AMERICAN ACADEMY OF FAMILY PHYSICIANS

October 2, 2023

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

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

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

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 Academy of Family Physicians (AAFP), representing 129,600 family physicians and medical students across the country, I write in response to the notice of proposed rulemaking, "Requirements Related to the Mental Health Parity and Addiction Equity Act" as published in the Federal Register on August 3, 2023, as well as the associated Technical Release.

The AAFP supports this 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 beneficiaries' access to MH/SUD treatment than to medical/surgical (M/S) treatment. **The AAFP has long advocated for improved access to behavioral healthcare, and we applaud the Departments for taking steps to ensure plans and issuers are providing appropriate behavioral health benefits and access to care.**

Specifically for the 2023 Proposed Rule and Technical Release, the AAFP recommends:

- **Implement appropriate guardrails to ensure plans and issuers continue to improve access to primary care while remaining in compliance with this proposed rule,**
- **Clearly establish metrics and recommendations for how plans should consider primary care physicians who provide MH/SUD care,**
- **Remove the exceptions for medical standards and waste, fraud, and abuse for application of NQTLs,**
- **Clarify throughout that data collection and analyses should be separate for MH and SUD benefits, and**

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- **Finalize proposals to implement data reporting and analyses, including for non-quantitative treatment limitations, and penalties for third parity administrators.**

Family physicians provide longitudinal care across a patient's lifespan, which often includes comprehensive mental health services. In fact, nearly 40 percent of all visits for depression, anxiety, or cases defined as "any mental illness" were with primary care physicians, and primary care physicians are more likely to be the source of physical and mental health care for patients with lower socioeconomic status and for those with comorbidities.[1] Family physicians also play a crucial role in safe pain management prescribing practices, screening patients for opioid use disorder (OUD), and prescribing and maintaining treatment of medications for OUD (MOUD). Primary care physicians are often the first point of care for patients and can provide necessary referrals or coordinate care with other mental health professionals when needed.

While screening, brief intervention, treatment, and prescribing for behavioral health concerns are key tenants of family medicine training and scope of practice, certain cases require care coordination between primary care physicians and psychiatrists, psychologists, clinical social workers, and other mental health professionals. Integrating behavioral healthcare into primary care settings, and vice versa, can address this by ensuring patients have a warm handoff between clinicians in-person or via telehealth consults. While many primary care physicians want to integrate behavioral health services in their practices, they face barriers like shortages in the behavioral health workforce, burdensome start-up costs, and payment and reporting challenges.

Overarching Recommendations

The AAFP agrees that this 2023 Proposed Rule is necessary and important to meaningfully improve patient access to important mental health services. However, the AAFP is concerned that if plans and issuers are narrowly focused on compliance with this rule as proposed, they may be inadvertently disincentivized from making equally important changes in M/S benefits, such as increasing primary care payment, expanding primary care networks, and reducing prior authorizations and other non-quantitative treatment limitations (NQTLs) in primary care. **To address this, the AAFP urges the Departments to implement appropriate guardrails to ensure plans and issuers continue to improve access to primary care while remaining in compliance with this proposed rule**. Furthermore, because plans and the Departments will have access to comparative data for M/S benefits, the Departments should include in the annual report to Congress what additional improvements have been made to reduce prior authorizations and increase network adequacy for primary care.

As previously mentioned, primary care physicians provide care for nearly 40 percent of all depression, anxiety, and "any mental illness" visit.[2] Given the scope of family medicine, the level of treatment may vary between physicians and practices, from physicians who provide extensive SUD treatment and pain management to those who regularly screen and provide referral and care coordination for depression or anxiety. **As a result, the AAFP strongly urges the Departments to provide clear guidance to plans and issuers for how to include primary care physicians who provide MH/SUD care in their analyses.** This guidance should consider primary care physicians who bill MH/SUD codes, care coordination codes, and E/M codes that include MH/SUD treatment. We recognize that counting all primary care physicians as mental health clinicians would vastly overestimate access to care, particularly for specialty mental health care, and would adversely impact patient access. Additionally, primary care physicians who do not provide extensive behavioral health care should not be penalized by plans. However, ensuring primary care physicians who provide MH/SUD care are appropriately represented in network analyses will help plans expand their MH/SUD network in the areas most lacking access.

