October 10, 2023

The Honorable Julie A. Su
Acting Secretary
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, D.C. 20710

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
1600 Pennsylvania Avenue NW
Washington, D.C. 20500

The Honorable Janet L. Yellen
Secretary
U.S. Department of Treasury
1500 Pennsylvania Avenue, NW
Washington, D.C. 20220

RE: Requirements Related to the Mental Health Parity and Addiction Equity Act

Dear Acting Secretary Su, Secretary Becerra, and Secretary Yellen:

The Healthcare Leadership Council (HLC) appreciates the opportunity to provide comments on the "Requirements Related to the Mental Health Parity and Addiction Equity Act" proposed rules.

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century healthcare system that makes affordable high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, homecare providers, group purchasing organizations, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach.

HLC thanks the departments of Labor, Health and Human Services, and Treasury (Departments) for your work to improve access to mental health and substance use disorder (MH/SUD) services. Our members are united in working to ensure parity for patients struggling with behavioral health challenges and have championed integrative care, health equity, and a robust workforce as key solutions to achieving parity.

Health plans are in the tenuous position of covering what we all consider a critical part of healthcare services in an environment with a simultaneous steep increase in service utilization and stubborn workforce shortage. The U.S. has made significant progress in providing access to MH/SUD services since the Mental Health Parity and Addiction Equity Act (MHPAEA) was enacted in 2008. Costs and utilization increased more in MH/SUD services compared to medical and surgical services (M/S) between 2008 and 2013.[1] More recently, in large part due to trends related to the COVID-19 pandemic, health plans have seen overall mental health services increase by 38.8 percent between 2019 and 2022.[2] Despite this clear increase in utilization, more needs to be done to ensure all Americans have access to these vital services. Nearly half the U.S. population (158 million people or 47 percent), is living in a mental health workforce shortage area.[3]

We are committed to achieving parity and are concerned that key components of the proposed rules will not only fail to meet the current workforce challenge but will disrupt the current path of progress in parity implementation. Specifically, the proposed rules add tremendous burdens to plans and issuers, include provisions that go beyond congressional intent, and lack necessary specificity to evaluate impact.

To remedy these concerns, we respectfully urge the Departments to consider the following recommendations:

Substantially All/Predominant Test

We understand that the lack of quantitative benchmarks has caused confusion related to the comparability between MH/SUD and M/S benefits and appreciate the Departments' attempt to make the comparative analysis more quantitative. However, while the current two-thirds test sounds promising in theory, the challenges that the Departments identified in the Final MHPAEA 2013 Rules remain today and underscore the abrupt and impractical shift the new proposed rules take. The Final rules stated, "While Non-Quantitative Treatment Limitations (NQTLs) are subject to the parity requirements, the Departments understood that such limitations cannot be evaluated mathematically. These final regulations continue to provide different parity standards with respect to quantitative treatment limitations and NQTLs, because although both kinds of limitations operate to limit the scope or duration of mental health and substance use disorder benefits, they apply to such benefits differently."

We are concerned that under the proposed test, many nonquantitative treatment limitations (NQTLs) would not be able to be applied, because they are not applicable to two-thirds of benefits for M/S services. A process that is common for a particular NQTL on the M/S side may not be the most appropriate process for MH/SUD benefits. For example, while electronic review may be the most common approach for M/S prior authorizations, the nature of MH/SUD conditions is such that diagnoses are subjective and not associated with clear biometric markers or objective findings. In this case, peer-to-peer review allows the provider to explain why the

[1] Impact of Mental Health Parity and Addiction Equity Act, Milliman (November 2017), https://www.milliman.com/-/media/milliman/importedfiles/uploadedfiles/insight/2017/impact-mental-health-parity-act.ashx.

[2] Telehealth and In-Person Mental Health Service Utilization and Spending, 2019 to 2022, JAMA Health Forum (August 25, 2023), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2808748?utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_term=082523.

[3] Health Workforce Shortage Areas, Health Resources and Services Administration, https://data.hrsa.gov/topics/health-workforce/shortage-areas

prescribed level of treatment is necessary. NQTLs, which are multifactorial and vary along multiple dimensions, are applied with much less frequency than quantitative treatment limitations (QTLs), which vary only along the dimension of dollars but are still a valuable tool.

We believe the existing tests that have been applied under the NQTL regulations for the last decade are a better foundation for determining whether an NQTL is more restrictive for MH/SUD benefits. We would be happy to work with the Departments on refinement and standardization that would improve the current NQTL tests.

