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October 17, 2023

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

The Honorable Janet Yellen
Secretary of the Treasury
1500 Pennsylvania Avenue NW
Washington, DC 20220

The Honorable Julie Su
Acting Secretary of Labor
200 Constitution Avenue NW
Washington, DC 20210

Submitted electronically via regulations.gov

RE: Proposed Rule: "Requirements Related to the Mental Health Parity and Addiction Equity Act" – 88 FR 51552 (REG-120727-21) —AHIP Comments

Dear Secretaries Becerra, Yellen, and Su:

AHIP appreciates the opportunity to comment on the proposed rules detailing "Requirements Related to the Mental Health Parity and Addiction Equity Act" (MHPAEA) from the Internal Revenue Service (IRS), Department of Labor (DOL), and Department of Health and Human Services (HHS) (collectively, the "Departments") published August 3, 2023 in the *Federal Register*. AHIP is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to making health care better and coverage more affordable and accessible for everyone.

Everyone deserves access to effective, affordable, and equitable mental health care and addiction services. Mental health care is health care. We agree that coverage of mental health and substance use disorder (MH/SUD) care must be on par with medical and surgical care. During the fifteen years since Congress enacted MHPAEA, health insurance providers have worked diligently to ensure mental health parity is reflected in benefit design and to educate our enrollees about the requirements and responsibilities of MHPAEA.

The proposed regulations have significant legal, policy, and operational flaws and should not be finalized. Perhaps more importantly, the proposed rules will not achieve the goals of increasing access to mental health care or substance use disorder treatment. Instead, we urge the Departments to take this opportunity to gather stakeholder feedback about the areas that remain unclear for achieving effective compliance with MHPAEA and use that feedback to inform a future NPRM that adheres to statutory authority while avoiding the unintended consequence of hindering the availability, affordability, or safety of mental health care and substance use disorder treatment.

We are proud of the increases in affordable, high-quality, and effective MH/SUD treatment facilitated and financed by health insurance providers, particularly in recent years as demand for MH/SUD treatment has grown. Since the enactment of MHPAEA in 2008, health insurance providers have introduced many innovations and improvements to expand access to MH/SUD services. These efforts include reaching out to more members, especially those at high risk, expanding telehealth availability, maximizing and expanding behavioral health networks, integrating behavioral health with physical health care, and reducing stigma.

Health insurance providers are committed to working with care professionals, federal and state policymakers, community organizations, and other health leaders to improve affordability, access, quality, and outcomes for everyone seeking mental health support. The fundamental challenge before us is a significant increase in demand for MH/SUD treatment that has far outpaced the number of available licensed providers to adequately meet that demand. We are concerned these proposed rules focus on documentation and demonstration of compliance with arbitrary new standards that will do nothing to increase the number of available MH/SUD providers or facilitate access to quality MH/SUD care. Instead, should these rules be finalized as proposed, there would be myriad unintended consequences, including increased health care costs, shifts away from value-based care for MH/SUD treatment, and proliferation of unproven and unsafe MH/SUD treatment.

Since the MHPAEA final rules were promulgated in 2013, spending by commercial health plans on MH/SUD care has nearly doubled. Today, most MH/SUD claims are from participating providers and there is parity for MH/SUD benefits. Further, health insurance providers are prioritizing MH/SUD benefits, expanding MH/SUD provider networks, and addressing health equity issues present in MH/SUD care. For individual health insurance coverage, mental health care is an Essential Health Benefits (EHB) required to be covered as part of the Affordable Care Act. For large group and self-funded group health plans, mental health benefits are a top priority of employer plan sponsors, who in turn demand robust MH/SUD networks and comprehensive benefits in their plan design. Surveys of large employers identify expanding access to mental health care as a top priority for employers. Health insurance providers have embraced the use of telehealth for delivery of behavioral health care, a development that has increased the number of

in-network clinicians and made it easier for consumers to seek care while also addressing health equity and reducing stigma.

AHIP recognizes there is a necessary role for demonstrating parity, but cautions against an inefficient, vague, and excessive approach that prioritizes analyses of health care coverage over access to health care itself. We detail concerns with the approach proposed that would overhaul comparative analyses required under current law. Prior to passage of the Fiscal Year 2021 Consolidated Appropriations Act (CAA), many health insurance providers were already following recommended best practices and performing comparative analyses of their MH/SUD benefits. With passage of the CAA, documented comparative analyses became required and must be made available to regulators upon request. However, continued uncertainty over the scope and interpretation of the Departments in their requests for documentation on non-quantifiable treatment limitations (NQTLs) have resulted in findings of insufficiency – even after significant resources have been spent on these documentation and information requests.

Our members are very concerned that the proposed rules, if finalized, would move our health care system further away from affordable, equitable, and accessible MH/SUD care for the millions of Americans who would benefit. The proposed approach would divert valuable resources from the provision of high-quality MH/SUD services while ignoring the very significant workforce shortages that are the primary driver of access issues. If the proposed rules were finalized, it is highly unlikely anyone who today is unable to obtain mental health care would be in any better position to do so.

In addition to the serious concerns we have about the impact of these proposed rules on patients seeking or receiving MH/SUD care, we detail legal issues with regulatory authority to issue these rules, as well as significant operational challenges. We believe the proposed rules exceed any reasonable interpretation of the text or purpose of both MHPAEA and the CAA. Additionally, the proposed rules exhibit Constitutional flaws and raise concerns under the Administrative Procedure Act (APA) and Paperwork Reduction Act (PRA). Setting aside legal issues, the proposed rules are largely unworkable for the very entities tasked with compliance. Essential components of the proposed rules are vague or entirely undefined, while others conflict with state laws, and many of the new requirements create compliance tests for health insurance providers that cannot be realistically passed.

We also provide feedback on additional proposals included in the proposed rules and in Technical Release 2023-01P and highlight areas where our members have operational concerns. Throughout these comments we suggest possible ways to approach some of these outstanding questions but believe new rulemaking is required by the Departments to fully elucidate these definitions so that regulated entities have clear notice about the terms of compliance. We recommend that the Departments engage stakeholders in a series of working sessions where

different common NQTLs can be worked through to ideally produce complete, templated, compliant comparative analyses.

The recommendations that follow are the result of significant discussion among AHIP member organizations, including legal input and the perspectives of behavioral health professionals employed by AHIP members who provided input on the clinical implications of the proposed regulatory changes, such as those that would substantially restrict utilization management.

Detailed recommendations are attached, but our key recommendations are that:

Legal Concerns with the Proposed Rules

- **The Departments should withdraw the proposed rules and re-start the process to create new proposed rules, beginning with the engagement of stakeholders in a series of working sessions to inform the policy and legal considerations.**

Policy and Operational Concerns

- **Eliminate the "no more restrictive" test that will be virtually impossible to operationalize while eliminating tools to ensure patients receive safe and appropriate care. Instead, the Departments should update the current design and application requirements to address the Departments' and stakeholders' underlying concerns with NQTLs as currently applied.**
- **The Departments should clarify that their intention for the new design and application requirement for NQTLs is not to create an outcomes-only determination of compliance, and the Department should outline which specific data are used in that determination.**
- **Work with stakeholders to define an exhaustive list of outcomes data that must be collected and evaluated for each NQTL. As new NQTLs are identified by the Departments or state regulators, required data sets for those NQTLs should also be defined. If new data points are identified as being necessary to evaluate an NQTL, then the list should be updated with adequate time for plans and issuers to come into compliance.**
- **Rescind the proposed special rule for network composition and the application of the material difference standard to network composition. Instead, work with stakeholders to develop a set of objective metrics of MH/SUD access.**
- **Develop a method to assess the access impacts of a health plan's MH/SUD telehealth offerings when evaluating network adequacy.**
- **Provide an exhaustive list of NQTLs for which comparative analyses must be provided upon request. If the Departments determine that a plan practice is an NQTL, the plan should be given a reasonable amount of time to compile the comparative analysis.**

- **Adopt the CMS guidance used in Medicaid and CHIP requiring plans to use a reasonable method to determine whether a given service is a MH/SUD benefit or a M/S benefit.**

Other Issues

- **If finalized, the applicability date for group plans should be modified to plan years beginning on or after the later of January 1, 2026 or two years following the date the final rule is published. For individual market plans, AHIP recommends that no less than two years elapse between the date the final rule is published and the date the first state's rate filings for the following plan year are due.**

We detail these recommendations because promoting high quality, affordable mental health and substance use disorder care is a top priority for AHIP. Health insurance providers do far more than process and pay for health care claims. We are in the business of providing solutions to health care challenges. The soaring demand for mental health support and ongoing addiction epidemics are massive challenges that AHIP and health insurance providers across the country are committed to addressing with impactful solutions. The proposed rule does not solve these issues. Rather, it creates new ones. It should be withdrawn. AHIP is ready and eager to join other health care stakeholders in advancing solutions to ensure everyone who seeks it has effective, affordable, and equitable mental health care and addiction services.

Sincerely,

Julie Miller

Julie Simon Miller
Interim CEO

Attachment

Attachment
AHIP Detailed Comments on "Requirements Related to the Mental Health Parity and Addiction Equity Act" Proposed Rules

I. Health Insurance Providers are Increasing Access to MH/SUD Care and Growing Provider Networks to Meet Higher Demand

Health insurance providers engage in a wide variety of activities and programs to improve MH/SUD care access, quality, and value for the populations they serve. The industry is raising patient awareness of the importance and availability of MH/SUD care, while working to reduce stigma, integrate MH/SUD and medical/surgical care, encourage collaborations with providers, and proactively identify MH/SUD care needs for members. Health insurance providers are facilitating and paying for more MH/SUD care than ever before, but the proposed rules appear to be based on faulty data and written for a bygone era before the significant advancements of the last fifteen years.

The results of these efforts can be clearly seen in studies of health insurance claims and expenditures since passage of MHPAEA. For instance, a recent AHIP analysis of employer-sponsored plans estimated that plan expenditures for MH/SUD care nearly doubled (from $33.9 billion to $60.8 billion) from 2013-2021.[1] Outside studies have shown similar growth, particularly during the COVID-19 pandemic and when accounting for the now commonplace use of telehealth services.