It is clear primary care plays a critical role in providing access to mental and behavioral health services, especially in many rural and underserved communities. However, integrated behavioral health often requires burdensome start-up costs and payment and reporting challenges that prevent sustainable implementation for many primary care practices. To better equip primary care clinicians to provide frontline mental health and SUD treatment, payments must move away from fee-for-service towards a well-designed value-based payment system that works best for primary care – one that provides prospective population-based payments that generate predictable and sustainable revenue streams. Prospective revenue supports a more comprehensive, team-based approach, including care the team provides outside of a "visit," which is generally not readily captured and paid under FFS, including mental health and SUD care. **The AAFP strongly encourages the Departments to use this proposed rule to advance behavioral health integration and value-based care.**

Finally, while the AAFP appreciates and agrees with many aspects of the 2023 Proposed Rule, which affects individual and group health plans, **we encourage the Departments to work with CMS to ensure Medicaid managed care, the Children's Health Insurance Program (CHIP), Medicare Advantage, Medicare Part D and Alternative Benefit Plans (ABPs) also have a strong set of rules in the Mental Health Parity and Addiction Equity Act (MHPAEA).** This is particularly critical given that these plans serve seniors, lower-income individuals, and families who are disproportionately Black, Latino, Native American, and from other marginalized and underserved communities. Many of the entities that serve as Medicaid MCOs also operate in the state-regulated insurance markets and serve as TPAs for employer-sponsored plans. HHS must also hold state Medicaid agencies accountable for strong oversight and MHPAEA enforcement.

Definitions

The Departments propose to define "mental health benefits" and "substance use disorder benefits" according to the appropriate chapters of the Diagnostic and Statistical Manual of Mental Disorders (DSM) and the mental, behavioral and neurodevelopmental disorders chapter of the International Classifications of Disease (ICD). This 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.

The AAFP agrees with this proposal and believes these changes will significantly improve clarity and increase access to care. Moreover, this change ensures that benefits will be defined by and consistent with "generally recognized independent standards." The AAFP encourages the Department to finalize this as proposed.

Purpose

The Departments propose to add a purpose section to the MHPAEA regulations. The new purpose section would include: "in complying with the provisions of MHPAEA and its implementing regulations, plans and issuers must not design or apply financial requirements and treatment limitations that in complying with the provisions of MHPAEA and its implementing regulations, plans and issuers must not design or apply financial requirements and treatment limitations that impose a greater burden on access (that is, are more restrictive) to mental health and substance use disorder benefits under the plan or coverage than plans and issuers impose on access to generally comparable medical/surgical benefits." This proposal would codify the intent of the MHPAEA to not only ensure parity of coverage of MH/SUD benefits, but also parity in plan beneficiaries' access to MH/SUD benefits in a manner comparable to M/S benefits.

The AAFP agrees with the intent of the proposed purpose section. The AAFP agrees that the existing 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. This result is contrary to the intent of the MHPAEA and must be addressed.

Provider Network Requirements

The Departments are proposing to require plans ensure there are no material differences in beneficiaries' access to MH/SUD providers compared to M/S clinicians. This includes the availability of clinicians accepting new patients, geographic location of providers relative to patients, and standards for clinician admission to the network.

The AAFP agrees that addressing lack of in-network MH/SUD clinicians is critical to ensuring appropriate access to care. Our members report regularly struggling to make referrals for more intensive behavioral health care when needed because of the lack of in-network behavioral health clinicians.

