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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: Requirements Related to the Mental Health Parity and Addiction Equity Act (File Code 1210-AC11)

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

On behalf of the American Medical Association (AMA) and our physician and medical student members, the AMA is pleased to offer comments on the U.S. Department of Health and Human Services (HHS), Employee Benefits Security Administration (EBSA), and the Internal Revenue Service (IRS) proposed rule, "Requirements Related to the Mental Health Parity and Addiction Equity Act (MHPAEA)." The AMA strongly supports all efforts to meaningfully enforce the MHPAEA. By every indicator, health plans subject to MHPAEA continue to fail to meet the law's requirements by a wide margin, exacerbating the nation's drug-related overdose and death epidemic, as well as the mental health crises affecting the nation. Without significant—and increased—authority to hold health plans accountable for MHPAEA violations, there is little reason to expect health plans will take any action to improve access to evidence-based care for individuals with a mental illness or substance use disorder (SUD). **Accordingly, while the AMA supports many of the proposals in this rule, enhanced enforcement of all of the MHPAEA's provisions, including those existing and proposed in this rule, is essential to realize the promise of MHPAEA.** We offer more detailed recommendations of opportunities for enhanced enforcement, as well as detailed comments on select areas of the proposed rule in the comments that follow.

Enhanced MHPAEA Enforcement

At its core, the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 was designed to help ensure that patients enrolled in certain health insurance plans receive and can access benefits and treatment for a mental health or substance use disorder (MH/SUD) on par with what they would receive for medical/surgical benefits. If coverage or access for MH/SUD benefits or care is

more restrictive, it should trigger a warning that a parity violation may exist. Overall, the AMA supports the proposed rule's clear intent to increase access to MH/SUD treatment. However, as stated throughout these comments, we believe the Departments' enforcement provisions need to go further.

MHPAEA has been in effect since 2008, and multiple improvements have been made to clarify the law's requirements in the past 15 years. As detailed in the proposed rule, various administrations have issued regulatory guidance, sub-regulatory guidance, and frequently-asked-questions (FAQs) on the law. Multiple administrations have engaged in considerable outreach with health plans, third-party administrators (TPAs), and others to try and help plans come into compliance with MHPAEA, including providing technical assistance, additional FAQs, and further guidance, including this proposed rule. The AMA applauds these efforts, while acknowledging that nearly all plans and issuers continually and routinely fail to comply with the law, including not even being able to provide accurate or sufficient information to regulators to evaluate compliance, which the proposed rule acknowledges. The introduction to the proposed rule makes the failures clear, saying that "despite this unprecedented outreach, plans and issuers continue to fall short of MHPAEA's central mandate to ensure that participants, beneficiaries, and enrollees do not face greater barriers and restrictions to accessing benefits for mental health conditions or substance use disorders than they face when accessing benefits for a medical condition or surgical condition." The AMA supports the proposed rule's efforts to clarify how non-quantitative Treatment Limitations (NQTLs) must be evaluated for parity compliance and reported to regulators, and we urge the Departments to reject plans' repeated claims that MHPAEA is too complicated.[1,2] After witnessing recurrent patient harm resulting from 15 years of health plans' repeated violations of MHPAEA, the AMA commends the Departments for taking a more assertive approach to enforce the law's patient protections.

Failure to comply with the parity law means that individuals with a mental illness or substance use disorder often have their care delayed and/or denied, which can have tragic consequences, including death by suicide, relapse, withdrawal, overdose, and death. The data underscoring these tragedies is staggering. In 2021, more than 57 million U.S. adults experienced a mental illness, but less than 50 percent received treatment, and nearly 35 percent of U.S. adults with a serious mental illness received no treatment.[3] According to Centers for Disease Control and Prevention (CDC) data, suicide was responsible for 48,183 deaths that year, and "suicide was the second leading cause of death for people ages 10-14 and 20-34."[4] For every death by suicide, there were hundreds of thousands of hospitalizations for self-harm and emergency department visits.

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[1] See for example, "As families struggle to get behavioral health coverage, enforcement of parity laws lags." Modern Healthcare. May 19, 2018. Available at https://www.modernhealthcare.com/article/20180519/NEWS/180519900/as-families-struggle-to-get-behavioral-health-coverage-enforcement-of-parity-laws-lags.

[2] See, for example, testimony to the National Association of Insurance Commissioners from representatives of America's Health Insurance Plans, the Association for Behavioral Health and Wellness, and the Blue Cross Blue Shield Association. NAIC Regulatory Framework (B) Task Force. March 25, 2021. Available at https://content.naic.org/sites/default/files/call_materials/Regulatory%20Framework%20TF%20Minutes_0.pdf.