Health insurance providers increased access to MH/SUD care during the COVID-19 pandemic, a period that exacerbated a mental health crisis in America. They also provided resources to help people avoid isolation and loneliness during times of extraordinary social distancing. In addition, health insurance providers were leaders in supporting access to MH/SUD care via telehealth, the

[1] The AHIP analysis estimated the total expenditure on behavioral health, including mental health and substance abuse disorder treatments, in the employer-sponsored market in 2013-2021 using the Merative® Commercial Claims Dataset. The study identified behavioral health enrollees using behavioral health diagnostic codes and behavioral health related procedure codes. Both inpatient and outpatient costs were included. The national expenditure was then estimated using the US Census national enrollment in the employer-sponsored market. All prices were adjusted for inflation. The analysis findings are available at https://ahiporg-production.s3.amazonaws.com/documents/AHIP-Analysis-of-Behavioral-Health-Spending-2013-2021.pdf

need for which was accelerated by the pandemic to reduce patients' and providers' potential exposure to the virus. A recent study published in JAMA Health Forum demonstrates the success of the industry's collective efforts during and following the acute phase of the pandemic:

- Mental health service use increased 22.3% during the acute phase of the pandemic (March to December 2020);
- While in-person visits decreased by nearly 40% during the acute phase, telehealth visits increased approximately ten-fold;
- By the end of the post-acute phase (January to August 2022), although in-person visits had returned to nearly 80% of pre-pandemic levels, the number of telehealth visits stabilized at approximately 10 times pre-pandemic levels;
- Overall, during the post-acute phase, mental health service use was nearly 40% higher than before the pandemic.[2]

These numbers demonstrating access stand in stark contrast to the outdated studies on which the Departments heavily rely to justify the heavy-handed policies in the proposed rules. For example, the Departments rely on a 2019 Milliman analysis that identified disparities in network use and provider reimbursement for mental health and physical health as justification for their proposal to compare certain outcomes data. However, this analysis was based on 2017 data and many of the other studies referenced by the Departments rely on studies that are several years old. More recent studies show a different story and are more appropriately used to show a more accurate picture of patient access to MH/SUD care. For example, the pandemic-driven reliance on telehealth caused a significant transformation in patient access and care delivery. Changes plans and issuers made during and following the COVID-19 pandemic to meet the needs of the people they serve were so substantial that they render older studies obsolete.

AHIP members also met the challenges of pandemic-driven demand increases for mental health services by expanding their networks of mental health practitioners. An August 2022 AHIP survey of commercial health plans that cover 95 million Americans showed that health plans are:

- Recruiting more mental health professionals and facilities to join plan networks,
- Helping their members get appointments, and
- Supporting primary care providers in caring for their patients with mild to moderate mental health conditions.[3]

These efforts have yielded positive results. AHIP members– in just the three-year period from 2019-2022 – grew the size of their provider networks by 48%. This growth helps patients access mental health care providers and facilities. Health insurers have also added more providers

[2] https://jamanetwork.com/journals/jama-health-forum/fullarticle/2808748
[3] https://www.ahip.org/news/press-releases/new-survey-shows-strong-action-by-health-insurance-providers-to-growing-mental-health-care-demands

eligible to prescribe medication assisted treatment (MAT) for people with opioid and other substance use disorders – more than doubling in-network MAT providers in the last three years.

Nearly 4 in 5 survey health insurance provider respondents have increased payments to providers in efforts to recruit more high-quality professionals to their plan networks. Most plans (83%) also help their members find available appointments and provide care navigation and support services, such as helping patients find the right level of care or providing transportation to their appointments.

In addition to these important steps, the survey also found that:

- All respondents (100%) provide coverage for tele-behavioral health services.
- The overwhelming majority of health plans (89%) are actively recruiting mental health care providers, including practitioners who reflect the diversity of the people they serve (83%).
- The number of providers eligible to prescribe MAT for substance use disorders, including opioid dependence, more than doubled – growing 114% over 3 years.
- A strong majority (72%) of plans are training and supporting primary care providers to care for patients with mild/moderate behavioral health conditions.
- A large majority (78%) use specialized case managers for follow-up after emergency room and inpatient care and/or starting new medications.

Much of the work health insurance providers do to facilitate MH/SUD care and improve access to services are not reflected in the proposed rule – any regulatory scheme should be based on a full picture of the industries it would regulate. Health insurance providers offer services such as staffing crisis lines, providing care navigators, raising awareness, and reducing stigma, all of which improve and ensure widespread access to MH/SUD services for the enrollees that our members serve. AHIP and our members are expanding access to MH/SUD care, and we remain committed to continuing these efforts to ensure patients are able to access the care they need when they need it.

II. Legal Concerns with the Proposed Rules

The Proposed Rules Go Beyond Reasonable Interpretation of MHPAEA and the CAA Amendments

The proposed rules suffer from several legal flaws, each of which provides a strong basis for the agency to withdraw the proposed rules and begin a new rulemaking or guidance process. Several legal flaws of the proposed rules arise from their conflict with both MHPAEA and the amendments passed in the CAA.

When Congress enacted the CAA, it amended MHPAEA.[4] Congress expressly required group health plans and health insurance issuers to make available to the Departments, upon request:

The comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to mental health or substance use disorder benefits, as written and in operation, are *comparable to, and are applied no more stringently than*, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits in the benefits classification.[5]

Congress, therefore, ratified the "comparable to" and "no more stringently than" compliance test for NQTLs that the Departments first had adopted in the 2010 MHPAEA Interim Final Rules and left intact in the 2013 Final Rules.[6]

It is a bedrock principle of administrative law that agencies are constrained by Congress and, therefore, may act only when and how Congress lets them.[7] When determining whether Congress unambiguously has spoken through a statute, a court must apply all the "traditional tools of construction," including "text, structure, history, and purpose."[8] Where "the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."[9] In finding that intent, "[i]t is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme."[10]

Congress unambiguously adopted the "comparable to" and "no more stringently than" test for NQTLs. The proposed rules, however, imposes a different requirement—that NQTLs applicable to MH/SUD benefits be no more restrictive than the predominant NQTL that applies to substantially all medical/surgical (M/S) benefits in the same classification.[11] Agencies cannot amend a statute by regulation.[12] Moreover, the Departments cannot adopt additional requirements that were not intended by Congress without "color[ing] outside the [statutory] lines."[13]

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[4] CAA, Pub. L. 116-260, 134 Stat. 1182 (Dec. 27, 2020) (Div. BB, Title II, Sec. 203 amending MHPAEA).
[5] 29 U.S.C. § 1185a(a)(8)(A)(iv) (emphasis added).
[6] 75 Fed. Reg. 5410, 5416 (Feb. 2, 2010); 78 Fed. Reg. 68240, 68245 (Nov. 13, 2013).
[7] *See La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986) ("[A]n agency literally has no power to act . . . unless and until Congress confers power upon it.").
[8] *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019) (quoting *Chevron*, 467 U.S. at 843 n.9); *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 707 (1991) (Scalia, J., dissenting).
[9] *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.,* 467 U.S. 837, 842–43 (1984) ("*Chevron*").
[10] *Davis v. Michigan Dep't of Treasury*, 489 U.S. 803, 809 (1989).
[11] 88 Fed. Reg. 51552, 51569 (Aug. 3, 2023).
[12] *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 328 (2014) ("We reaffirm the core administrative-law principle that an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate.").
[13] *Cent. United Life Ins. Co. v. Burwell*, 827 F.3d 70, 72 (D.C. Cir. 2016).

The practical impact of applying the "substantially all/predominant test" to NQTLs would be the elimination of almost all medical management of MH/SUD benefits. This is in direct contravention to the express statutory text that provides:

Nothing in this section shall be construed—
[. . .] as affecting *the terms and conditions of the plan or coverage* relating to such benefits under the plan of coverage, except as provided in subsection (a).[14]

A core tenet of statutory interpretation is to interpret the statute to give meaning to all of the statute.[15] But the proposed rules would read out of existence this savings clause and render the statutory language irrelevant.[16] The Departments certainly lack authority to void a statutory clause.

Likewise, the proposed rules' imposition of a "meaningful benefit" requirement has no basis in statute. MHPAEA by its own terms does not require a group health plan or health insurance coverage to provide any MH/SUD benefits.[17] MHPAEA does, however, require that any MH/SUD benefits are provided in parity with covered M/S benefits.[18] As explained above, Congress expressly adopted criteria for evaluating NQTL compliance when it amended MHPAEA in the CAA. Congress did not adopt any "meaningful benefit" criteria. The Departments invent the concept out of whole cloth. As *WVA v. EPA* found "[a]gencies have only those powers given to them by Congress, and enabling legislation is generally not an open book to which the agency may add pages and change the plot line. We presume that Congress intends to make major policy decisions itself, not leave those decisions to agencies."[19]

Finally, the Departments do not have the statutory authority to require an immediate cessation of a benefit based on their review. Although the Departments do have the authority to assess penalties and to take plans and issuers to court, they lack any general grant of authority to require immediate cessation of a plan term (*i.e.*, cease and desist authority). Further, by proposing that any of the Secretaries may order immediate cessation, the Departments are violating the statutory division of authority (HHS for issuers, DOL for self-funded plans, IRS for self-funded plans and church plans). The Constitution vests all lawmaking authority in Congress and commands the

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[14] 29 U.S.C. § 1185a(b)(2) (emphasis added).
[15] *Nielsen v. Preap*, 139 S. Ct. 954, 969 (2019) ("[T]he interpretive canon against surplusage…[is] the idea that 'every word and every provision is to be given effect.'" (quoting ANTONIN SCALIA & BRYAN GARNER, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 174 (2012))); *see also Montclair v. Ramsdell*, 107 U.S. 147, 152 (1883) (Courts must strive "to give effect, if possible, to every clause and word of a statute…").
[16] *Hibbs v. Winn*, 542 U.S. 88, 101 (2004) ("A statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant…").
[17] 29 U.S.C. § 1185a(b)(1).
[18] *Id*. at (a).
[19] *WVA v. EPA* at 2609 (cleaned up and internal citations omitted).

executive branch to faithfully execute laws duly enacted by Congress; simply put, if Congress has not authorized it, the executive branch cannot do it.[20]

Recommendation:

- **We recommend that the Departments withdraw the proposed rules and initiate a new process to propose regulations that do not contain these statutory flaws.**

- **We recommend the new process begin with the engagement of stakeholders in a series of working sessions to inform the policy and legal considerations underlying such rules.**

The Proposed Rules Fail to Follow the Requirements of the Administrative Procedure Act and the Paperwork Reduction Act

Other legal flaws in the proposed rules arise from their violation of core principles of the Administrative Procedure Act (APA) and the Paperwork Reduction Act.

The Proposed Rules are Arbitrary and Capricious

Novel and unprecedented interpretations of a statute undermine settled expectations and require clear direction from Congress.[21] Both the APA and Supreme Court precedent requires agencies to take reliance interests into account when appropriate.[22] Agencies may change policy, but must provide a "reasoned explanation" for the change.[23] The agency's interpretation must be "based on a consideration of the relevant factors" and must not reflect a "clear error of judgment."[24]

Here, the Departments have not provided a reasoned explanation or sufficiently evaluated the reliance interests of plans and issuers on previous guidance. The proposed rules' wholesale changes to substantial compliance obligations, whipsawing group health plans and health insurance issuers by deviating from the "comparable to" and "no more stringent than" requirements, is inconsistent with the CAA and the proposed rules lack a reasoned explanation for the deviation. As a result, the proposed rules create substantial uncertainty about plans' and issuers' legal obligations and make long-term planning, such as benefit design and utilization management, difficult.