The AAFP is strongly supportive of expanded coverage and payment of telehealth services and believes that when implemented thoughtfully, telehealth can improve both access to care and patient experience. Telehealth serves as an important tool to expand access to mental health services, particularly in medically underserved areas, and to reduce stigma related to seeking mental health care. When used within a patient's medical home for primary care or with a trusted mental health professional, telehealth can be a valuable tool in expanding equitable access to timely, high-quality mental health care.

The AAFP generally does not support counting the availability of telehealth services provided by virtual, direct-to-consumer (DTC) companies towards meeting minimum federal access standards for *primary and physical emergency care.* However, tele-mental health services provided by virtual, DTC companies could, in some cases, be an appropriate substitute for in-person care and significantly increase beneficiaries' access to needed behavioral health services when there is a shortage of in-person behavioral health clinicians. The AAFP encourages the Departments to ensure plans are not inappropriately incentivizing enrollees to use DTC telehealth services when in-person mental health clinicians are available and may better meet the needs of the patient. **The AAFP believes insurance plans covering telehealth services should be required to cover services provided by all in-network clinicians and not be permitted to limit coverage to only select virtual-only or DTC clinicians.**

Provider Network – Technical Release

As it relates to the associated proposed relevant data requirements for NQTLs related to network composition as detailed in the technical release, the AAFP agrees that data collection on each individual network composition component is necessary for ensuring equitable access.

The AAFP recommends the Departments require that the data points for MH services and SUD services be separately collected, analyzed and reported, consistent with MHPAEA statutory and regulatory requirements. We also urge the Departments to require that all data be collected, analyzed, and reported by age group, including children and adolescents, and by race/ethnicity (where possible). The Departments should also develop uniform definitions and methodologies for the collection of all data points so that valid data are collected and can be compared across plans or issuers.

Payment Rates

As proposed in the technical release, plans will be required to analyze allowed amounts for CPT codes 99213 and 99214 (M/S) and CPT codes 90834 and 90837 (MH/SUD) and compare M/S and MH/SUD payment rates to each other, across clinician types, and to the national Medicare rate for these codes.

The AAFP supports this comparison and encourages the Departments to finalize a transparency clause for this provision, so that payment rates may be easily verified for accuracy. The AAFP supports transparency and equity in physician compensation and believes transparency extends to payers' payment policies and fee schedules.

Further, the AAFP supports parity of health insurance coverage and payment for patients, regardless of medical or mental health diagnosis. Comparing the allowed amounts for select CPT codes that represent medical evaluation and management (E/M) services (99213 and 99214) and psychotherapy services (90834 and 90837) is one approach to evaluating parity of payment. The AAFP recommends the Departments be mindful of the following when making such comparisons:

- The E/M services and psychotherapy services in question involve different amounts of physician time. For instance, code 90834 nominally describes "45 minutes with patient" while 99214 nominally describes "30-39 minutes of total time...on the date of the encounter." Code 99213 describes only 20-29 minutes.
- The E/M services and psychotherapy services in question are also presumed to involve different amounts of physician work. According to the Medicare physician fee schedule, codes 99213 and 99214 involve 1.30 and 1.92 work relative value units (RVUs), respectively. By comparison, codes 90834 and 90837 involve 2.24 and 3.31 work RVUs, respectively.
- E/M services and psychotherapy services also differ in the direct practice expense inputs involved.

To the extent the codes vary in time, work, and practice expense, the Departments should not expect payments to be equivalent. However, they should still be comparable and on relative par with each other. One way the Departments can determine whether the payments are on par is to divide a payer's allowed amount for each service by the RVUs assigned to the service under the Medicare physician fee schedule. If payment parity exists, the resulting dollars per RVU (often referred to as the "conversion factor") should be the same or relatively close in amounts.