[3] Mental Health By the Numbers. National Alliance on Mental Illness. Available at https://www.nami.org/mhstats.

[4] Facts About Suicide. Centers for Disease Control and Prevention, National Center for Injury Prevention and Control. May 8, 2023. Available at https://www.cdc.gov/suicide/facts/index.html.

For children, concerns about the lack of access to evidence-based care for mental health and addiction services also has long been a problem. The COVID-19 pandemic brought many of those issues to the forefront. Beginning in April 2020 at the outset of the COVID-19 Public Health Emergency, the proportion of children's mental health–related ED visits among all pediatric ED visits increased and remained elevated through October. Compared with 2019, the proportion of mental health–related visits for children aged 5–11 and 12–17 years increased approximately 24 percent and 31 percent, respectively,[5] underscoring the increased need for mental health services for our nation's youth, as these challenges still exist today.

The AMA appreciates that the proposed rule seeks to expand oversight and enforcement of NQTLs. However, if health plans truly wanted to play a constructive role in increasing access to MH/SUD care, they would simply remove NQTLs. By their very design, NQTLs—whether by prior authorization, concurrent or retrospective payment review, or limited formulary design—inherently limit and restrict access to care. This is not new to health insurance companies, as research showing wide disparities between medical/surgical and MH/SUD care has long existed.[6]

There are nearly 44 million people aged 12 or older who need treatment for a substance use disorder, but only about 6 percent of people received any treatment, according to the Substance Abuse and Mental Health Services Administration (SAMHSA).[7] There are many reasons why individuals with an SUD do not receive treatment, but access to timely, evidence-based, affordable care continues to be a key, structural barrier.[8] The AMA acknowledges that not all individuals with an SUD want to begin treatment, but we also note that 87 percent of individuals with an SUD had either private coverage, Medicaid, Medicare, or other forms of insurance.[9] At a time when more than 100,000 Americans are dying each year from a drug-related overdose, and more than 640,000 Americans have died of a drug-related overdose since 2014,[10] the AMA believes that every barrier—NQTL and otherwise--must be removed to help increase access to timely, affordable, evidence-based care for SUD.

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[5] Leeb RT, Bitsko RH, Radhakrishnan L, Martinez P, Njai R, Holland KM. Mental Health–Related Emergency Department Visits Among Children Aged <18 Years During the COVID-19 Pandemic — United States, January 1–October 17, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1675–1680. DOI: http://dx.doi.org/10.15585/mmwr.mm6945a3external icon.

[6] See, for example, Addiction and Mental Health vs. Physical Health: Widening disparities in network use and provider reimbursement. Milliman Research Report. November 19, 2019. Available at https://www.milliman.com/-/media/milliman/importedfiles/ektron/addictionandmentalhealthvsphysicalhealthwideningdisparitiesinnetworkuseandproviderreimbursement.ashx.

[7] 2021 National Survey of Drug Use and Health. U.S. Substance Abuse and Mental Health Services Administration. Highlights and key data available at https://www.samhsa.gov/data/sites/default/files/2022-12/2021NSDUHFFRHighlights092722.pdf.

[8] Medications for Opioid Use Disorder Improve Patient Outcomes. The Pew Charitable Trusts. December 17, 2020. Available at https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2020/12/medications-for-opioid-use-disorder-improve-patient-outcomes.

[9] See Table 5.8B – Drug Use Disorder in Past Year: Among People Aged 12 or Older; by Age Group and Geographic and Socioeconomic Characteristics, Percentages, 2021. 2021 National Survey of Drug Use and Health. U.S. Substance Abuse and Mental Health Services Administration.

[10] Ahmad FB, Cisewski JA, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2023. Available at https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.