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[20] *See* U.S. Const. Art. I and Art. II.

[21] *See West Virginia v. EPA*, 142 S. Ct. 2587, 2605, 2608 (2022) (characterizing agency action as entailing "novel," "unheralded," and "unprecedented" interpretations and invoking the major questions doctrine); *see also Sackett v. EPA*, 143 S. Ct. 1322, 1365 (2023) (Kavanaugh, J., concurring in judgment) (a "longstanding and consistent agency interpretation reflects and reinforces the ordinary meaning of the statute").

[22] *See National Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005) (agency must "adequately explain[] the reasons for a reversal of policy"); *Smiley v. Citibank (S.D.), N.A.*, 517 U.S. 735, 742 (1996) (agency change that "does not take account of legitimate reliance on prior interpretation" would be arbitrary).

[23] *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016).

[24] *Judulang v. Holder*, 565 U.S. 42, 53 (2011) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983)).

Compliance with the Proposed Rules is Impossible

The proposed rule noted that every entity examined by the Departments after enactment of the CAA failed to demonstrate compliance with MHPAEA under the current rules.[25] Now, rather than following Congress's express statutory direction in the CAA for the Departments to provide additional guidance so that plans and issuers can better understand and achieve their obligations,[26] the Departments have opted to add more requirements via the proposed rules, including requirements that are impossible to implement. This is directly contradictory to MHPAEA as amended by the CAA, which required finalization of any then-extant draft guidance or regulations by June 27, 2022.[27]

The impossibility also is demonstrated by the Departments' own failure to be able to provide model analyses or specifics that would demonstrate compliance. Finally, the proposed rules are inherently impossible to comply with: if the plan's data is bad, the plan is non-compliant, and if the plan's data is good, the Departments may still find the plan to be non-compliant. This is the definition of an arbitrary and capricious result in violation of the APA.

Regulatory Impact Analysis Fails to Adequately Consider the Additional Costs Imposed by the Proposed Rules

Agencies have long treated cost as a centrally relevant factor when deciding whether to regulate. Consideration of cost reflects the understanding that reasonable regulation ordinarily requires paying attention to the advantages and the disadvantages of agency decisions."[28] Agencies must consider the costs of compliance, and other costs, "before deciding whether regulation is appropriate and necessary."[29] While the proposed rules do provide an estimate of the proposed rules' costs, they fail to account for the substantial compliance costs incurred by group health plans and health insurance issuers since enactment of the CAA. The proposed rules drastically reconfigure the NQTL compliance framework, essentially forcing regulated entities to start over. Moreover, the proposed rules will require changes to benefit designs and, as a result, changes to premium and administrative expenses.

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[25] Proposed Rule at 51562.

[26] The CAA directed the Tri-Agencies to issue: guidance to plans and issuers to assist plans and issuers in satisfying the requirements of the CAA, see CAA section 203, (a)(2) [amending ERISA § 712(a) to add new paragraph (7)], (a)(3) [amending Internal Revenue Code § 9812(a) to add new paragraph (7)], and section 203(b); a Compliance Program Guidance Document, see CAA section 203, (a)(1) [amending PHSA § 2726(a) to add (8)(C)(i)], (a)(2) [amending ERISA § 712(a) to add (6)(A) – (D) and (8)(C)(i)], (a)(3) [amending Internal Revenue Code § 9812(a) to add (6)(A) –(D) and (8)(C)(i)], and section 203(b); and finalized versions of any draft or interim guidance and regulations relating to mental health parity that were in process at the time of enactment within 18 months from the date of enactment (*i.e.* by no later than June 27, 2022) see CAA section 203, (a)(1) [amending PHSA § 2726(a) to add (8)(C)(ii)], (a)(2) [amending ERISA § 712(a) to add (8)(C)(ii)], (a)(3) [amending Internal Revenue Code § 9812(a) to add (8)(C)(ii)], and section 203(b).

[27] *Id*. at CAA section 203, (a)(1), (a)(2), and (a)(3).

[28] *Michigan v. EPA*, 576 U.S. 743, 753 (2015).

[29] *Id*. at 759.

The Proposed Rules Violates the Paperwork Reduction Act

The proposed rules require voluminous collections and documentation of information subject to ambiguous, unclear criteria. Compliance with the proposed rules will entail substantial time and expense. This is particularly true given the Departments' failure to articulate the format and other parameters necessary to produce "outcomes data" and comparative analyses. The proposed rules violate the PRA because they lack sufficient specificity and direction regarding the categories and types of information that must be collected and provided in order to minimize the burdens of providing it.

Recommendation:

- **We recommend that the Departments withdraw the proposed rules and re-start the process to create new proposed rules that do not contain these APA and PRA flaws.**

- **We recommend that the re-started process begin with the engagement of stakeholders in a series of working sessions to inform the policy and legal considerations underlying such rules.**

The Proposed Rules Violate the Core Constitutional Principle of Due Process

Health insurance providers cannot reasonably comply with rules where required elements are vague or undefined and standards for mandatory tests are not clear. Throughout the proposed rules, many critical terms that would be essential components of a compliant NQTL comparative analysis are either vaguely defined or undefined. When such critical components are left to interpretation, there is uncertainty around what the tests are, what the standards for meeting the tests are, and how to provide the right information to demonstrate compliance. Regulators and auditors can end up with very different perspectives on requirements, which we observe in the market today. This leads to substantial uncertainty for plans making every effort to meet the requirements of compliance – not to mention frustration for regulators.

The Due Process Clause "requires the invalidation of laws [or regulations] that are impermissibly vague."[30] The vagueness doctrine addresses two concerns: "first, that regulated parties should know what is required of them so they may act accordingly; second, precision and guidance are necessary so that those enforcing the law do not act in an arbitrary or discriminatory way."[31] The proposed rules fail on both counts. For example, "relevant data" for outcomes does not give plans and issuers a reasonable opportunity to know what information is required to be collected, retained and/or measured in order to demonstrate compliance. As a result, plans and issuers do not have sufficient notice of what is required and how to comply. While in some instances issues can be addressed through follow-on guidance and FAQs, these do not generally have the force of law. Furthermore, the Departments ask for suggestions of definitions for some of these terms, but

[30] *F.C.C. v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012).
[31] *Id.*

for others, there is no direct inquiry nor appropriate anticipation of how a proposed term would apply to the wide variety of NQTLs that are included in the proposed rules.

In many instances, without clear definitions and detailed examples, we are uncertain about the applicable scope and effect of certain elements of the proposed rules, and thus are limited in the extent to which we can provide meaningful feedback to the Departments.

Throughout these comments we suggest possible ways to approach some of these questions but believe that additional work must be done by the Departments to provide clear and meaningful definitions.

Recommendation:

- **We recommend that the Departments withdraw the proposed rules and re-start the process to create new proposed rules that do not violate the core Constitutional guarantee of Due Process.**

- **We recommend that the re-started process begin with the engagement of stakeholders in a series of working sessions to inform the policy and legal considerations underlying such rules.**

The Proposed Rules Will Increase Existing Interpretive Variation Among State Regulators

The proposed rules will lead to the undesirable result of increasing the variability of interpretations between the Federal government and State governments and between one state and another. The CAA amendments to MHPAEA became effective in February 2021. In addition to the requirements on plans and issuers to prepare and submit NQTL comparative analyses to regulators, the law required the Departments to issue comprehensive guidance to assist plans and issuers in satisfying the requirements of the CAA. The Departments issued FAQ Part 45 in April 2021,[32] which provided an overview of the law's requirements and recommended plans use pre-existing guidance, such as the 2020 version of the DOL's Self-Compliance Tool,[33] to compile their comparative analyses.

Following review by and subsequent outreach from the Departments, none of the initially submitted comparative analyses submitted between April 2021 and July 2022 were deemed to contain sufficient information for a parity review.[34,35] AHIP joined with other groups

[32] https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-45.pdf
[33] https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/mental-health-parity/self-compliance-tool.pdf
[34] https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf
[35] https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis

representing employers, plans, issuers, and service providers in April 2022 to request more comprehensive guidance from the Departments to improve the sufficiency of the comparative analyses submitted. The group also requested the Departments issue model templates and examples to assist plans and issuers in the preparation of their comparative analyses. The group met with the Departments in June and November 2022 to reiterate these requests and to share ideas for improving the guidance for plans and issues. However, no additional guidance, instructions, or templates were released.

Because there has been insufficient guidance released from the Departments, state Departments of Insurance (DOIs) created their own templates and submission tools for NQTL comparative analyses and have each established unique expectations and requirements for submission and content. Our members report that these variations between federal and state requirements and between the states exist not only in matters of process, but also – critically – in matters of interpretation. We are concerned that these proposed rules, if finalized as proposed, will exacerbate interpretive variation between the states and between the Departments and the states and increase plans' compliance costs.

Recommendation:

- **The Departments should withdraw the proposed rules and re-start the process to create new proposed rules that do not raise the prospect of undesirable and inefficient variability.**

- **We recommend the new process begin with the engagement of stakeholders in a series of working sessions where the standards discussed throughout the proposed rules can be more clearly defined and where different common NQTLs can be worked through to produce complete, templated, compliant comparative analyses.**

III. Policy and Operational Concerns with the Proposed Rules

In addition to the legal problems raised by the proposed rules, the proposed rules also raise significant policy and operational concerns. Those concerns, combined with the legal concerns or even by themselves, provide a strong basis for withdrawing the proposed rules and re-starting the rulemaking process.

New NQTL Requirement: "No More Restrictive" Requirement - (c)(4)(i)

The Departments propose to add a new three-part test for each NQTL to the existing six-part comparative analysis required under the CAA. Reviewed together, the proposed requirements for NQTLs will require substantial time and resources from plans and issuers, noticeably increasing administrative costs for plans without providing a clear benefit to their health plan members.

The first part of the proposed test provides that a plan or issuer may not apply any NQTL to MH/SUD benefits in any classification that is more restrictive, as written or in operation, than the predominant NQTL that applies to substantially all M/S benefits in the same classification. To comply with these proposed rules, plans and issuers would be required to follow similar steps to those that apply when analyzing parity with respect to financial requirements or quantitative treatment limitations under the 2013 final regulations, even though NQTLs are non-quantitative by definition.

This "no more restrictive" requirement itself requires its own four-step subtest that will involve extensive data collection and evaluation from multiple parts of a health plan's organization. The subtest requires that plans determine:

- The portion of plan payments for M/S benefits subject to an NQTL in a classification;
- Whether the NQTL applies to substantially all (at least two-thirds) M/S benefits in the classification;
- The predominant variation of the NQTL that applies to M/S benefits in the classification; and
- Whether the NQTL, as applied to MH/SUD benefits in the classification, is more restrictive than the predominant variation of the NQTL as applied to substantially all M/S benefits.