The AAFP also commends the Departments for requiring payment rate data to be "compared to billed rates." The relative ratio of payment allowances to billed charges for M/S services compared to MH/SUD service can offer another perspective on parity. Payment rates as a percentage of billed charges may also profoundly affect the availability of MH/SUD clinicians longer term, as potential clinicians make decisions on whether to enter the field based in part on compensation. A similar comparison that we recommend to the Departments is to evaluate the ratio of paid in-network amounts to out-of-network (OON) billed market rates for MH/SUD and M/S. The billed rates of OON clinicians are another representation of the market rate.

As noted, the Medicare Fee Schedule RVUs may be used as a standardized metric for comparison of rates under M/S benefits. **However, the AAFP emphasizes that Medicare payment rates have failed to keep up with inflation and should not be considered adequate to ensure equitable, timely access to care without appropriate adjustments for M/S and MH/SUD benefits**. According to the American Medical Association's analysis of Medicare Trustees report data, Medicare physician payment has been reduced by 26 percent when adjusted for inflation over the past 20 years.[3] Practically speaking, this means that physicians are struggling to cover the rising costs of employing their staff, leasing space, and purchasing supplies and equipment - let alone make investments to

transition into value-based payment models. In 2023, Medicare pays $33.89 ($33.8872) per relative value unit under the Medicare Physician Fee Schedule, which is less than the $36.69 ($36.6873) it paid when Medicare moved to a single conversion factor in 1998. If the 1998 amount had simply kept pace with inflation, it would be $68.87 today. Both the Medicare Payment Advisory Commission and the Medicare Board of Trustees have recently shared concerns that existing Medicare physician payment rates are failing to keep up with rising practice costs and formally recommended that Congress update payments to protect beneficiaries' access to care.[4, 5]

Furthermore, the AAFP notes that Medicare is not subject to MHPAEA and may not be an effective comparison for MH/SUD benefits without additional adjustments beyond those made for M/S benefits. Medicare rates are also not meaningful for children and adolescents since this population does not participate in the program. While Medicaid includes this population, regional variation of rates and overall underpayment for services makes this an inappropriate tool for comparison. The AAFP recommends the Departments provide an additional comparison tool for pediatric-specific services.

Time and Distance Standards

The AAFP strongly supports the suggestion that the Departments collect detailed data on the percentage of enrollees who can access specified clinician types in-network within a certain time and distance. We strongly agree with the Departments' view that this data would help with the assessment of a plan/issuer's operational compliance with respect to any NQTLs related to network composition. We also recommend that the Departments collect data on appointment wait times, which are an essential metric to measure network adequacy and the most critical for participants/beneficiaries seeking timely access to care. The Department of Health and Human Services 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 mental health and substance use disorder services of 10 business days and require such independent secret shopper surveys. These standards align with appointment wait time metrics that have been adopted for Qualified Health Plans.

To protect physician practices and ensure plans take appropriate actions to comply with wait time standards, the AAFP recommends the Departments clarify that plans must hold physicians and practices harmless if their wait times are longer than the required standards under this rule. The onus for meeting wait time standards must be on plans and issuers. Thus, the Departments should consider additional regulatory guardrails to ensure plans do not pass on wait time standards requirements to their in-network clinicians and practices by requiring them to schedule appointments within a certain timeframe or including other stipulations in contracts.

In collecting data, the Departments should collect data on routine and crisis appointments, including for follow-up and ongoing care. Granular data that distinguishes between types of care and initial appointments versus ongoing care is necessary to ensure patients are receiving effective care and are not being forced to wait for follow-up after an initial visit. Data should be disaggregated by age group to assess wait times and travel distance for children and adolescents.

Family physicians report barriers and long wait times for patients seeking sub-specialty care. In many regions, these long wait times are particularly challenging for pediatric sub-specialty care. The AAFP urges the Departments to consider adopting the 30-day appointment wait time standard for specialty care that was finalized for Marketplace plans to address these challenges.