It is also important to consider some of the more disturbing features of the epidemic:

- **Youth are dying at increasing rates.** Comparing overdose rates in July-December 2019 to July-December 2021, researchers found that "median monthly overdose deaths among persons aged 10–19 years increased 109 percent; [and] deaths involving illicitly manufactured fentanyl increased 182 percent."
- **Overdoses among pregnant people are on the rise.** From 2017 to 2020, there was a relative increase of 81 percent in pregnancy-associated overdose mortality. Researchers found the increases in 2020 "were more pronounced than increases during any prior year."[11]
- **American Indian and Alaskan Native men aged 15-34 are dying at the highest rate for younger men.** From March 2021 to August 2021, the age-adjusted death rate was 42 per 100,000 cases involving any drug, compared to 20.5 per 100,000 during the same time period in 2018.[12]
- **Older Black men are dying at the highest rates overall from overdoses.** From March 2021 to August 2021, non-Hispanic Black or African American men aged 35-64 had an age-adjusted death rate of 61.2 per 100,000; an increase from 30.6 per 100,000 during the same time period in 2018. In comparison, the age-adjusted drug overdose death rate for white males increased from 26.6 per 100,000 to 40.7 per 100,000 during the same time periods, respectively.[13]

Any policy, such as prior authorization that restricts access to evidence-based care for a SUD will cause these trends to continue to worsen. When prior authorization policies are applied to SUD benefits, for example, it often results in delayed or denied care, as well as treatment abandonment, which can lead to relapse, painful withdrawal, overdose and death.[14] **This is why the AMA strongly urges all health plans and policymakers to support removing all prior authorization, step therapy or other harmful utilization management for medications to treat opioid use disorder (MOUD) altogether.** As described in more detail below, **the AMA similarly urges increased scrutiny of how health plans use prior authorization and other NQTLs to delay and deny care for treatment of OUD.**

While the AMA remains at a loss to explain why health plans continue to use NQTLs in ways that openly violate the MHPAEA, the AMA urges the Administration to increase actions to hold plans and issuers accountable in a meaningful way for their repeated violations of the law. We have several specific recommendations:

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[11] Bruzelius E, Martins SS. US Trends in Drug Overdose Mortality Among Pregnant and Postpartum Persons, 2017-2020. *JAMA.* 2022;328(21):2159–2161. doi:10.1001/jama.2022.17045.

[12] Han B, Einstein EB, Jones CM, Cotto J, Compton WM, Volkow ND. Racial and Ethnic Disparities in Drug Overdose Deaths in the US During the COVID-19 Pandemic. *JAMA Netw Open.* 2022;5(9):e2232314. doi:10.1001/jamanetworkopen.2022.32314.

[13] Han B, Einstein EB, Jones CM, Cotto J, Compton WM, Volkow ND. Racial and Ethnic Disparities in Drug Overdose Deaths in the US During the COVID-19 Pandemic. *JAMA Netw Open.* 2022;5(9):e2232314. doi:10.1001/jamanetworkopen.2022.32314.

[14] CDC in a 2018 report emphasized that when prior authorization is required, "A patient may lose interest, lose access to their doctor, lose transportation, suffer an injury, or even die from an overdose." Evidence-Based Strategies for Preventing Opioid Overdose: What's Working in the United States An introduction for public heath, law enforcement, local organizations, and others striving to serve their community. U.S. Centers for Disease Control and Prevention. 2018. Available at https://www.cdc.gov/drugoverdose/pdf/pubs/2018-evidence-based-strategies.pdf.

- First, the AMA urges the Administration to seek Congressional authority to give the U.S. Department of Labor (DOL) the authority to levy civil monetary penalties against plans that do not comply with the law,[15] including significant daily fines for failure to submit sufficient comparative analyses when requested.
- Second, the AMA urges that the DOL, HHS and IRS use existing authority to prohibit plans and issuers from imposing NQTLs for mental health (MH) or SUD services if they cannot affirmatively demonstrate that they are no more restrictive as written or in operation when compared to medical/surgical benefits.
- Third, the AMA urges that the IRS use its existing authority to levy fines against violations from single employer or multiple employer plans up to $500,000.[16]
- And finally, we urge the Administration to continue efforts to enforce MHPAEA, including extending its enforcement protections to all Medicaid managed care programs, 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.

After 15 years of health plans' MH and SUD parity violations, the AMA urges the Administration to take these more aggressive steps as part of its broad strategy to increase access to evidence-based care for patients with a mental illness or SUD. Plans' failures have likely harmed millions of their enrollees, and without ramped-up enforcement, there is little reason to think their future behavior will be any different.

Data Collection on Parity and Network Adequacy

The AMA agrees with the proposed requirement that plans analyze the impact of an NQTL on access to MH/SUD services as part of a 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.

