evaluate NQTLs more carefully as they design and apply plan benefits and during the comparative analysis.

Meaning of Terms - (a)(2)

ASAM 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.

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)

We support the revisions to the list of NQTLs, including relating to "network composition," and the clarification that this list is "non-exhaustive." As referenced above, we urge the Departments to add "scope of covered services" as an identified NQTL.

Provisions of Other Law - (d)(3)

We urge 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: "<u>All requested plan</u> information shall be made available to claimant and may not be withheld as proprietary or <u>commercially protected information</u>." It is

important that obligations of plans/issuers be made as explicit as possible wherever they appear.

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

ASAM 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 <u>sentence</u> 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 may refuse 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 by preventing selective citation of the proposed regulations.

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

ASAM 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 <u>their public-sector employer</u> <u>affirmatively opted-in to discriminating against individuals needing MH/SUD services</u>.

We urge HHS 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." While ASAM agrees with the Departments concern about this issue, 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 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 must be prohibited. 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>.

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 a similar approach in 2001 when it required healthcare 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 oblige 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 a contract - with any TPA they hire - which 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 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 full 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 MH/SUD 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 <u>California</u>, <u>Virginia</u>, and <u>Washington</u>, have recently required health plans to cover MH/SUD crisis services. Washington has made clear that <u>coverage of MH/SUD crisis services is necessary for health plans to comply with MHPAEA</u>. HHS should include MH/SUD crisis services within the MH/SUD EHB category. Additionally, when finalizing this rule, we encourage 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. We urge 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.

ASAM members report patients and clinicians spending significant amounts of time on making multiple calls to determine whether a particular provider is in-network due to inaccurate provider directories (and finding months-long waiting lists when an in-network provider is finally identified). In addition, ASAM members who are non-psychiatrist, addiction specialist physicians report that provider directories often list only their primary board (e.g., family medicine) but do not indicate that they are also an addiction specialist.

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, HHS and DOL must strengthen enforcement with existing claims procedure requirements. 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.

ASAM 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.

ASAM members report receiving confusing denial letters that do not provide critical information to understand why requested services were not approved in full or the rationale. For example, if a medication is denied, sometimes no reasons are given, and no acceptable alternatives are provided.

HHS Must Propose and Finalize MHPAEA Rules for Medicaid

While we appreciate 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 from 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

ASAM has included numerous citations to supportive research, including direct links to the research. 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. Thank you for the opportunity to comment on this important issue. If you have further questions, please contact Kelly Corredor, Chief Advocacy Officer at the American Society of Addiction Medicine, at kcorredor@asam.org.

Sincerely,

Brian Hurley, MD, MBA, FAPA, DFASAM President, American Society of Addiction Medicine