As discussed above, the AAFP believes telehealth serves as an important tool to expand access to mental health services, particularly in medically underserved areas, and to reduce stigma related to

seeking mental health care. When used within a patient's medical home for primary care or with a trusted mental health professional, telehealth can be a valuable tool in expanding equitable access to timely, high-quality mental health care. The AAFP encourages the Departments to ensure plans are not inappropriately incentivizing enrollees to use DTC telehealth services when in-person mental health clinicians are available and may better meet the needs and preferences of the patient. The AAFP believes insurance plans covering telehealth services should be required to cover services provided by all in-network clinicians and not be permitted to limit coverage to only select virtual-only or DTC clinicians.

Out-of-Network Utilization

The AAFP supports requiring plans to collect data on OON utilization. Family physicians regularly struggle with referrals due to lack of in-network MH/SUD clinicians. Moreover, studies indicate that the percentage of services received OON is a key indicator of the availability of in-network services. Due to the higher cost-sharing of OON services, individuals rarely choose to obtain care OON if adequate in-network services are available on a timely basis. The landmark Milliman report demonstrates the importance of such data and how frequently MH/SUD care is obtained OON compared to M/S care. The data should be disaggregated by age groups, so that utilization by children and adolescents can be distinguished from adults. This is particularly important given our country's ongoing youth mental health emergency and that half of lifetime mental health conditions begin by age 14 .

Percentage of In-Network Providers Actively Submitting Claims

The AAFP supports requiring plans to report data on the percentage of in-network clinicians actively submitting claims. This is an important step to guard against plans and issuers overstating availability of services by listing significant numbers of in-network clinicians not actively submitting claims. Accurate collection of this data is critically important to determining the true adequacy of a network and whether patients are actually able to access and utilize care when they need it. his metric is essential to understanding real access availability and can help to illuminate other issues which may be limiting in-network access, such as low reimbursement that incentivizes clinicians to remain out-of-network and cater to cash-pay patients. Again, this data should be disaggregated by children and adolescents. The AAFP encourages the Departments to include all types of pediatric clinicians, beyond child psychiatrists and child psychologists.

Network Admissions

In assessing network composition and access to MH/SUD services, the AAFP urges the Departments to review the criteria and processes by which plans and issuers determine which clinicians to admit into networks and/or how plans or issuers define when a network is considered "full" or "closed." Reports from MH/SUD clinicians suggest that they are often denied participation in networks due to the networks being "closed" or "full," even though patients are unable to find appropriate clinicians in that network. Other clinicians who are eventually admitted into networks report having to wait as long as nine months to be added.

Network Availability and Distribution of Professions

The Departments propose to also focus on whether clinicians are accepting new patients. Given high demand for MH/SUD services, we think that it is important to add a "limited availability" category based on our understanding that few MH/SUD clinicians have broad availability to accept new patients. A MH/SUD clinician with just a few time slots available does not add significant capacity to plans or issuers' networks.

It is also important to require metrics on the number of available clinicians who fill high demand needs in the network, such as those seeing children and adolescents, those who specialize in eating disorders or LGBTQ patients, and those who meet the language needs of the population served by the network. While the Service Utilization metrics below in these same categories would address how much certain services are being utilized, it may be that while there is a reasonable level of, for example, eating disorder services provided by in-network clinicians, those clinicians may be completely full. Thus, it is also important to assess whether new patients with these specialized needs can find available clinicians.

Safe Harbor

The Technical Release also requested feedback on the potential of a "safe harbor" for NQTLs related to network composition, with the goal of providing flexibilities to plans and issuers in developing their network without compromising equitable access to MH/SUD care. If the safe harbor is met, the plan or insurer would not be subject to Federal enforcement under MHPAEA with respect to NQTLs related to network composition for a specified time. **The AAFP understands the desire to target the Departments' enforcement resources most effectively, but we urge the Departments not to finalize a safe harbor measure at this time given the lack of complete and accurate data on current network make-up and beneficiary access**. Because network adequacy remains difficult to define and accurately measure, the AAFP is concerned this safe harbor has the potential to be harmful if the data collection requirements are not capturing a full and complete picture of participants/beneficiaries' access to MH/SUD service. Such a safe harbor should only be considered when the Departments and key consumer stakeholders are confident that the data collected accurately captures actual access to MH/SUD services.