Portion of Plan Payments Subject to an NQTL

AHIP appreciates the Departments' efforts to create an adjudication system for NQTLs that relies on objective standards and data. However, as proposed, the requirements inadequately account for the inherent differences of NQTLs when compared to QTLs or financial requirements. For example, for the first part of the "no more restrictive" requirement, the plan must determine the portion of plan payments for M/S benefits expected to be subject to the NQTL based on the dollar amount of all plan payments for M/S benefits in the classification expected to be paid for the plan year. This data collection would not – and could not – capture the requests (such as for prior authorization) that were not approved and therefore did not lead to a paid claim, nor would it capture requests that were not approved but resulted in the patient receiving a different treatment. While the treatment received would be captured in the assessment, the treatment initially requested would not be. Not having the full universe of requests accounted for in the calculation means that the results will not correctly reflect the portion of services subject to an NQTL. Further, many NQTLs, including medical management, assessments related to medical necessity, determinations for experimental/investigational treatments, and provider network admissions standards, are not attached to claims, and no guidance is provided on how plans should operationalize this test.

The "no more restrictive" test and its component determinations would also create a complication in a common way patients receive prescription drugs for MH/SUD conditions. Coverage of prescription drugs – particularly for M/S conditions – is covered under both the

medical and pharmacy benefits of a health insurance plan. Generally, drugs covered under the medical benefit are those administered in a hospital or outpatient setting by a medical professional, while drugs covered under the pharmacy benefit are self-administered by the patient. While each plan may have a unique division of drugs covered under the pharmacy and medical benefits, nearly every plan has some drugs divided this way. This division complicates the performance of the "no more restrictive test" because the cost of drugs administered this way are frequently included in a bundled payment for the treatment or procedure. It is therefore difficult to calculate the amount of the payment that represents the cost of the drug subject to an NQTL.

"Substantially All" Test

Of particular concern to our members is the requirement that any NQTL must be applied to "substantially all" M/S benefits in a classification (or relevant subclassification) to be applied to any MH/SUD benefit in that classification. While this requirement is patterned after the quantitative test for the application of quantitative treatment limitations (QTLs) and financial requirements, AHIP does not believe that this test can or should be translated to NQTLs, given their nonquantitative nature.

While we appreciate the desire to deploy a test with clear-cut results, the flawed calculations preceding the proposed "substantially all" test will make the application of NQTLs (encompassing most, if not all, medical management requirements) virtually impossible for any MH/SUD services, because they are not applicable to two-thirds of benefits for M/S services due to the inherent differences in MH/SUD and M/S care and the sheer number of M/S services and medications as compared to the number of MH/SUD services and medications. The application of the quantitative test inappropriately groups all services within a classification (or relevant subclassification) and reduces the determination of when and whether to apply medical management to an arbitrary calculation, rather than on medical evidence or service-specific factors.

The judicious application of NQTLs by plans and issuers ensures that patients receive the right care, in the right setting, at the right time and ensures that patients receive high-quality, evidence-based care in safe settings. This goal is especially important in promoting a system of care that supports patients receiving treatment in the least restrictive setting and services that best meet their needs. This doctrine of least restrictive care is fundamental to preserving the progress made over the last several decades in transitioning patients from institutional settings into less restrictive community-based settings. The concept of least restrictive care is also a key component of level of care guidelines, including those of the American Society of Addiction Medicine (ASAM) which, for example, supports initiating treatment of opioid use disorder in the least restrictive, effective setting appropriate for the patient's needs.[36] The "substantially all" test

[36] https://www.asam.org/asam-criteria/about-the-asam-criteria

will make it nearly impossible to have a medical management framework that supports the goal of least restrictive care for MH/SUD patients and instead result in increased lengths of stay at higher levels of care than are indicated by evidence-based guidelines. While the Departments propose an exception for consistency with independent professional medical or clinical standards, this exception, according to the Departments, is designed to be extremely limited. Moreover, as discussed further in our comments, there is no substantive explanation for how and which standards may be applied to qualify for the exception.

Predominant Variation

In the illustrative examples, the method for determining the predominant variation of an NQTL is simple and straightforward. However, in practice, NQTLs are multi-factorial, and these easy-to-determine situations are likely the exception, rather than the rule. The examples indicate that if a plan applies an NQTL (such as prior authorization) in a way that contains differences based on the manner of review ("auto adjudication vs. manual review") and based on the number of levels of review ("first-level review vs. first-level review and peer-to-peer review") each difference is considered an NQTL variation. This approach will require plans to track potentially dozens of variations, such that the predominant variation may ultimately apply to only a small percentage of M/S services.

A predominant variation (reflecting a unique set of decisions, as explained above) that may be common for an M/S NQTL may not be similarly appropriate for MH/SUD benefits in the same classification. For example, electronic review may be the predominant variation for an NQTL in an M/S classification. However, on the MH/SUD side, the nature of MH/SUD conditions is such that diagnoses can be subjective and not associated with clear biometric markers or objective findings, so requiring a different method of review, such as peer-to-peer review, allows the provider to explain why the prescribed level of treatment is necessary, even when a recommended treatment does not meet criteria or there is a gray area in the criteria.

The proposed rules provide little guidance about how a plan is expected to determine what a particular variation of an NQTL is or whether there is a variation at all. It is also not clear from the proposed regulatory text or the preamble discussion how to identify a variation in the NQTL. The Departments propose in this and other sections to require plans to identify and distinguish between different NQTL types, different variations of the same NQTL, different factors for designing and applying the NQTL, and different variations of factors for applying the NQTL, but do not define most of these terms and provide little to no guidance to determine how to characterize a given aspect of an NQTL. Yet the distinction is critical given that each of these elements is subject to a different documentation and analysis requirement. Because the scope of potential "variations" is not limited, the proposed requirement to apply quantitative testing for every different variation creates an impossible task for regulated health plans.

In theory, a strictly quantitative test could provide certainty for plans and issuers to know when they may apply an NQTL and remain in compliance with MHPAEA. However, while QTLs and financial requirements vary only along the dimension of dollars or other easily quantified metrics, such as visit limitations, NQTLs vary along multiple dimensions. This makes the "no more restrictive" test ill-fitted for this situation. For example, how would an insurer conduct this test on NQTLs related to network composition? There is no clarification in the proposed rules or the Technical Release about how a plan or issuer would apply the steps of the test – particularly the substantially all and predominant variation sub-tests – to reimbursement rates or provider contracts. Issues like how to count value-based payment arrangements, different rates for different professional licenses, and various state network contracting requirements are also not addressed in this proposed rule. Given the Departments are primarily concerned with access provided by the network, we do not believe the application of this test is appropriate for the NQTL comparative analysis and an exception from this test is needed.

In AHIP's view, the existing tests and the current design and application requirements that have been applied under the NQTL regulations for the last decade, while still needing some refinement and standardization, are a better foundation for determining whether an NQTL is more restrictive for MH/SUD benefits.

As currently proposed, the "no more restrictive" requirement, and the "substantially all" requirement twists the language of the statute to institute an all-but-total prohibition on legitimate, evidence-based medical management requirements.

As discussed above, such a prohibition of common medical management techniques, even when offered in parity under the NQTL rule, is legally impermissible because it is not consistent with the statute, which contains a savings clause that preserves these common processes. See Code § 9812(b)(2); ERISA § 712(b)(2); PHS Act § 2726(b)(2) ("Nothing in this section shall be construed . . . in the case of a group health plan (or health insurance coverage offered in connection with such a plan) that provides mental health or substance use disorder benefits, as affecting the terms and conditions of the plan or coverage relating to such benefits under the plan or coverage, except as provided in subsection (a).") The proposed rules cannot read this statutory savings clause out of existence and therefore cannot prohibit common medical management techniques.

The "no more restrictive" requirement also falls short in its ability to compare inherent differences in the administration of M/S benefits as compared to MH/SUD benefits, particularly, as mentioned above, when value-based care or other innovative payment structures are in place. For example, many procedure-based stays in hospitals are paid through a Diagnosis-Related Group Reimbursement (DRG), a calculation-based, single-payment rate that is intended to cover a patient's entire stay in a hospital – regardless of the duration of the stay. While some external factors may adjust the rate amount, the bundled payment model rewards efficiency and high-

quality care. Under the DRG payment model, medical necessity reviews to determine whether continued inpatient treatment is appropriate are unnecessary, as the payment model rewards providers who do not keep a patient in the hospital longer than necessary.

In contrast, our members report that inpatient hospitals and residential facilities that treat MH/SUD conditions generally consent only to *per diem* rates for patient treatments. A per-diem-only payment model does not carry the built-in incentive for an inpatient facility not to keep a patient longer than necessary, and in fact, the model does the opposite and pays more the longer a patient remains in that setting. As a result, plans and issuers often apply concurrent review requirements at set time markers during an inpatient stay. While these can vary by plan, diagnosis, and severity, these reviews for MH/SUD inpatient treatment serve the same purpose as the DRG payment model for M/S inpatient treatment: ensuring that the patient remains in the facility only as long as is medically necessary. However, under the "no more restrictive" requirements, plans and issuers would not be able to use this NQTL because it is not applied to two-thirds of the M/S benefits in the same classification and may not qualify for an exception based on standards of generally accepted care or standards to prevent fraud, waste, and abuse, as described in the preamble.[37] As mentioned above, not recognizing inherent differences in the administration of MH/SUD benefits also conflicts with the universal goal to promote a model of care that relies on the least restrictive environment appropriate to a patient's needs.

Finally, it is not clear (and the Departments do not specify) what instances of non-compliance would be captured by the new quantitative test that are not already captured by the existing rules, including the comparative analysis requirement. In the examples provided, non-compliance would be clear in both. If the Departments seek to require this type of onerous and costly administrative testing, it must be justified.

Recommendation:

- **Because the "no more restrictive" test will be virtually impossible to operationalize and because it will remove nearly all legitimate insurer tools to ensure patients receive safe and appropriate care, AHIP recommends that the Departments do not finalize the test and instead update the current design and application requirements to address the Departments' and stakeholders' underlying concerns with NQTLs as currently applied.**

- **If the Departments move forward to finalize the "no more restrictive" requirement, an alternative approach could be for the Departments to establish a comparison of the proportion of prior authorization use and denials between MH/SUD and M/S. If**

[37] While we appreciate the Departments' inclusion of exceptions for care consistent with independent professional medical or clinical standards or standards addressing fraud, waste, and abuse, we are concerned that these exceptions may be so limited that they will be interpreted to exclude legitimate, evidence-based medical management and fraud detection practices that benefit patients.

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. Such a policy would encourage plans to use prior authorizations in the areas where they will be of the most value to patient care and to discourage fraud, waste and abuse.