The July 2023 DOL/HHS/IRS Report to Congress made clear that "most comparative analyses failed to evaluate the relative stringency of how the NQTL was applied to mental health or substance use disorder benefits versus medical/surgical benefits." If plans cannot—or do not—sufficiently evaluate current effects of NQTLs—it is unclear how they will evaluate additional requirements. This is not to say that additional reporting and compliance requirements are not needed. Quite the contrary, **the AMA urges that when a plan fails to meet the existing requirement to evaluate coverage of MH/SUD services relative to medical/surgical services, the plan be held accountable through the imposition of fines and prohibition against using the NQTL until the plan can demonstrate compliance with the law.**

Throughout the proposed rule, the Departments ask for comment on extending parity requirements to many different types of NQTLs. The AMA generally supports a broad interpretation of whether a process, factor, utilization management protocol, condition, term, benefit, or any other aspect of an NQTL limits or restricts access to care for MH/SUD as compared to medical/surgical care. We further support the

[15] The AMA, in a February 1, 2022, letter to The U.S. Senate Committee on Health, Education Labor and Pension, urged similar action. See, https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2022-2-1-Letter-to-Congress-re-MHPAEA-Murray-and-Burr-final.pdf.

[16] See, 26 USC 4980D: Failure to meet certain group health plan requirements.

Departments' focus on disparities in reimbursement for MH/SUD treatment providers, evidentiary standards, network adequacy standards, benefit and formulary design including for certain populations and sub-populations, including racial and ethnic minorities, other types of historically marginalized or underserved communities, and pediatric populations. The AMA supports the Departments' proposal that plans and issuers evaluate outcomes data for NQTLs as part of a reasonable parity audit to ensure that NQTLs imposed by plans are not more restrictive or have disparate impacts on MH/SUD services. **In particular, we recommend that plans be required to report approval and denial rates, reasons for denial, appeal rates, and denials overturned upon appeal for prior authorization and other utilization management programs and compare these outcomes data for MH/SUD care vs. those for medical/surgical treatment.** These—and other proposals in the rule directing plans to evaluate NQTLs—are no more than extensions of the central purpose of MHPAEA—which is to ensure MH/SUD coverage and care is on par with medical and surgical coverage and care.

Defining Independent Professional Medical or Clinical Standards with Greater Specificity

The AMA urges changes to the proposed exceptions relating to "independent professional medical or clinical standards." The language proposed is too general and could be exploited by health plans to patients' detriment. The AMA highlights that several states have taken action on this issue by adopting a strong definition of "generally accepted standards of care" for MH/SUD services. Strong definitions have been enacted, for example, in Illinois, California, Georgia, and New Mexico.

The AMA supports[17] the following definition for "generally accepted standards of care" to be used for the definition of "independent professional medical or clinical standards," which has been adopted from the state laws noted above:

> "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."*

Under the proposed rule, "independent professional medical or clinical standards" could allow for nontransparent, proprietary criteria created and licensed by for-profit publishers to establish "the independent professional medical or clinical standards." There are multiple problems that could arise from health plans exploiting the proposed standards as currently loosely defined. For example, plans could argue that their criteria are developed "independently" even if influenced by or created out of financial self-interest of the publishers seeking continued licensing agreements with managed care organizations. Plans could also claim that their criteria are "peer-reviewed," but without identifying or

[17] See, for example, AMA statement applauding enactment of California Senate Bill 855, which provides a definition of "generally accepted standards of care" consistent with this recommendation. https://www.ama-assn.org/press-center/press-releases/ama-applauds-california-s-groundbreaking-mental-health-reform-law.

vetting reviewers for their purported expertise or potential conflicts of interest, it is impossible to gauge the academic rigor or non-bias methods of these so-called peer reviewers. Additionally, plans could say that the "independent" standards are "unaffiliated with plans and issuers" even if these companies communicate with payors/licensees about desired changes to their criteria.

The AMA views objectively "independent professional medical or clinical standards" as standards developed and published by professional, nonprofit medical associations such as the American Society of Addiction Medicine (ASAM) Criteria and the age-specific Level of Care Utilization System (LOCUS) family of criteria developed by the American Association of Community Psychiatrists and the American Academy of Child and Adolescent Psychiatry. These criteria are what medical professionals use to determine the best course of treatment and should be relied upon by the Administration when evaluating how an NQTL affects medical necessity determinations and all other NQTL considerations. **We urge the Departments to ensure that the final rule makes a clear distinction between standards established by evidence-based medical professionals compared to those created by plans, issuers, and others more concerned with limiting access to MH/SUD care and financial self-interest.**

The July 2023 Report to Congress highlights over and over that plans and issuers have failed to provide the evidentiary standards used to create an NQTL for MH/SUD compared to medical/surgical benefits. The types of evidentiary standards supported by the AMA are those that medical professionals use on a daily basis and should be the standard applied when considering the care that patients receive for MH/SUD and medical/surgical care. Using a consistent standard as we recommend provides multiple benefits:

- **Full transparency and accessibility.** Consumers, providers, and other stakeholders could readily access the criteria being used to determine whether specific MH/SUD services are, in fact, appropriate to meet individual patient needs.
- **Protections 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.
- **External validation.** Nonprofit clinical criteria are subject to rigorous peer review, validation studies in real-world clinical settings, and are reviewed in professional and scholarly journals.
- **Consistency.** This consistent definition relying upon medical professionals' evidence-based guidance, moreover, would provide plans and issuers with the type of clear guidance they can use for employers and their employees. The AMA emphasizes that the standard of care for MH/SUD should not vary by state, or by plan, and we strongly urge the Administration to adopt this clear, consistent definition to guide MHPAEA enforcement.

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

- **Evaluate divergence from "independent professional medical or clinical standards."** Plans and issuers should be required to analyze how any MH or SUD criteria/guidelines they use diverge from "independent professional medical or clinical standards." Such analyses should be done for medical/surgical benefits within the classification of care and be subject to the NQTL comparability and stringency test.

- **Require specific data reporting for the medical necessity/appropriateness.** Such data should include the number of authorizations (and denials) 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 criteria/guidelines for MHPAEA review.** The July 2023 Report to Congress detailed numerous examples of regulators being unable to review the criteria, guidelines or other information related to an NQTL. The AMA strongly recommends that the Administration require plans and issuers to include such criteria and guidelines as part of their comparative analysis submissions. Failure to do so should subject the plans and issuers to the maximum daily fines until they comply. We again point out that using standards relied upon by the nation's physicians would promote consistency and integrity in the standards and process.

Fraud Waste and Abuse Exception

The AMA does not support the proposed exception relating to fraud, waste, and abuse. We endorse meaningful efforts to address fraud, waste, and abuse, but plans often cite fraud, waste, and abuse as reasons for their inappropriate and often dangerous prior authorization and other harmful utilization management policies and practices. Plans and issuers should not be allowed to use fraud, waste, and abuse as an excuse to deny or otherwise limit access to medically necessary care. Rather than create an exception, the AMA emphasizes the need for plans and issuers to rely upon the generally accepted standard of care as laid out by professional medical association guidelines. Just as the evidentiary standards and factors in analyzing medical/surgical benefits should be uniform, so should they be treated for comparing MH/SUD care. As detailed in the 2023 MHPAEA Report to Congress, investigators found that plans and issuers often claimed risk of fraud, waste, or abuse as a factor in applying prior authorization and other utilization management limitations on care.[18] Investigators further highlighted how plans and issuers "did not explain: identified those benefits; what evidentiary standards or processes were used; or whether such considerations were applied in a similar fashion to evaluate both MH/SUD benefits and medical/surgical benefits." The AMA understands the need to protect against fraud, waste, and abuse. At the same time, we do not support plans and issuers using this as a blanket excuse to simply deny care.

To combat fraud, waste, and abuse, plans and 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 medical/surgical benefits. 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. We agree that plans and issuers should have the ability to address fraud, waste, and abuse in the delivery of MH, SUD, and medical/surgical benefits. The AMA agrees with other commentators that **the appropriate vehicle for doing so in the parity context is through the NQTL design and application analysis, not a stand-alone exception.** If plans and issuers have strategies and processes for identifying fraud, waste, or abuse, they should use medical standards as the standard for evaluation—and ensure that plans and issuers are not imposing more stringent requirements for MH/SUD benefits as pre-text for simply delaying and denying care.

[18] MHPAEA Comparative Analysis Report to Congress. Department of Labor, Department of Health & Human Services, Department of the Treasury. July 2023. Available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf.

Prohibition on Discriminatory Factors and Evidentiary Standards

We strongly support the proposed provision that would prohibit a plan/issuer from relying on any factor or evidentiary standard if it discriminates against MH/SUD benefits. This provision is vital to ensuring that plans and issuers, in designing and applying any NQTL, do not attempt to rely on a factor or evidentiary standard that is itself discriminatory. This can occur when plans or issuers use historic data or discriminatory structures as the basis for designing and applying an NQTL or metrics that have not been subject to MHPAEA. For example, plans commonly justify discriminatory reimbursement rates by citing the Medicare Fee Schedule. Medicare, however, is not subject to MHPAEA and has long undervalued MH/SUD services. Another example from the proposed rule itself is the application of discriminatory factors and evidentiary standards relating to plans requiring prior authorization for a prescription of buprenorphine to treat OUD. The proposed rule correctly states that the ASAM national practice guideline is the recognized professional medical standard, and that it "does not support prior authorization every 30 days" for the OUD medication, despite it being a common feature of many plans. This point also underscores why the Departments should remove exceptions for so-called "independent" standards. Finally, evidentiary standards based on internal plan information, such as utilization measures used to establish benchmarks and thresholds, may be discriminatory and flawed if based on historical, pre-MHPAEA data. For example, plans using historical data to establish limits on the number of allowable treatment days at a MH/SUD facility may be setting inappropriately low thresholds that do not comply with the MHPAEA.