Substantially All / Predominant Test for NQTLs

The AAFP 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, the AAFP 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, plans or issuers may not apply the NQTL to MH/SUD benefits within that classification. If a plan/issuer does apply an NQTL to "substantially all" M/S benefits within a classification of care, a plan/issuer must then show that the NQTL applied to MH/SUD benefits within that classification is no more restrictive than the predominant variation applied to M/S benefits within the classification.

However, the AAFP also notes that levels of NQTLs for M/S benefits are already far too high. Administrative burden is one of the leading causes of practice closures and physician burnout, which comes from, in part, processes like prior authorization and step therapy. These processes already take up significant physician and staff time, and reduce time spent with patients. Physicians have noted that prior authorization requirements are continually increasing and imposing significant, time-intensive and cumbersome administrative tasks on physicians and their staff, which also contributes to burnout. According to an American Medical Association (AMA) survey, 85 percent of physicians report that the burden associated with prior authorization is "high" or "extremely high" and 30 percent of physicians report that prior authorization has led to a serious adverse event for a patient in their care. [6] The survey reports that physicians and their staff spend almost two business days each week completing an average of 40 prior authorizations per physician, per week.

The AMA survey also highlights the impact of prior authorization on patients: 90 percent of physicians say that prior authorization somewhat or significantly impacts patients' clinical outcomes. Furthermore, 79 percent of physicians report that issues related to prior authorization can at least sometimes lead to patients abandoning their recommended course of treatment while 94 percent of physicians report care delays associated with prior authorization. These delays increase wait times for medical services and prescriptions for patients while diminishing access to timely care. Further, a study of physician time in ambulatory practice across four states and several specialties reports physicians spend 27 percent of their total time on direct clinical face time with patients and almost 50 percent of their total time on electronic health record (EHR) and desk work, which includes working through prior authorization requests with plans.[7] Taken together, evidence demonstrates that prior authorizations are causing care delays, worsening patient outcomes and satisfaction, and are a significant driver of administrative burden and physician burnout.

The AAFP strongly agrees that plans should accurately track the level of NQTLs applied to MH/SUD benefits and M/S benefits to ensure patient access is not adversely affected. As previously mentioned, the AAFP urges the Departments to implement appropriate guardrails to ensure plans and issuers continue to improve access to primary care, including by reducing NQTLs, while remaining in compliance with this proposed rule.

Exceptions to NQTL Requirements

The Departments are proposing exceptions for the NQTL requirements based on "independent professional medical or clinical standards (consistent with generally accepted standards of care)" and "waste, fraud, and abuse."

The AAFP strongly urges the Departments to remove both exceptions when finalizing this rule. While we appreciate the Departments' statement in the preamble that both exceptions are meant to be "narrow," previous experiences under existing regulations indicates that plans and issuers will adopt and implement significant benefit exclusions and administrative barriers based on either exception.

To begin, there is sufficient precedent that use of similar "clinical standards" exception have been inappropriately applied. Previously, the Departments removed the proposed 2010 MHPAEA's NQTL exception for "clinically appropriate standards of care" based on comments from stakeholders and because:

> "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."

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

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

Absent a full removal of the exception for clinical standards, the AAFP recommends the Departments significantly strengthen the definitions for such standards. The example framing in the preamble of "independent professional medical or clinical standards" indicates that these standards "must be independent, peer-reviewed, or unaffiliated with plans and issuers." The AAFP is concerned that 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." Thus, the AAFP recommends a stronger definition:

> "Independent professional medical or clinical standards" mean standards of care and clinical practice that are generally recognized by mental health care clinicians practicing in relevant clinical specialties such as primary care, 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.