- **If the Departments move forward to finalize the "no more restrictive" requirement, AHIP requests that the Departments clarify the treatment of services that would be subject to an NQTL but are exempted based on external criteria. For example, some plans and issuers have (and some states require) programs to exempt from prior authorization requirements any provider who meets a set of criteria (such as high approval rates for services that require approval). AHIP recommends the Departments clarify that services performed by an exempted provider be included in both the numerator and denominator of the calculation for the portion of plan payments subject to the NQTL, as the NQTL still applies to that service, and it is the provider who has received the exception. AHIP opposes counting services provided by an exempted provider only in the denominator.**

- **Similarly, if the Departments move forward to finalize the "no more restrictive" requirement, AHIP recommends the Departments exempt the network composition NQTL from the "no more restrictive" requirement, as the test for that requirement is not tailored to assess the network composition NQTLs.**

New NQTL Requirements: Design and Application Requirements - Non-discrimination as a Factor in Assessing Comparability and Stringency - (c)(4)(ii)
The Departments propose additional requirements related to design and application of the NQTLs. Plans cannot impose an NQTL, unless, as written and in operation, the processes, strategies, evidentiary standards, or other factors used in "designing and applying" the NQTL to MH/SUD in the classification are comparable to, and are applied no more stringently than M/S. For determining comparability and stringency, a plan may not rely upon any factor or evidentiary standard if the information, evidence, sources, or standards on which the factor or evidentiary standard is based "discriminates" against MH/SUD benefits as compared to M/S benefits.

AHIP is committed to the principle that every American deserves access to high-quality, affordable health care, regardless of race, color, national origin, sex, gender identity, sexual orientation, age, or disability. We strongly support federal protections that prohibit discrimination and ensure that care is available and accessible to every American. However, the proposed rules establish a framework whereby any disparate outcome could presume discrimination. The proposed definition of "discrimination" is "biased or not objective, in a manner that results in less favorable treatment of mental health or substance use disorder benefits, based on all the relevant facts and circumstances including, but not limited to, the

source of the information, the purpose or context of the information, and the content of the information." The definition suggests that if an evidentiary standard results in disparate outcomes, then it is biased and cannot be used. However, this definition and resulting standard duplicates the requirement for plans and issuers to take reasonable action to address material differences in outcomes, as determined by collection and evaluation of relevant data.

AHIP is also concerned that, as designed in the proposed rules and explained in the preamble, this non-discrimination requirement is difficult to fully comply with during the construction of an NQTL. While the preamble imagines simple, clear-cut examples of discriminatory factors, in practice, predicting the ultimate outcomes of a factor's application is far more difficult, such that even careful adherence to the spirit and letter of the design and application requirement could still lead to a finding of violating the non-discrimination sub-requirement. Further, the proposed rules are unclear on how regulators will adjudicate these factors. For example, if an NQTL shows reduced access in outcomes to MH/SUD benefits, is it automatically non-compliant because the evidentiary standard is *per se* biased, or would it be evaluated as only likely non-compliant under the material differenced standard? Can a plan satisfactorily document and demonstrate the *absence* of bias in a factor when it designs an NQTL? If so, what documentation and evidence would be necessary for regulators to make such a determination?

Recommendation:

- **AHIP requests that the Departments clarify that their intention for this requirement is not to create an outcomes-only determination of compliance and to outline which specific data are used in that determination. This is particularly important if the required outcomes data go beyond that required for the 6-step NQTL comparative analysis or the outcomes data evaluation requirement.**

New NQTL Requirements: Required Use of Outcomes Data, Material Differences, and Special Rule for NQTLs Related to Network Composition - (c)(4)(iv)

Data Collection Requirements

The Departments propose to codify a requirement that a plan or issuer must collect and evaluate data to assess the impact of the NQTL on access to MH/SUD and M/S benefits "in operation." The outcomes data a plan or issuer would be required to collect and evaluate for all NQTLs would include, but not be limited to, the number and percentage of relevant claims denials, as well as any other data relevant to the NQTLs.

In addition, the Departments propose specific data collection requirements for NQTLs related to network composition that are consistent with the type of data the Departments and/or States have examined in their MHPAEA compliance reviews and investigations. This data would include, but not be limited to:

- In-network and out-of-network utilization rates (including data related to provider claim submissions),
- Network adequacy metrics (including time and distance data, and data on providers accepting new patients), and
- Provider reimbursement rates (including as compared to billed charges).

The third part of the new NQTL requirements imposes a proactive requirement for plans and issuers to collect and evaluate extensive amounts of data. This represents a substantial departure from the existing six-step comparative analysis that requires plans and issuers to evaluate data currently collected. In many cases, health insurance providers are not currently collecting this data as part of their normal operations, nor is such collection possible with current data collection systems. As a result, this new data collection and evaluation requirement will substantially increase compliance costs for all plans and issuers, as new (though yet undefined) data will be required to be collected and plans and issuers will need to invest in and build systems to collect, store, and evaluate this data. Additionally, in order to collect this data, insurers will have to increase the patient-level data that providers report when they file claims or otherwise submit data to plans and issuers, thus increasing providers' paperwork burdens, and potentially creating disincentives for providers to participate in health plan networks.

Moreover, the proposed rules do not address an important service delivery model that relies on specialized managed behavioral health organization (MBHO) carve-out vendors. MBHOs are sometimes used by health plans and issuers as part of their plan design. Use of an MBHO has the potential to significantly improve care for members impacted by MH/SUD conditions, including through:

- Focusing solely on mental health and substance use disorders services in their expertise;
- Efficient contracting, cost and quality monitoring, and appropriate treatment management;
- Offering coordination of care to reduce duplication and inefficiencies;
- Providing targeted care management and care coordination for individuals with complex care needs;
- Developing contractual performance standards to ensure high quality of care for individuals;
- Implementing provider access standards to ensure that members can receive timely care from health care providers and specialists; and
- Promoting transparency of program design and accountability of the contractors and providers involved within the program.

The level of detail and type of data requested under the proposed rules pose unique challenges for plans and issuers that use MBHO vendors, given that under such arrangements two different entities are involved in managing and administering M/S and MH/SUD benefits. In recognition

of the importance of preserving the viability of this type of care model, AHIP requests that the Departments work with relevant stakeholders to identify benchmarks that MBHO vendors can meet in order to demonstrate compliance with MHPAEA.

Additionally, AHIP seeks clarification from the Departments about the treatment of pharmacy networks where they are used and what types of outcomes data are appropriately applied to the pharmacy classification, as there will be some differences in the way networks operate for pharmacies in comparison to other providers. AHIP requests that pharmacy networks be excluded from the network composition NQTL.

Recommendation:

- **AHIP recommends the Departments work with plans and issuers, as well as providers, to define an exhaustive list of outcomes data that must be collected and evaluated for each NQTL. As new NQTLs are identified by the Departments or state regulators, required data sets for those NQTLs should also be defined. If new data points are identified as being necessary to evaluate an NQTL, then the list should be updated with adequate time for plans and issuers to come into compliance.**

- **AHIP recommends that the Departments further detail the process to determine whether a plan's data collection and evaluation process is "reasonably designed" to assess the impact of the NQTL. The requirement that plans evaluate "all relevant data" does not provide a standard or procedure for collection and evaluation. Plans and regulators are likely to have differences in opinions around what data is relevant; and given the intense administrative burden of conducting outcomes analysis and tight timeframe for demonstrating compliance, we ask that the Departments clarify their expectation around the outcomes data requirements.**

- **AHIP recommends that the Departments work with stakeholders to develop a series of benchmarks that vendors can meet to be deemed compliant with MHPAEA. MBHOs that meet or exceed the benchmarks would be deemed compliant while MBHOs that do not meet a specific benchmark would be open to an audit specific to that benchmark. Additionally, the Departments should consider allowing accreditation standards to be the basis of a parity-compliant "model" for MBHOs.**

- **AHIP recommends the Departments clarify that pharmacy networks are not subject to the network composition NQTL.**

- **AHIP supports the level of aggregation proposed in the Technical Release (aggregated for all plans or policies using the same network of providers or schedule**

of reimbursement rates), which will ensure that there are enough claims to be examined.

Material Differences

Under the proposed rules, to the extent the relevant data reveal material differences in access to MH/SUD benefits as compared to M/S benefits, the differences would be considered a strong indicator that the plan or issuer violates the proposed "no more restrictive" requirement and the design and application requirements. While material differences alone would not automatically result in a finding of noncompliance, a plan or issuer would be required to take and document reasonable action to address any material differences in access as necessary to ensure compliance, in operation, with the "no more restrictive" requirement and the design and application requirements.

The Departments ask for comments on defining "material difference" in the final rules. AHIP appreciates the Departments' seeking input; however, we note that, as the concept of material difference sits at the crux of the new MHPAEA regulations, it is perplexing that for a test that will ultimately determine compliance or noncompliance, the Departments essentially ask for suggestions for defining noncompliance under MHPAEA. This type of inquiry is appropriate for an RFI, but leaving a critical element of the proposed rule up for suggestions without any guidance for what the Departments are considering, makes evaluation of the proposed rule as a whole very difficult. We further note that several of the proposed examples reference a plan's meeting or not meeting the material difference standard—again hinging the application of these examples on a standard that the Departments do not precisely define in the proposed rules.

AHIP would likely oppose any vague standard that relies on a subjective or arbitrary determination. The idea of a "material difference" is one that implies a serious or significant variation – a difference that is more than just numerically different. Instead, a "material difference" would need to be so large as to have a major effect on the access to care in MH/SUD, implying the need to consider both the size of the difference and the total number of those affected. For example, if three MH/SUD providers were denied accreditation out of 100, and three M/S providers were denied accreditation out of 5,000, this would not be meaningfully different because of the very small numbers of providers affected in either instance. As the Departments work to establish the definition of "material difference," we offer three guidelines or criteria for consideration. The definition should:

- Identify and rely upon clear metrics that will be examined for each NQTL;
- Identify only those measures where there is a high likelihood of noncompliance;
- Seek to minimize false red flags by ensuring that only statistically significant differences (calculated at a 95% confidence interval) are flagged for review.

However, even with a definition that meets the above criteria, the material difference standard relies on an assumption of simple statistical comparability between data related to M/S and MH/SUD treatment. AHIP and our members dispute this notion and believe that even data-based comparisons between MH/SUD treatments and M/S treatments will lead to many false "red flags," subsequent inquiries that find no noncompliance, and requirements for plans and issuers to address material differences that result from *MHPAEA-compliant* NQTLs.

Requiring plans and issuers to address material differences resulting from otherwise compliant NQTLs is the most problematic feature of the material difference standard. As discussed above, Congress expressly adopted criteria for evaluating NQTL compliance when it amended MHPAEA in the CAA. Congress did not adopt any "material difference" criteria. The Departments impermissibly create this concept instead of utilizing the criteria in the statute itself. Thus, the Department's interpretation of "in operation", resulting in a requirement of no material differences in outcomes, is impermissible under the statute. The CAA's addition of the comparative analyses' assessment of MH/SUD NQTLs for parity with M/S benefits "as written and in operation" applies only to parity of the process and operational application of the NQTL – not to the outcomes of the NQTLs.