Special Rule for NQTLs Related to Network Composition

Inadequate networks are one of the most significant barriers to individuals accessing needed MH/SUD care. The AMA strongly supports the rule's proposed provisions relating to "network composition," which would address many access-related issues, including a current lack of transparency surrounding MH/SUD networks. The AMA has consistently advocated for requiring payers to provide accurate, timely information about which providers in an enrollee's network are accepting new patients. This information should also be disaggregated by certain patient and population demographics to identify any inequities in care for certain populations or sub-populations, including pediatric populations, racial and ethnic minorities, or other types of historically disenfranchised or underserved communities. The AMA has pursued this type of action due largely to the fact that patients with a mental illness or SUD in particular routinely report an inability to access evidence-based care.

In addition, when plans and issuers evaluate SUD networks, the AMA urges that they be required to specifically gather data with respect to whether SUD providers prescribe any of the FDA-approved medications to treat SUDs. This is particularly important with regard to OUD given that methadone is only available in federally regulated Opioid Treatment Programs, and buprenorphine generally is only offered in office-based settings in the community. Given that these medications are considered the gold standard of care by addiction medicine physicians, an adequate network to treat OUD must have an adequate network of physicians who can prescribe these critical medications—and are actively accepting new patients. If a plan or issuer does not know whether a provider offers MOUD—and is actively accepting new patients—there is almost no way for the plan or issuer to confirm whether a network is adequate.

The AMA further supports the special rule that would automatically institute in-network composition for NQTLs "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" for a particular plan or issuer. This requirement should not only be maintained, but proactively enforced, again with patient demographics and sub-populations in mind.

Final Determinations of Noncompliance

The AMA strongly supports the provision giving the Secretaries the ability to direct plans/issuers not to impose an NQTL after a final determination of noncompliance. The AMA recommends, however, changing the "may" to a "shall" to indicate that the plan shall not be permitted to apply a non-compliant NQTL. Plans have been permitted for far too long to continue to use non-compliant NQTLs while MHPAEA investigators suffer through repeated delays due to plans' and issuers' failure to provide sufficient information requested—and required—by law. The AMA commends the Secretaries for their patience, but we believe that enough is enough.

We therefore recommend that the Departments consider more aggressive tactics given the scope of plans' violations for the past 15 years. Specifically, **the AMA recommends that if a plan does not provide sufficient information for a regulator to determine whether the plan is compliant with an NQTL's effect(s) on MH/SUD benefits or care, the plan should be prohibited from imposing the NQTL until such time that the plan does provide sufficient information to the regulators and the regulators confirm that the NQTL is in fact compliant.** Plans—not patients and physicians—should bear the burden of compliance.

The scope of the regulators' task in evaluating plans' submissions combined with the plans' failures year after year to provide sufficient information to regulators argues strongly for increasing plans' obligations for undertaking these mandatory analyses. In the July 2023 Report to Congress, the Departments make clear that they have far too few investigators to review the tens of thousands of plans they regulate. Of the 2.5 million health plans under DOL's EBSA jurisdiction, "EBSA has one investigator for every 7,700 health plans."[19] The AMA appreciates the collaborative approach the Departments attempt with plans to help bring them to compliance, but more decisive measures are needed in the face of rampant and ongoing noncompliance by health plans—a compliance failure that is widely acknowledged to have increasingly exacerbated harm to vulnerable populations that MPHAEA was enacted to protect. If a plan is not willing or able to perform its statutorily required comparative analyses for NQTLs, and then fails to provide sufficient information to regulators when asked, the AMA strongly recommends plans be prohibited from imposing those NQTLs until regulators can verify they are compliant. Plans' failures on this front are mere administrative tactics to delay and deny care to patients with a mental illness or SUD. Patients have waited long enough. The AMA urges this reasonable step to increase enforcement and compel compliance for patients' health and well-being for all.