Similarly, the AAFP supports removing the NQTL exception for fraud, waste, and abuse. While plans and issuers have a responsibility to mitigate fraud, waste, and abuse, we know that this exception has been used in the past to inappropriately deny or otherwise limit access to medically necessary care. The AAFP is concerned that including this exception will allow plans to continue inappropriately applying NQTLs for MH/SUD benefits, as well as for M/S benefits.

Required Use of Outcomes Data & Actions to Address Material Differences in Access

The Departments propose to require a plan or 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. Plans or issuers must take "reasonable action" to address "material" differences in access shown by this data.

The AAFP agrees that 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 and issuers must rely on process-related justifications and arguments that inappropriately justify disparate access to treatment. By requiring plans and 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.

However, the AAFP notes that "material differences" is not defined in statute. The Departments could consider requiring plans to take action whenever the data shows *any* difference in access. **Absent this change, the AAFP urges 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.**

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

and lack of access to urgent, lifesaving care, the AAFP strongly urges the Departments to finalize separate data requirements from MH and SUD.

HHS Request for Information (RFI)

Third-party Administrators

When there is a failure to comply with MHPAEA, the Departments are considering applying incentives or penalties to insurance companies or third-party administrators (TPAs) who design and administer these plans on behalf of employers and groups. Right now, the penalties are applied to employers and large groups who fund or sponsor the plan. Group health plan sponsors depend on TPAs to design and manage plans in a way that complies with MHPAEA, but plan sponsors (usually employers) are ultimately responsible for compliance and would be penalized when not in compliance.

The AAFP agrees with the Departments concern about this issue and encourages the Departments to use all possible avenues to hold both self-funded plan sponsors and TPAs accountable for MHPAEA compliance. Recent reports have highlighted ongoing problems where TPAs, who are the experts in health plan design and administration and who make critical coverage decisions, refuse to provide essential information, including data, to the employer plan sponsor by claiming that such information is "proprietary" or has "commercial value." TPAs' refusal to provide information and data on plan design and access to benefits fundamentally inhibits MHPAEA compliance and cannot be allowed to stand. The Departments have repeatedly made clear that such plans or issuers must provide such information. In the 2015 MHPAEA FAQ XXIX (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 preamble.

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

Finally, we urge the U.S. Department of Labor (DOL) to use ERISA's strong protections to hold TPAs accountable as ERISA fiduciaries and co-fiduciaries. Under 29 U.S.C. 1132(a)(5), DOL may bring legal action against any fiduciaries that violate MHPAEA, including TPAs, as incorporated into ERISA through 29 U.S.C. 1185a. Further, under 29 U.S.C. 1134, DOL is granted the power, "in order to determine whether any person has violated or is about to violate any provision of this subchapter," including MHPAEA, and to "make an investigation" and to "inspect such books and records and question such persons as he [the Secretary] may deem necessary to enable him [the Secretary] to determine the facts relative to such investigation." Thus, DOL may investigate TPAs for acts or

practices that violate MHPAEA and can sue to enjoin such practices. Finally, DOL is authorized under 29 U.S.C. 1135 to "prescribe such regulations as he finds necessary or appropriate to carry out the provisions of this subchapter." **We urge DOL to use its substantial authority and discretion to ensure that TPAs have adopted policies and procedures that are MHPAEA-compliant.**

Provider Directories

The Departments have requested feedback on how to improve provider directories through rulemaking. Provider directories serve a number of functions across the health care ecosystem. Plans collect information from physicians, other clinicians, and facilities to inform beneficiaries about where to seek in-network care in their community, provide practice information (e.g. phone number, address, and hospital affiliations), indicate whether a practice is accepting new patients, what languages are spoken, and more. Plans also use information from physicians and other clinicians to process billing, claims, and other expenses and to understand where gaps in available clinicians may exist.