AHIP also notes the difficulty of making comparisons of MH/SUD and M/S services across benefit classifications, as some MH/SUD services may not fit neatly into the existing classifications and have no clear comparison to M/S services. Oftentimes, these treatments were developed as innovative methods to avoid hospitalizations or residential treatments for individuals with especially challenging MH/SUD conditions and promote less restrictive settings of care. For example, there is no M/S service that is adequately comparable to a partial hospitalization program (PHP) or intensive outpatient program (IOP), both of which are treatment options for MH/SUD conditions and support patients being closer to their community in recovery. These intensive treatments feature several hours of treatment multiple days per week, but the patient is not required to live in a residential or inpatient facility to receive services.

Even within a benefit classification, the difficulty and unfairness of comparison remains. For example, for many prescription drugs for MH/SUD conditions, NQTLs are often based on safety protocols, such as for controlled substances scheduled by the U.S. Drug Enforcement Administration. While some of these protocols may be outlined in, for example, independent professional medical or clinical standards, AHIP recommends the Departments state that these important protections may remain in place.

Recommendations:

- **AHIP recommends the Departments not finalize the material difference standard, which would require that plans and issuers alter MHPAEA-compliant NQTLs to**

ensure that no difference exists in outcome measures for MH/SUD benefits versus M/S benefits.

- **If the Departments move forward and finalize the "material difference" standard, AHIP recommends the Departments propose through notice and comment rulemaking a clear-cut definition and adjudication standard for material differences that will provide plans and issuers clear rules for the structuring and evaluation of NQTLs. If the definition varies depending on the type of NQTL or data, the Departments should provide specificity about that variance.**

- **Additionally, AHIP recommends the Departments provide specific guidance on the treatment of benefits like PHP and IOP in comparisons by benefit classification.**

Special Rule for NQTLs Related to Network Composition and Addressing Material Differences Related to Network Composition

Under the proposed rules, when designing and applying one or more NQTLs related to network composition standards, a plan or issuer fails to meet the requirements of the proposed "no more restrictive" requirement and the design and application requirements, in operation, 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. Plans and issuers would be required to take action to address material differences in access or no longer impose the relevant NQTLs.

For this special rule and the requirement to address material differences with respect to network composition, AHIP reiterates our concerns as expressed with the general material difference standard, and we oppose the Departments' finalizing both the special rule and the special application of the material difference standard to network composition. We oppose the proposal that would find a plan noncompliant upon any material difference in network composition NQTLs with no opportunity for a plan to explain the difference (other than for provider shortages, but then only in limited circumstances).

There are challenges with conducting the material difference evaluation using the data points proposed by the Departments in the preamble and in the accompanying Technical Release. For instance, when looking at out-of-network residential or inpatient facilities, there is a substantive difference between utilization of a facility that is near the patient's home or family and utilization of an out-of-state or "destination" facility that is not captured in simple data points. Utilization of out-of-network providers and facilities will also likely be higher for PPO plans that have more generous out-of-network coverage policies that patients can choose to use, and out-of-network use may be higher in states where there are fewer overall facilities, meaning people may need to leave their immediate area for treatment (including for reasons such as an insufficient number of beds or because they need highly specialized treatment). There are also new out-of-network access points for the delivery of MH/SUD care that policies should encourage, including

crisis care delivery systems and school-based care, but these innovations could impact out-of-network utilization and data on those points.

As with hard-to-compare services, AHIP also highlights the general challenges that exist in comparing provider types across MH/SUD and M/S treatments. Generally, there are more non-physician providers billing for MH/SUD services than for M/S services, which makes simple comparison across provider types more difficult. In addition, there are newer, non-licensed specialties in mental health (*e.g.*, non-licensed peer support specialists, non-licensed behavioral analysts providing therapy to individuals with autism spectrum disorder) that may require additional medical management, credentialing, or oversight to ensure patients receive the most appropriate care.

There are also distinct trends in practice environments for MH/SUD providers as compared to M/S providers. M/S providers are more likely to practice in integrated groups and value-based payment models, while MH/SUD providers (particularly facilities, as noted previously) are less likely to accept such payment arrangements, which may skew reimbursement data. Similarly, M/S providers often have greater overhead in terms of more specialized technology and staff than MH/SUD providers, which can also factor into reimbursement data. MH/SUD providers are more often in small or solo practices with limited back-office support, and as a result may be less willing to take on the administrative burden of joining networks or increasing patient loads. MH/SUD providers are also more often practicing via telehealth and across state lines.

As AHIP noted previously, the COVID-19 pandemic represented a substantial shift in the way many Americans sought and received MH/SUD treatment. In addition to expanding the method by which a patient can receive treatment, telehealth allows insurers to address regional provider shortages in ways that alleviate immediate demand while they continue working to grow local provider networks for in-person services. We recognize that telehealth-only MH/SUD treatment may not be appropriate for every patient's need, but telehealth can help increase access, fill gaps left by provider shortages, and is often preferred by some patients for its convenience. The proposed rules offer no substantive consideration of or credit for the ways telehealth has increased access to patient care for MH/SUD treatment and addressed longstanding provider shortages. If network adequacy is to be evaluated, a concrete method to judge the access impacts of telehealth must be included. For example, one AHIP member reports that more than 50% of their routine outpatient MH/SUD visits now occur through telehealth. While the distribution varies by carrier, metrics around time and distance are much less relevant when such a substantial portion of MH/SUD care is delivered via telehealth. As we noted previously, the Departments rely on several older studies that predate the COVID-19 pandemic. The changes plans and issuers made during and following the pandemic to meet the needs of the people they serve were so substantial that they render older studies – and old methods of measuring access – obsolete.

With respect to assessing reimbursement rates, the Departments discuss and request comments on rates to use as a comparator for data collection and evaluation. AHIP opposes comparison of reimbursement rates to billed charges, as the Departments note they are considering. Billed charges are arbitrary values set solely by providers. Requiring plans and issuers to meet a certain threshold of billed charges creates a perverse incentive for providers to increase billed charges in a bid to force higher reimbursement rates with no negotiation or constraints on price increases.

Similarly, while there may be some value in comparisons to Medicare rates for services, AHIP notes that some MH/SUD providers may not be independently covered by Medicare while others are only newly covered by the program. For instance, MH/SUD services provided by marriage and family therapists and mental health counselors for MH/SUD conditions was authorized by Congress less than one year ago in the Fiscal Year 2023 Consolidated Appropriations Act (although the provision will not be effective until January 2024).[38] Other services may have limitations on MH/SUD care that are not comparable to those in the commercial insurance market. Additionally, Medicare generally sets a single national standard for rates, and a strict comparison would allow no flexibility for plans and issuers to vary rates by geographic market or based on other market factors.

AHIP also opposes requiring plans to use individual provider reimbursement rates for evaluation and recommends the Departments consider the use of base rates or set fee schedules instead. The base rate or fee schedule is the starting point for every negotiation between a plan and a provider and should therefore be the data evaluated for comparison. Individually negotiated rates reflect the results of a provider's negotiating skills, while a base rate or fee schedule reflects that plan's policies, rate-determination process, and adherence to MHPAEA's requirements.

If the Departments require comparison of reimbursement rates between MH/SUD and M/S providers (as opposed to a comparison of reimbursed rates and billed charges, for instance), those comparisons should be reflective of differences in education and licensure requirements and the expenses necessary to operate a practice. Operating costs, for instance, for a MH/SUD inpatient facility and a M/S inpatient facility vary widely, as M/S facilities often have higher staffing requirements and much more expensive equipment, among other factors. Here again, we also raise the issue of bundled payments or other innovative, non-fee-for-service payment arrangements and the difficulty plans will have in comparing between M/S and MH/SUD services when innovative or value-based arrangements are used.

Recommendations:

- **AHIP urges the Departments to rescind the proposed special rule for network composition and the application of the material difference standard to network composition. Instead, we encourage the Departments to work with stakeholders to**

[38] Sec. 4121 of P.L. 117-328. https://www.congress.gov/bill/117th-congress/house-bill/2617/text

develop a set of objective metrics of MH/SUD access. If certain levels of performance are 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.

- **AHIP urges the Departments to develop a method to assess the access impacts of a health plan's MH/SUD telehealth offerings when evaluating network adequacy.**

New NQTL Requirements: Exceptions for Consistency with Independent Professional Medical or Clinical Standards and Standards Addressing Fraud, Waste, and Abuse - (c)(4)(v)

The Departments propose that an NQTL applied to MH/SUD benefits in any classification would not be considered to violate the no more restrictive requirement if the NQTL impartially applies independent professional medical or clinical standards or applies standards related to fraud, waste, and abuse, that meet specific requirements. In particular, the Departments propose an exception for a plan that impartially applies generally recognized independent professional medical or clinical standards (consistent with generally accepted standards of care) to M/S benefits and MH/SUD benefits. The Departments propose a second exception for NQTLs that are reasonably designed to detect or prevent and prove fraud, waste and abuse based on indicia of fraud waste and abuse that have been reliably established through objective and unbiased data.

AHIP strongly supports the inclusion of exceptions for the new NQTL requirements. If the Departments finalize the "no more restrictive" requirements, these exceptions are critically important to preserving the ability, albeit on a more limited basis, to ensure safe, appropriate, evidence-based care. However, many of our members have expressed confusion about how these exceptions, as proposed and as explained in the preamble, may be used. For example, while treatment guidelines may discuss how to determine the appropriate level of care for a given diagnosis or stage of treatment, the guidelines do not make recommendations for how a plan should ensure the guidelines are followed (in other words, which NQTLs can or should be used to ensure appropriate care is provided). While this exception is referenced in proposed Examples 5 and 6, there is no substantive explanation providing information for plans and issuers about how the standards may be applied. There are no examples in the preamble or proposed examples in the regulatory text providing additional information about the application of standards addressing fraud, waste, and abuse nor any guidance for what sources might qualify as "indicia of fraud waste and abuse that have been reliably established through objective and unbiased data." AHIP members have expressed concern about their ability to manage and respond to suspicious behavior when they see it, such as a provider who bills for a total of 25 hours of service in a single day.

The Departments requested comments on ways to better frame or define these exceptions. For "independent professional medical or clinical standards," AHIP highlights the definition of

"generally accepted standards of mental health or substance use disorder care" enacted by the Georgia legislature in 2022 as one approach the Departments could consider:

"Generally accepted standards of mental health or substance use disorder care" means evidence based independent 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, addiction medicine and counseling, and behavioral health treatment. Valid, evidence based sources reflecting generally accepted standards of mental health or substance use disorder care may include peer reviewed scientific studies and medical literature, consensus guidelines and recommendations of nonprofit health care provider professional associations and specialty societies, and nationally recognized clinical practice guidelines, including, but not limited to, patient placement criteria and clinical practice guidelines; guidelines or recommendations of federal government agencies; and drug labeling approved by the United States Food and Drug Administration.[39]

This definition is preferable over definitions passed in other states because it makes clear that these standards are not exclusively standards developed by professional groups or organizations that may be biased and/or not supported by consistent evidence.