Additionally, the AMA recommends that this authority to prohibit non-compliant NQTLs be extended to state departments of insurance. State departments of insurance have primary enforcement authority for state-regulated fully insured plans and have played a leading role in enforcing MHPAEA. Prohibiting plans from continuing policies of regular non-compliance that result in delayed and denied treatment for a mental illness or SUD is critical to helping to put teeth into MHPAEA compliance and enforcement—and will result in increased access to care for those with a mental illness or SUD.

[19] July 2023 Report to Congress.

Additional Provisions

There are many other areas of the proposed rule that the AMA supports. These include:

- Examples relating to prohibited exclusions of autism and eating disorder coverage.
- Definitions for "mental health benefits" and "substance use disorder benefits" to 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).
- Definitions for key terms such as "evidentiary standards," "factors," "processes," and "strategies." Adding definitions for these terms will help improve clarity by removing health plans' ability to claim they do not understand their meaning.
- Eliminating self-funded non-federal government plans' ability to opt out of MHPAEA. Hundreds of thousands of public employees and their family members will benefit from MHPAEA protections if this provision is adopted. Accordingly, when finalized, the AMA urges that the Departments immediately request plans' NQTL compliance analyses to ensure they are taking the necessary steps to comply with MHPAEA.
- Additional requirements for NQTL comparative analyses. The AMA generally supports the proposed additional details and requirements, including that the plan or issuer must inform their beneficiaries of corrective action plans, which will promote transparency and beneficiary engagement.
- Clarifying that "any applicable State authority" may request a comparative analysis to support state efforts to ensure and enforce parity requirements for patients.
- Holding TPAs accountable for MHPAEA compliance. The AMA urges that the final rule additionally requires plan sponsors to insert MHPAEA compliance provisions into their contracts with TPAs.
- For MH/SUD emergency services, the AMA supports the principle that if a plan/issuer covers physical health emergency services (including emergency medical services and emergency transport), it must cover comparable MH/SUD emergency/crisis services (including mobile crisis response) under the same standards, including no prior authorization or other barriers that lead to delayed or denied care.

Connection of parity violations to physician health and wellness

Health plans' violations of MH/SUD parity laws have far-reaching consequences. The AMA supports comments from the Dr. Lorna Breen Heroes' Foundation, which highlighted how greater parity enforcement can help reduce physicians' administrative burdens when treating patients with a mental illness or SUD. These burdens include prior authorization, step therapy, and trying to find a psychiatrist or addiction medicine physician or addiction psychiatrist within an inadequate network—all areas covered in the proposed parity rule. The AMA will continue to fight to remove all prior authorization policies for FDA-approved MOUD.

Administrative burdens, such as prior authorization, force physician offices to spend inordinate amounts of staff time and resources submitting paperwork to justify to health plan bureaucrats medically necessary care for their patients. Physicians train for at least 8-10 years to ensure that they provide their patients

with the standard of care, which is why the AMA recommended above ensuring that the generally accepted standard of care as put forward by professional medical associations is used as the standard by health plans. When health plans devise their own standards, the inevitable result is to force physicians to justify their reasoning for providing broadly accepted, evidence-based standards of care—typically so the health plan can delay treatment and possibly avoid payment. This pernicious use of NQTLs to delay and deny care is devastating to patients' health and well-being—as well as to physician practices. For a child with a treatable mental health condition, prior authorization causes unnecessary—and preventable—harm and trauma,[20] and for a patient with OUD, the consequences of delayed and denied care can be deadly.[21]

AMA survey data[22] show that, on average, physician practices complete 45 prior authorizations per physician per week. This adds up to nearly two business days, or 14 hours, each week dedicated to just completing prior authorizations. A very real cost of these burdens is their contribution to physician burnout. Physicians are struggling to hire staff for their practices, get back on their feet following the pandemic, and focus on what they were trained to do—provide care to patients. But rather than focusing on patient care, physicians are being forced to accommodate endless health insurer requirements and devote their time, their staff's time, and extensive resources to helping patients access the care they need. As the country is facing a mental health and substance use epidemic, we are also facing a looming physician workforce shortage. Physicians are burnt out. Data suggest that one in every five physicians is planning to leave practice within two years. Administrative burdens, especially prior authorization, play a major role in that burnout, as 88 percent of physicians describe the burden associated with prior authorization as high or extremely high.