Lack of Specificity in Proposed Rules Including "Material Difference"

HLC is concerned that many critical terms that would be essential components of a compliant NQTL analysis are left either vaguely defined or undefined. Critical components (such as what a test comprises, the standards for meeting that test, and compiling the proper information to demonstrate compliance) are left to interpretation. Regulators and auditors are likely to have different perspectives on requirements, leading to substantial uncertainty for plans and issuers trying to meet the requirements of compliance, as well as frustration for regulators.

Below are several examples where definitions and specificity are needed:

- How will the "substantially all" test to be calculated in different benefit categories?
- What constitutes a single "predominant" NQTL when the NQTL has multiple steps or processes that may all vary on M/S benefits?
- What are "Independent Medical" and "Clinical Standards"?
- What does it mean to "apply" the Independent Medical or Clinical Standards
- What must be included in an NQTL that meets an exception?
- What is a "standard" related to fraud, waste and abuse?
- What is a "meaningful benefit" and what constitutes a "material difference"?
- How does a plan distinguish between normal health plan operations and NQTLs?
- How does a plan demonstrate a factor or evidentiary standard is unbiased?
- How does a plan know what constitutes "any other data relevant" for the data collection and evaluation requirement?
- What are "substantially all" inpatient M/S services when paid under value-based risk-arrangements?

As a key example, the lack of definition for "material difference" and "outcomes data," terms at the core of NQTL requirements compliance, make it impossible for plans and issuers to even fully evaluate the proposed rules, let alone prepare for compliance.

The Departments propose to mandate that plans collect and evaluate outcomes data in a manner reasonably designed to assess the impact of the NQTL on access to MH/SUD benefits. Relevant data includes the number and percentage of claims denials and any other data relevant to the NQTL required by state law or private accreditation standards. We seek additional information on what outcomes data is to be collected and what the process is for determining whether the outcomes data is reasonably designed. Simply stating this is "all relevant data" does not provide plans a standard on how to conduct these analyses.

The Departments note that to the extent the relevant data show "material" differences in access to MH/SUD benefits as compared to M/S benefits, the differences will be considered a "strong indicator" that the plan violates the NQTL Rule. We appreciate the Department's seeking input on what "material difference" means in terms of the regulation. However, given that evaluating a material difference sits the crux of the new MHPAEA regulations, we are perplexed that it has

been left to this stage of the process and not requested earlier through an RFI or another process to inform the proposed rules. Lack of guidance for what the Departments are considering and lack of clear examples, make evaluation of the proposed rules and preparation of meaningful comments difficult.

Given the challenges that come with the lack of specificity in key elements of the new NQTL standards, we urge the Departments not to finalize the proposed rules, and to instead engage stakeholders in a series of working sessions where different common NQTLs can be worked through to ideally produce complete, templated, compliant comparative analyses before moving forward with finalizing NQTL requirements. If the Departments choose to move forward with the current process, we strongly urge you to delay the implementation timeline to allow time to work with stakeholders to add specificity to the proposed rules and allow plans and issuers to prepare for the tremendous additional cost and resource burdens these changes present.

Independent Clinical Exception

The Departments outline a proposed exception to certain parts of the NQTL analysis for "independent professional medical or clinical standards." We support the Departments' proposal to create this independent clinical standards exception in the proposed rule but request additional language to ensure that the exception provides a pathway by which health plans can rely upon expert clinicians familiar with the delivery of MH/SUD care in order to ensure that members are receiving interventions that are appropriate, high-quality, and above all not dangerous.

We are concerned that lack of clear definitions in the proposed rule will be a barrier to implementation. For an independent clinical exception to be useful, there must be agreement on what constitutes an "independent professional or medical clinical standard" and acknowledgement that if the standard is recognized, a plan or issuer can also take reasonable action to ensure that the standard is being followed. For example, if a medical standards organization determines that a MH/SUD treatment is only appropriate for individuals with certain clinical characteristics, but may be harmful for patients with other characteristics, we believe that the ability to authorize that service ahead of delivery would advance goals of both improved quality and efficient use of our members' premiums.