In addition to the Georgia definition for "generally accepted standards of mental health or substance use disorder care," a potential definition for "independent professional medical or clinical standards" could include examples of valid, evidence-based sources, such as third-party guidelines or criteria, scientific articles, disinterested experts in the field, or expert panels convened by accrediting organizations. We believe including these specific examples will ensure that the definition is not inappropriately limited to one type of source.

As mentioned above, because clinical guidelines may discuss how to determine the appropriate level of care for a given diagnosis or stage of treatment, but typically do not make recommendations for how a plan should ensure the guidelines are followed (in other words, which NQTLs can or should be used to ensure appropriate care is provided), AHIP also requests the Departments consider adding an exception for practices to ensure high-quality care. We propose this third exception because, as drafted, the two exceptions to prevent fraud, waste, and abuse and to ensure care is consistent with independent professional medical or clinical standards are not enough by themselves to curb substandard or ineffective treatment and behaviors, which insurers unfortunately see in the MH/SUD treatment space. For example, AHIP members report that they see situations with some frequency that may not reach the level of fraud, waste and abuse, but provided treatment is substandard. This below-average care fails to adequately treat patients' conditions, trapping them in cycles of treatment with little to no improvement. Our members report that these patients are less likely to complain about ineffective MH/SUD

[39] GA Code § 33-21A-13(a)(2) (2022)

treatment (as compared to M/S treatment), as they may not be aware of the situation or may internalize responsibility for a treatment that does not work. We are concerned that the proposed framework – even with the two proposed exceptions – will not allow insurers to identify and address this type of activity, and we request the inclusion of an additional exception for ensuring the provision of high-quality care.

Recommendations:

- **AHIP requests the Departments provide additional context and examples to explain how the exceptions may be used by plans and issuers.**

- **AHIP recommends the Departments adopt Georgia's definition for "generally accepted standards of mental health and substance use disorder care," as well as include a list of acceptable sources, such as third-party guidelines or criteria, scientific articles, disinterested experts in the field, or expert panels convened by accrediting organizations.**

- **AHIP requests the Departments add an exception for the application of practices to ensure the provision of high-quality care.**

New NQTL Requirements: Illustrative, Non-Exhaustive List of NQTLs - (c)(4)(iii)
The proposed rules include additional NQTLs, such as credentialing standards and procedures for ensuring network adequacy. The Departments also make clear that the list of NQTLs included in the rule is non-exhaustive and that there are additional NQTLs not listed. The Departments are not proposing to issue an exhaustive list of NQTLs and make clear that even if an NQTL is not included on the list, a plan or issuer is not excused from compliance with the same standards and framework outlined in the proposed rule.

AHIP asks the Departments to provide an exhaustive list of NQTLs, particularly those for which comparative analyses must be produced upon request. As we have highlighted in previous conversations with regulators, some plan practices, such as case management, have divided regulators on whether and under which circumstances such practices are considered to be an NQTL (and must have an accompanying analysis). A definitive list would eliminate uncertainty, direct activity to the areas of greatest concern, promote consistency across the industry, and avoid waste.

As noted previously, AHIP opposes the proposed special rule for network composition and the associated creation and inclusion of network composition as an NQTL on the proposed NQTL list. If the Departments finalize the proposed rule, changes must be made to avoid inadvertently undermining integrated delivery and value-based payment models. Integrated delivery systems are designed to provide value-based health care through two care delivery models: (1) within a self-contained delivery system where providers operate within the same organization, allowing

care to be delivered with very few NQTLs, and (2) with a contracted network of community providers ensuring adequate access. Just as the existing MHPAEA regulations recognize that tiered networks warrant similar but separate analysis for QTLs, if the Departments finalize the proposals, they must be revised to allow integrated health plans to conduct similar but separate evaluations and analyses for NQTLs of (1) their integrated care delivery models and (2) their community contracted networks. Treating these distinct care delivery models as separate NQTLs would permit integrated health plans to maintain their unique delivery systems while also expanding their overall networks to include contracted community providers.

Additionally, AHIP opposes the proposed inclusion of network adequacy as a network composition NQTL. In the discussion of the application of the special rule for network composition, the Departments note their view that minimum time and distance standards set by a private accreditation organization or by other Federal or State programs may not have been designed with purposes of MHPAEA compliance in mind. Therefore, in order to comply with the proposed requirements, a plan or issuer may need to go beyond the minimum times and distances outlined in such standards, and also ensure that they do not result in less favorable treatment for MH/SUD benefits under the plan or coverage. Further, telehealth is neither considered nor credited for the access improvements it makes to time and distance.

Recommendations:

- **AHIP recommends the Departments provide an exhaustive list of NQTLs for which comparative analyses must be provided upon request. If the Departments determine that a plan practice is an NQTL, the plan should be given a reasonable amount of time to compile the comparative analysis.**

- **AHIP encourages the Departments to work with private accrediting organizations and especially administrators of other Federal or State programs to understand how their minimum time and distance standards were developed (including whether MHPAEA compliance was considered) and to advise on ways to alter the standards to meet MHPAEA's requirements, ideally to enable compliance with private accreditation and/or Federal or State network adequacy standards to satisfy MHPAEA requirements. Alternately, the Departments could develop and propose through notice-and-comment rulemaking a network adequacy standard that appropriately factors in compliance with MHPAEA.**

- **AHIP again urges the Departments to develop a method to assess the access impacts of a health plan's MH/SUD telehealth offerings when evaluating network adequacy.**

Effect of Final Determination of Noncompliance - (c)(4)(vii)
The Departments propose that, if a plan or issuer receives a final determination that it is not in compliance with the comparative analysis requirements with respect to an NQTL, the NQTL

would violate the substantive NQTL requirements and the relevant Secretary may direct the plan or issuer not to impose the NQTL, unless and until the plan or issuer demonstrates compliance with the requirements of MHPAEA or takes appropriate action to remedy the violation. The Departments would evaluate the facts and circumstances involved in the specific violation and nature of the underlying NQTL to determine whether to require immediate cessation of the application of the NQTL.

As noted above, the Departments do not have statutory authority to require an immediate cessation of a benefit based on their review. Although the Departments do have the authority to assess penalties and to take plans and issuers to court, they lack any general grant of authority to require immediate cessation of a plan term (*i.e.*, cease and desist authority). Further, by proposing that any of the Secretaries may order immediate cessation, the Departments are violating the statutory division of authority (HHS for issuers, DOL for self-funded plans, IRS for self-funded plans and church plans). Congress has not authorized the Departments to require an immediate cessation of a benefit based on their review. Consequently, the Departments cannot do so.

Additional Procedural Review Prior to Non-Compliance Determinations

The Departments do not address in the proposed rules what procedural protections they intend to implement prior to issuing a final determination of noncompliance. The CAA provides for severe consequences for final determinations of noncompliance, including sending required notices to plan enrollees and being publicly named in the annual report to Congress.

The Departments should provide a hearing for plans and issuers to appear before either DOL or HHS. The Departments could offer a DOL National Office review or an HHS Center for Consumer Information and Insurance Oversight ("CCIIO") Director review. The Departments can and should coordinate these reviews in order to ensure plans and issuers are treated consistently and with fairness. Such a review would permit a plan or issuer to request a review of the preliminary findings before a final determination of noncompliance is issued, and a final determination of noncompliance would not be issued until the review is completed. This review would include analysis of the plan's or issuer's submitted written materials, including supplementary materials, and a joint conference. After completion of the review process, the DOL National Office or CCIIO Director would issue a written determination of compliance or non-compliance within six months.

Recommendation:

- **In order to preserve plans' and issuers' procedural rights, AHIP recommends the inclusion of some form of independent and coordinated review before a final determination of noncompliance may be issued.**

Timeline for Notice to Participants and Beneficiaries Following a Final Noncompliance Determination - (d)(4)(i)
After a final determination of noncompliance, the proposed rules would require that, within seven calendar days of the receipt of the final determination of noncompliance, the plan or issuer must provide a standalone notice to all participants and beneficiaries enrolled in the plan or coverage that the plan or issuer has been determined to not be in compliance with the requirements of these proposed rules. The plan or issuer would also be required to provide a copy of the notice to the Secretary, any service provider involved in the claims process, and any fiduciary responsible for deciding benefit claims within the same time frame.

Feedback from AHIP members indicates that seven calendar days is not a sufficient period of time for an insurer to compile and provide the information (other than the proposed standard notice) required by the proposed rules, which include:

- A summary of any changes made as part of the corrective action plan specified to the Secretary following the initial determination of noncompliance, including an explanation of any opportunity for a participant or beneficiary to have a claim for benefits reprocessed;
- A summary of the Secretary's final determination that the plan or issuer is not in compliance with MHPAEA, including any provisions or practices identified to be in violation of MHPAEA, any additional corrective actions identified by the Secretary in the final determination notice, and information on how participants and beneficiaries can obtain a copy of the final determination of noncompliance from the plan or issuer;
- Any other actions the plan or issuer is taking to come into compliance with MHPAEA;
- Information on when the plan or issuer will take (or has taken) such actions;
- A clear and accurate statement explaining whether the Secretary has indicated that those actions, if completed, will result in compliance; and
- Contact information for questions and complaints, with a statement explaining how participants and beneficiaries can obtain more information about the notice, including a phone number and an email or web portal address for the plan or issuer, and contact information for the relevant Department.

Recommendation:

- **If the Departments finalize notice requirements with the full list of information outlined in the proposed rules, AHIP recommends plans and issuers be given 45 days to distribute the notices to enrollees.**

Requirement to Provide "Meaningful Benefits" for MH/SUD Conditions - (c)(2)(ii)(A)
The proposed rules require that a plan or issuer would not be considered to provide benefits for the MH condition or SUD in every classification in which M/S benefits are provided unless the plan or issuer provides meaningful benefits for treatment for that condition or disorder in each

classification, as determined in comparison to the benefits provided for M/S conditions in such classification. This requirement would mean that plans and issuers cannot provide, for example, only one limited benefit for a MH condition or SUD in that classification. The proposed amendment would also make explicit in the regulations the Departments' interpretation that the requirement to provide coverage in each classification in which medical/surgical benefits are provided applies on a condition or disorder basis.

AHIP supports efforts to ensure that MH/SUD care is appropriately covered, and patients can access services that are medically necessary. However, while MHPAEA is not a benefit mandate, the proposed "meaningful benefits" requirement could be interpreted to require plans and issuers to provide coverage for the entire universe of possible treatments for a MH/SUD condition, including for treatments that are of dubious quality, safety, and efficacy and those that are not recommended by evidence-based clinical standards. For these reasons, AHIP opposes the "meaningful benefits" requirement and urges the Departments not to finalize.