Moreover, as NQTL requirements dictate treatment and often conflict with the generally accepted standards of care that physicians know are best for their patients, these processes become dangerous to patients. Thirty three percent of physicians report that prior authorization has led to a serious adverse event for a patient in their care including hospitalization, permanent impairment or death, and 89 percent of physicians report that prior authorization has a negative impact on clinical outcomes. These reckless intrusions into the patient-physician decision making process mean that despite knowing what is best for their patients, physicians are unable to provide that care. Continued and constant exposure to these barriers, and the ongoing negative impact on the patients they have been trusted to care for is extremely demoralizing to physicians.

Currently, physician practices must spend a significant amount of time and resources navigating complex insurance regulations and negotiating with insurance companies to ensure that their patients receive the care they need. A 2022 survey from the Physicians Foundation found that 85 percent of the physicians who reported staff shortages rated administrative burdens as impactful. This problem is particularly acute for referring and authorizing care for mental health issues and substance use disorders, where barriers like excessive reauthorization requirements both pose a barrier to care for patients and exacerbate the existing administrative burden on physicians.

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[20] In D.C., a fight over 'Kafkaesque absurdity' of insurance delays, denials. The Washington Post. May 28, 2023. Available at https://www.washingtonpost.com/dc-md-va/2023/05/28/dc-prior-authorization-reform/.

[21] Kentucky Bill To Remove Prior Authorization Aims To Help Opioid Users Get Treatment. WKU. February 19, 2019. Available at https://www.wkyufm.org/health/2019-02-19/kentucky-bill-to-remove-prior-authorization-aims-to-help-opioid-users-get-treatment.

[22] https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

Of note, administrative tasks such as prior authorization can be particularly burdensome for physicians in smaller practices. Data from the AMA's 2022 Physician Practice Benchmark Survey show that many more psychiatrists work in smaller practices compared with other medical specialties: 45 percent of psychiatrists work in practices that include between one and four physicians, compared with 33 percent for all specialties combined.[23]

The proposed rule's streamlining of access to care is a win-win for both patients and physicians by improving access to care while reducing bureaucratic administrative burdens. **By providing clear and transparent information about the limitations of insurance coverage, these regulations will help to reduce the time and resources that clinicians need to spend navigating insurance regulations and negotiating with insurance companies.**

Comments on Technical Release 2023-01P

In addition to the Proposed Regulation, the AMA would like to provide comments on the Departments' Technical Release 2023-01P,[24] which are aligned with our comments on the Proposed Regulation. We support the collection and evaluation of the four proposed additional types of data for plans and issuers to use as part of their comparative analyses for NQTLs related to network composition. The additional data will be key metrics for demonstrating that a plan or issuer's NQTLs related to network composition do not place greater restrictions on access to MH/SUD benefits than on M/S benefits. **It is important to note that these additional data elements will be critical to informing the robust enforcement measures that we are recommending the Departments pursue for all MHPAEA provisions, including both current provisions and the new proposals in this rule.** More specific data elements on out-of-network utilization, percentage of in-network providers actively submitting claims, time and distance standards, and reimbursement rates should provide the Departments with additional information that they can use to better enforce the MHPAEA.

As noted throughout this comment letter, the AMA generally supports proposals that require plans, issuers and TPAs to collect and evaluate data to help ensure compliance with the MHPAEA. We appreciate that the Departments have provided extensive examples to help explain how the information requested would help with compliance. Given 15 years of plan and issuer failures, however, we urge that the effort to require more data not be undertaken without simultaneous enforcement efforts. Plans and issuers for years have relied on the common excuses that they do not know how to complete comparative analyses, follow parity instruction forms, and otherwise continue to not provide sufficient information to the Departments or state parity investigators. **The AMA therefore recommends that until plans and issuers can exhibit good faith efforts to comply with the law and significantly increase patient access to MH/SUD treatment, an enforcement safe harbor should not be offered.**

As we have previously discussed, the July 2023 Report to Congress made clear that "most comparative analyses failed to evaluate the relative stringency of how the NQTL was applied to mental health or substance use disorder benefits versus medical/surgical benefits." The AMA sees the Technical Release and the call for the collection and evaluation of additional data types as a helpful set of principles. **Ultimately, we want the Technical Release to serve as a real opportunity to prompt action from the Departments to better enforce MHPAEA's patient protections.**

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[23] https://www.ama-assn.org/about/research/physician-practice-benchmark-survey.
[24] https://www.dol.gov/agencies/ebsa/employers-and-advisers/guidance/technical-releases/23-01.

Thank you for the opportunity to provide these comments. If you have any questions, please contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,

James L. Madara, MD