Many primary care physicians are in-network with several private payers, in addition to Medicaid, Medicaid managed care, Medicare, and Medicare Advantage plans. As a result, physicians are required to submit duplicative information to multiple sources, taking up valuable time that could otherwise be spent on patient care. Moreover, payers require some information that must be updated regularly, such as when a physician is accepting new patients. Practices report a significant amount of staff time working to update various directories and registries.[8] Physicians and other clinicians lack a streamlined and efficient way to provide such information to plans on a regular basis, leading to inaccurate or out of date information. The accuracy of provider directories remains a significant challenge, leading to frustration among plans, physicians, and patients. Inaccurate directories create barriers to timely, affordable care for patients and additional administrative tasks for primary care physicians when referring patients to specialists or other services.

The AAFP appreciates the Departments' commitment to improving provider directories to reduce the administrative burden placed on physicians and more effectively help patients find in-network clinicians and health care facilities. To simplify administrative tasks, the AAFP supports the use of a centralized clearinghouse or health data utility to allow physician practices to report their data once rather than multiple times to each payer. The AAFP also urges the Departments to require periodic independent third-party testing of provider directories to assess the accuracy of information and that a sufficient percentage of clinicians are accepting new patients. We encourage the Departments to use secret shopper surveys to hold plans accountable for the accuracy of their published directories.

Telehealth

The AAFP strongly agrees with the Departments that telehealth is a vital tool to expand access to mental health services, particularly in rural and medically underserved areas. Telehealth allows physicians to support patients seeking mental health and SUD care by providing them time and flexibility to overcome issues caused by transportation, cost, child-care, stigma, and other barriers to treatment. When used within a patient's medical home for primary care or with a trusted mental health professional, telehealth can be a valuable tool in expanding equitable access to timely, high-quality mental health care. However, telehealth services provided by DTC companies are typically not integrated into patients' primary care or coordinated with the primary care physician and can result in care fragmentation. Additionally, in recent years many for-profit start-ups have begun marketing themselves as a more accessible source of mental health care but some early reports indicate patients may not be receiving safe, high-quality care. The dangers of these types of companies extends beyond disrupting the established patient-physician relationship but can range from misusing patient data to making patients vulnerable to medical misinformation and can even lead to patient harm.[9, 10, 11]**The AAFP urges the Departments to work with health plans and issuers to ensure**

the telehealth services patients are being connected to are safe, evidence-based, and coordinated with a patient's usual source of primary care.

The AAFP encourages the Departments to allow telehealth and virtual-only care companies for mental health and SUD only when in-person clinicians are not sufficient to the needs of the population. The AAFP believes insurance plans covering telehealth services should be required to cover services provided by all in-network clinicians and not be permitted to limit coverage or require initial consultations to only select virtual-only or DTC clinicians. Further, HHS should advise plans against incentivizing enrollees to use DTC telehealth services, for example, by direct marketing or offering lower copays for those services, as this can lead to care fragmentation and in some cases steer patients to the inappropriate modality of care.

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.

The AAFP has applauded investments in the 988 Suicide and Crisis Lifeline and efforts to expand MH/SUD crisis services under Medicare. While every benchmark plan includes EMS and emergency transport services, very few include mental health crisis (i.e., emergency) response or crisis stabilization services. A number of states, including California, Virginia, and Washington, have recently required health plans to cover MH/SUD crisis services. Washington has made clear that coverage of MH/SUD crisis services is necessary for health plans to comply with MHPAEA. HHS should include MH/SUD crisis services within the MH/SUD EHB category. Additionally, when finalizing this rule, we encourage the Departments to make clear that, if a plan or 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).

The AAFP again applauds the Departments for your work to improve beneficiary access to mental health care, and we look forward to working with you to finalize this rule. For additional questions, please contact Morgan Bailie, Senior Regulatory Specialist, at mbailie@aafp.org.

Sincerely,

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American Academy of Family Physicians, Board Chair

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