If the Departments move forward with the "meaningful benefits" requirement, AHIP recommends the Departments define "meaningful benefits" to mean those benefits that, in combination across settings, constitute the most common safe and effective methods of treatment for a given condition. Additional alternatives include: (1) considering a plan or issuer to satisfy the "meaningful benefits" requirement if they cover at least one primary treatment for a MH/SUD condition or disorder in a classification as determined by evidence-based clinical standards; and (2) considering any plan design that covers at least the benefits of an Essential Health Benefit (EHB) benchmark plan as covering "meaningful benefits" for the purposes of MHPAEA compliance. These options would provide plans with clearer standards and ensure patients have access to high-quality, safe, and evidence-based MH/SUD treatments.

Regardless of the approach chosen, AHIP highlights the need for clarity about the classifications (and related subclassifications) for some MH/SUD benefits. AHIP members have shared that some MH/SUD benefits do not fit neatly into the benefit classifications and subclassifications as M/S services, so flexibility and clarity are needed in how the "meaningful benefits" requirement is tied to benefit classifications.

Recommendations:

- **AHIP recommends the Departments not finalize the "meaningful benefits" requirement.**

- **However, if the Departments move forward with the requirement, AHIP recommends an alternative approach, such as defining "meaningful benefits" to mean 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.**

- **Additionally, AHIP requests that, if the Departments finalize a "meaningful benefits" requirement, that both clarity and flexibility are provided with respect to the classification of MH/SUD benefits.**

New and Revised Definitions – (a)(2)

Medical/Surgical (M/S) Benefits and Mental Health and Substance Use Disorder (MH/SUD) Benefits

AHIP supports defining M/S and MH/SUD benefits consistently with generally recognized independent standards of current medical practice, such as the ICD or DSM, for the many services and treatments which may be used only to treat MH/SUD conditions (*e.g.*, psychotherapy) and those which may be used only to treat M/S conditions (*e.g.*, cardiac surgery). For these services, it is a straightforward matter to define the benefit as either M/S or MH/SUD, consistent with the proposed rules.

However, plans have encountered much confusion among stakeholders and regulators regarding whether and when MHPAEA applies to a benefit that can be used to treat both M/S and MH/SUD condition. The issues arise over a very specific set of circumstances, including speech and occupational therapy for Autism Spectrum Disorder (ASD), surgery for gender dysphoria, or nutritional counseling for eating disorders. Our members have expressed concern that if speech therapy for ASD is an unlimited covered benefit, but speech therapy for a stroke is a covered benefit subject to visit limits, the resultant disparity may be viewed as discriminatory (not to mention confusing and hard to administer).

One way to address this confusion would be to align the proposed rules with the existing guidance issued by CMS regarding MHPAEA compliance for Medicaid and CHIP plans to ensure operational consistency and clarity.[40] Under this guidance, plans must use a reasonable method for defining services commonly used to treat both MH/SUD and M/S conditions, as long as that methodology is applied consistently across both M/S and MH/SUD benefits. For example, one such method a plan may employ defines the service based on whether the service is predominantly used for M/S or MH/SUD using the plan's annual claims experience spending on the service in question. AHIP believes the CMS guidance is instructive for all scenarios where a plan must assign a treatment/service to one category of benefits or the other for purposes of plan design and administration of plan terms and conditions, including financial requirements, QTLs and NQTLs. Given that guidance already exists with respect to Medicaid and CHIP plans, we recommend the Departments adopt CMS' approach to create consistency and avoid confusion.

[40] https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/faq101117.pdf

Recommendation:

- **AHIP recommends that the Departments adopt the CMS guidance requiring plans to use a reasonable method to determine whether a given service is a MH/SUD benefit or a M/S benefit.**

Processes

The Departments propose to define "processes" to mean actions, steps, or procedures that a plan or issuer uses to apply an NQTL. "Processes" would include requirements established by the plan or issuer for a participant or beneficiary to access benefits, including through actions by a participant's or beneficiary's authorized representative, or a provider or facility.

AHIP believes this proposed definition is too broad and focuses only on the end result of access to benefits, which is inconsistent with years of guidance and regulations. We therefore recommend that the definition be narrowed to focus on the operational application of any requirements, rather than on the end result.

Evidentiary Standards

The Departments propose to add a definition of the term "evidentiary standards" to mean any evidence, sources, or standards that a group health plan or coverage considered or relied upon in designing or applying a factor with respect to an NQTL, including specific benchmarks or thresholds.

As we noted in our discussion on the definition of independent professional medical or clinical standards, we believe some standards established by professional groups or organizations could be biased and/or not supported by consistent evidence and are therefore concerned with these standards being listed as "evidentiary standards."

Factors

The proposed definition of "factors" subsumes both "processes" and "strategies." The preamble states that "the definition of the term 'factors' should be read broadly, so that factors are all information, including processes and strategies (but generally not evidentiary standards), that a group health plan (or health insurance issuer offering coverage in connection with such a plan) considered or relied upon to design an NQTL or used to determine whether or how the NQTL applies to benefits under the plan or coverage."

The breadth of this definition makes the requirement, that plans identify and define every factor used to design or apply an NQTL and describe how factors are used in the design or application of the NQTL, more onerous. As discussed in our comments on proposed (c)(4)(ii), we are also unclear, given the breadth of the definition, how a plan demonstrates that a factor is unbiased for the purposes of the comparative analyses.

AHIP recommends narrowing the definition of factors to distinguish this element from evidentiary standards, processes, and strategies and to describe the information relied upon to design an NQTL (*i.e.*, the basis for the plan's application of an NQTL).

Treatment of Specific Conditions

In response to requests from interested parties, the Departments confirm that eating disorders and ASD are MH conditions for purposes of MHPAEA. The Departments solicit comments on other specific MH conditions or SUDs that may warrant additional clarification for purposes of analyzing parity and compliance with MHPAEA.

We appreciate the clarity that eating disorders and ASD are mental health conditions and would appreciate similar clarity around gender dysphoria and gender-affirming care.

NQTL Comparative Analysis Requirements - new sections at 26 CFR 54.9812-2, 29 CFR 2590.712-1, and 45 CFR 146.137

The Departments propose to codify in regulations the CAA requirements that a plan or issuer that imposes any NQTL on MH/SUD benefits must perform and document comparative analyses of the design and application of all NQTLs. The new proposed rules also set forth the content requirements for NQTL comparative analyses, including the proposed requirement that plans and issuers include and evaluate relevant data as part of their comparative analyses to ensure compliance with MHPAEA.

AHIP and our member plans expected the proposed rules would lay out clear expectations for the comparative analyses required by the CAA. AHIP and other industry stakeholders, including groups representing our employer clients, have repeatedly asked the Departments for more substantive guidance on the expectations for these analyses. We have also requested tools to help complete the analyses, including templates, lists of the exact data plans should prepare for review, and lists of NQTLs for which plans must produce a prepared analysis upon request from regulators.

We appreciate the steps the Departments take toward providing this information in the proposed rules. However, the amendments to the existing MHPAEA rules and the proposed new sections create more confusion by merging definitions and creating additional complexity. For example, proposed content element 1 requires plans to confirm the "substantially all" test has been completed, including consideration of the predominant variation, and insurers are uncertain that this can be operationalized with all NQTLs. It also requires plans to provide all policies, guidelines, provider contracts, or any other document where the NQTL "appears or is described," which is overbroad.

The proposed rules define factors broadly and fail to distinguish them from evidentiary standards, merging and confusing elements 2 and 3 (*e.g.*, element 2 requires identification of all

factors "considered and relied upon," including evidentiary standards). These steps also require plans to provide detailed descriptions of each factor, including evidence and sources relied upon, with dates and relevant citations, which will be challenging to operationalize.

Content element 4 would also create operational challenges in its breadth. It requires plans to consider the factors identified and described above, but with quantitative data and any other relevant analyses, including any records that other factors were considered and not applied, plus any policy or procedure, checklists, manuals, forms, and other documentation used in strategy designing the NQTL that will show whether a plan is meeting the threshold.

In AHIP's view, the comparative analysis proposed rules should further clarify for plans and issuers the entire comparative analysis process by:

- Providing a complete list of NQTLs for which a plan must produce a comparative analysis upon request,
- Delineating the number of comparative analyses plans should conduct,
- Distinguishing the definitions between each component of the analysis (*e.g.*, factors, evidentiary standards, processes, strategies), and
- Limiting each step of the analysis to a particular component. For example:
    - Step 1: Identify the NQTL;
    - Step 2: Describe the factors or reason for the NQTL being applied;
    - Step 3: Describe the evidentiary standards relied upon;
    - Step 4: Show the written process and strategy;
    - Step 5: Show the in-operation process and strategy; and
    - Step 6: Describe the conclusion.

IV. Other Issues

Applicability Date

AHIP appreciates the Departments' recognition of the substantial amount of time needed to implement the sweeping new changes in the proposed rules in the group market, as well as the delayed application needed to implement the changes in the individual market. We further note that compliance with the proposed rules will require plans and issuers to build new tools to collect and store the data that will be required to be collected, which, according to our members, will take at least 18 months. We understand that improving access to MH/SUD care is a top priority for the Administration. However, given the uncertainty of when the final rule will be published and the significant lead time that will be required to implement any changes and new provisions, the applicability date should be tied to the issuance of the final rule.

Recommendation:

- **AHIP recommends that the applicability date for group plans be modified to plan years beginning on or after the later of January 1, 2026 or two years following the date the final rule is published.**

- **For individual market plans, AHIP recommends that no less than two years elapse between the date the final rule is published and the date the first state's rate filings for the following plan year are due.**

Request for Information: Crisis Services

A key part of health insurance providers' work is helping patients navigate to the right place along the care continuum based on their unique needs, including access to crisis services. Crisis services are a vital part of the behavioral health continuum of care, and the successful implementation of the 988 Suicide & Crisis Lifeline is an important first step in increasing access to the spectrum of crisis care services that includes community-based providers offering mobile crisis and crisis stabilization services.

AHIP has participated in a number of discussions and working sessions with SAMHSA to identify challenges and opportunities to increase access to crisis intervention services. In addition to sharing SAMHSA's national guidelines for crisis care, as well as guidelines specific to youth mental health crisis care, AHIP has supported the development of national standards and definitions for crisis services, sufficient federal and state funding for crisis services, and uniformity and alignment in billing and coding of crisis services. Progress on these goals will help the sustainability of the crisis care system by fostering a common understanding of the key components of quality crisis care and increasing utilization of crisis care codes for billing purposes.

At the local level, our members are partnering with community-based organizations to meet the needs of the communities they serve, noting that crisis services requires a local perspective rather than a "one size fits all" approach. Across the behavioral health continuum, workforce capacity remains a challenge, and continued efforts to build the workforce, especially the paraprofessional workforce, including peers, should be a key priority of policymakers.