We suggest the following additional clarification to the exception for independent professional medical or clinical standards:

- Define "independent professional medical or clinical standards" as the use of standards by independent third-party organizations that utilize the input of clinicians practicing in the areas of the standard. This would include (1) standards by organizations such as InterQual, Milliman, etc.; (2) reliance on a peer-reviewed scientific article if it is considered in the context of the breadth of scientific literature on the same subject (e.g., a new randomized control trial that refutes findings from three previous case study reports); or (3) the recommendations from independent expert panels that include representation from expert clinicians in the relevant field.
- Make clear that this exception includes the use of means reasonable to ensure that care is delivered in accordance with these standards. Plans and issuers have decades of experience managing care in these areas and also have a strong incentive to do so in a way that minimizes administrative burden, so the risk of inappropriate limitation of care is low if the independent standards are followed. Conversely, if the "independent professional medical or clinical standards" exception is interpreted in such a way that plans are forbidden from using standards, then there are serious risks to the health and safety of patients.

- Adopt allowances for plans and issuers to rely on health plan medical policy documents if these documents rely upon evidence-based, peer-reviewed, and/or national society medical and clinical standards. These documents are widely depended upon by issuers and plans.
- Define and provide examples as to what fraud, waste, and abuse controls would fall within the exception. Many protocols could be related to fraud, waste, and abuse. Without further clarity, regulated entities face substantial uncertainty in determining whether a particular practice is covered by the exception.

Network Composition NQTL Per Se Test for Compliance

Under this proposal, a plan would fail to meet the requirements of the NQTL Rule if the relevant data show material differences in access to in-network MH/SUD benefits as compared to in-network M/S benefits in a classification. The proposed test ignores the practical realities surrounding provider recruitment that may make satisfaction of this standard impossible. We believe plans and issuers should not be penalized and automatically deemed noncompliant despite their good faith efforts to comply with MPHAEA.

In addition to the already noted challenges around lack of or vague definitions, the Notice of Proposed Rulemaking (NPRM) does not include model analyses or even specific examples that would demonstrate compliance. We are also concerned that the proposed rules do not provide plans and issuers the ability to indicate why reasonable differences exist between MH/SUD access and M/S.

By imposing such a stringent requirement, the Departments may foster perverse incentives in network negotiations with plans and insurers. Plans have a fiduciary obligation to ensure that the network contractors are quality contractors, and some providers, particularly mental health providers, may choose to avoid that vetting process and thus avoid contracting with a network.

Given the Departments are primarily concerned with outcomes of the network, we do not believe the application of this test is appropriate for the NQTL comparative analysis and, therefore, an additional exception from this test should apply.

Lack of Focus on Quality of MH/SUD Services

Throughout the NPRM, there seems to be a key assumption that more care is better care, but this is not always the case. Often, NQTLs are critical in determining the quality of a member's treatment. We urge the Departments to consider quality of treatment as they work to modernize the MHPAEA.

Many people engaged in treatment are not receiving the appropriate quality of care. Only 1 in 4 residential facilities that treat adolescents in the U.S. for opioid use disorder offer buprenorphine, which is the only medication for adolescents ages 16 to 18 approved by the Food and Drug Administration.[4] Additionally, only a handful of states, including New York and Massachusetts, require that licensed addiction treatment centers offer medication for opioid use disorder and follow other best practices.

[4] Lack of Buprenorphine Access for Adolescents in Residential Facilities, National Institutes of Health (June 27, 2023), https://www.nih.gov/news-events/nih-research-matters/lack-buprenorphine-access-adolescents-residential-facilities#:~:text=Only%201%20in%204%20residential,opioid%20use%20disorder%20in%20adolescents.

There is a clear need for U.S. Department of Labor (DOL) to hold providers accountable to gold-standard treatment if consumers are to be able to trust the care they are receiving is safe and effective. A recent Government Accountability Office report found significant challenges in monitoring youth treatment facilities due to challenges states face in data collection, with significant variation in terms used at the facility level. The report found that federal agencies have been inconsistent in addressing state and federal program noncompliance and recommended improved state oversight and stronger enforcement to hold facilities accountable.[5]

Safe Harbors

New compliance requirements outlined in this proposed rule will add substantial administrative burden to the operation of health plans and issuers as well as enforcement costs to the Departments. We appreciate the Departments' acknowledgement of this challenge and interest in providing an enforcement safe harbor to somewhat ease these burdens. However, the current proposal with a safe harbor based only on the proposed NQTLs is too narrow to adequately capture plans and issuers' good faith efforts to comply with parity requirements.

While the proposed rules seek to be expansive in their approach to reducing barriers to receiving MH/SUD services, there are many aspects of work health plans do to improve access to these services that are not captured in this framework, including staffing crisis lines and clinics, providing care navigators, among other activities that improve access to MH/SUD services not captured in the proposed comparative analyses. Additionally, there is no substantive consideration of how telehealth has increased access and addressed network shortages.

As the Departments prepare guidance for the future safe harbor, we encourage them to work closely with stakeholders to develop a set of objective metrics for MH/SUD access. If certain levels of performance could be achieved on these metrics, then the plans or issuers could earn a safe harbor from producing the full NQTL comparative analysis across plans in a business line and region. Below are some examples of metric frameworks plans and issuers could use to show MH/SUD access standards are met:

- **A standardized survey.** If members indicated a high level of satisfaction of access to MH/SUD services, this could mitigate the need for a complete network analysis.
- **Compare prior authorization use and denials between NH/SUD and M/S.** If these results were comparable and below certain market thresholds, then prior authorization NQTLs could be deemed compliant without the need to conduct the full NQTL comparative analysis.
- **Create a reasonable rate threshold for reimbursement of out-of-network providers.** If a plan's reimbursement rate falls within the safe harbor, that plan would not be required to provide a network adequacy comparative analysis or any additional parity reporting.
- **Medical management standards.** The Departments could convene a commission of independent stakeholders to develop a consensus standard for how certain services that are likely to be inappropriately utilized should be managed. If a plan or issuer demonstrates their process follows these recommendations, then they could be deemed

[5] Child Welfare; HHS Should Facilitate Information Sharing Between States to Help Prevent and Address Maltreatment in Residential Facilities, Government Accountability Office (January 2022), https://www.gao.gov/assets/gao-22-104670.pdf.

in compliance for that particular NQTL. Such a safe harbor would dramatically reduce the plan analysis and documentation burden and would also improve the efficiency of review for auditors and regulators.

Meaningful Benefits Requirement

We do not believe the meaningful benefits requirement is warranted under MHPAEA or the Consolidated Appropriations Act of 2021(CAA) and recommend the Departments not finalize this requirement. The effect of this proposal would be to essentially convert the MHPAEA requirements for parity between MH/SUD and M/S benefits into a MH/SUD benefit mandate. Congress did not choose to create such as mandate in either the MHPAEA or the CAA, and we are concerned that finalizing this requirement may create legal ambiguity that could ultimately delay efforts for comprehensive benefits rather than advance those efforts.

We support coverage for MH/SUD services and are concerned this requirement for meaningful benefits may be outside the scope of the MHPAEA legislation. For example, 29 U.S.C. §1185a(b) states “[n]othing is this section shall be construed as requiring a group health plan (or health insurance coverage offered in connection with such a plan) to provide any mental health or substance use disorder benefits…”.

MHPAEA was never intended to mandate coverage for all services in all classifications. Requiring a full scope of coverage on the MH/SUD side rather than as defined by the plan is more generous than what is offered on the M/S side. Under the proposed requirement, it may be interpreted that plans would have to cover treatments with potential quality concerns (such as wilderness therapy) or offer residential treatment for depression or anxiety disorders. Consumers will struggle to understand why, in effect, all the MH/SUD benefits are covered whereas equally important M/S benefits will be subject to medical necessity limitations.

Alternatively, we would propose a definition of meaningful benefits that would reflect a standard that is applied for M/S benefits. For example, “meaningful benefits are those benefits that, in combination across settings, constitute the most common safe and effective methods of treatment in the medical community for a given condition.”

We also propose an objective standard for plans to meet meaningful benefits standards. States have designated benchmark plans (EHB Benchmark plans) for essential health benefits in the exchanges. As these are designated by the state, and the states would have primary enforcement over MHPAEA compliance, we seek that the Departments allow that any plan design that covers at least the benefits of an EHB benchmark plan also be considered to cover "meaningful benefits" for the purposes of MHPAEA compliance. This would provide plans with an objective standard to meet these requirements, streamline compliance, and reduce administrative costs.

HLC and our member organizations stand ready to work with the Departments to improve comparative analyses compliance, including by establishing meaningful and achievable standards for NQTLs.

Thank you for the opportunity to provide feedback on the critical topic of parity for mental health and substance use disorder services. HLC and our member organizations stand ready to work with the Departments to improve comparative analyses compliance, including by establishing meaningful and achievable standards for NQTLs.

HLC looks forward to continuing to engage with the Departments on this important issue. If you have any questions, please do not hesitate to contact Debbie Witchey at dwitchey@hlc.org or 202-449-3435.

Sincerely,

Mary R. Grealy
President