

January 10, 2025

The Honorable Julie Su Acting U.S. Secretary of Labor 200 Constitution Avenue, N.W. Washington, D.C. 20210 The Honorable Janet Yellen Secretary of the Treasury 1500 Pennsylvania Avenue, N.W. Washington, D.C. 20220

The Honorable Xavier Becerra Secretary of Health and Human Services 200 Independence Avenue, S.W. Washington, D.C. 20201

Dear Secretaries Su, Becerra, and Yellen,

Thank you for your collective effort to develop the Final Rule "Requirements Related to the Mental Health Parity and Addiction Equity Act (MHPAEA or Final Rules)," published on September 23, 2024 (89 Fed. Reg. 77586) by the U.S. Department of Labor (DOL), U.S. Department of Health and Human Services (HHS), and U.S. Department of Treasury (collectively, "the Departments").

The Association for Behavioral Health and Wellness (ABHW) shares the Departments' goal of promoting access to comprehensive mental health (MH) and substance use disorder (SUD) benefits and would like to work with the Departments to ensure that compliance is not overly burdensome, enforcement prioritizes substantive comparability of limits and access over paperwork and the cost to implement the law and subsequent regulations does not make premiums prohibitive for patients. To that end, we urge the Departments to delay the enforcement implementation of the Final Rules for one year to reexamine certain provisions and ensure that the application and enforcement are practical, effective, and efficient.

ABHW is the national voice for payers managing behavioral health (BH) insurance benefits. Our member companies provide coverage to approximately 200 million people in the public and private sectors to treat MH, SUD, and other behaviors that impact health and wellness. Since its inception, ABHW has been at the forefront of and an advocate for MH and SUD parity and was instrumental in drafting the legislation for the initial MHPAEA of 2008. Our

members have worked tirelessly over the past 16 years to implement parity for behavioral health services.

ABHW appreciates the important changes made to the Final Rules, including eliminating the proposal to apply substantially all/ predominant tests to non-quantitative treatment limitations (NQTLs) and the proposed special rule for network composition.

The Final Rules assert in the new "purpose" section that compliance with the parity statute and regulations means that "plans and issuers must not design or apply financial requirements and treatment limitations that impose a greater burden on access (that is, are more restrictive) to [MH/SUD] benefits under the plan or coverage than they impose on access to [M/S] benefits in the same classification of benefits." This emphasis on the comparability of *access* (i.e., the *impact* of the limits) diverges from the statutory text, which exclusively addresses the comparability of the *limits* themselves. This shift also contradicts the Departments' long-held position that MHPAEA outcomes are not indicative of compliance.

The changes to the comparative analyses of non-quantitative treatment limitations (NQTLs) add significant new documentation requirements but lack the specificity and clarity necessary for health plans to understand whether their documentation will be determined to be sufficient. Health plans are still awaiting clarifying information and illustrative de-identified examples regarding the development and application of NQTLs, which were required in the 21st Century CURES Act of 2016 and the Consolidated Appropriations Act of 2021 (CAA 2021) and have yet to be produced.

Furthermore, the extreme complexity and administrative burden of implementing the new documentation requirements make compliance even more challenging, with no clear theory for how the additional narrative complexity will generate improved access for members seeking MH/SUD benefits. This diverts significant funding, time, and resources from helping patients struggling with MH and SUD conditions to new onerous paperwork requirements.

Please see our detailed comments below that demonstrate the need to delay the enforcement of these Final Rules to revise these key provisions because of the substantial compliance hurdles and statutory overreach.

# I. Definitions for "Mental Health Benefits" and "Substance Use Disorder Benefits" (Effective January 1, 2025):

Commentary in the preamble of the Final Rules interprets the regulatory definitions for "mental health benefits," "substance use disorder benefits," and "medical/surgical benefits" to

require plans and issuers to "characterize items and services as medical/surgical benefits, mental health benefits, or substance use disorder benefits based on the condition or disorder being treated." Thus, claims and authorizations for "cross-over services" that are delivered to treat both MH/SUD and M/S conditions—including speech and occupational therapy, urgent care, surgeries (e.g., for gender dysphoria), and a wide range of other services—must be treated as MH/SUD benefits or M/S benefits based on the condition being treated. In other words, the same service delivered by the same provider must be covered as two different types of benefit, subject to different protections, depending on the condition being treated.

As ABHW has previously warned, this new interpretation, which has never before been expressed in guidance and, to our knowledge, has never been enforced, will engender several perverse consequences.<sup>1</sup>

First, this interpretation incentivizes providers treating patients with comorbid MH/SUD and M/S conditions to list the primary diagnosis for the visit as a MH/SUD condition as a strategy to "game the system" to avoid treatment limits and/or to reduce the patient cost-sharing obligations. This may occur in a variety of contexts, such as urgent care or even radiology and diagnostics, where an x-ray coded with a primary diagnosis of a tobacco use disorder to screen for lung cancer may stretch the credibility of what a reasonable person should understand to constitute "substance use disorder treatment."

Second, requiring plans to cover the same service delivered by the same provider more generously for a patient with an MH/SUD condition than a patient with an M/S condition discriminates against individuals with M/S conditions. Where the M/S condition is the cause of a disability, such discrimination would likely violate the terms of the Americans with Disabilities Act (ADA). Conversely, in some cases, this new interpretation could also require MH/SUD benefits to have a higher cost-sharing than the corresponding M/S benefits.

Third, this novel interpretation is out of step with general industry practices for benefit authorizations, claims determinations, and related health plan operations, most of which are not currently designed to process claims and authorizations differently based on the condition being treated. The Departments' regulatory impact assessment does not account for the high cost and significant disruption to health plan operations across the country of requiring plans to reconfigure their claims and authorization platforms to accommodate this new interpretation.

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<sup>&</sup>lt;sup>1</sup> See APPENDIX A – ABHW Proposal on Definitions for Benefits Under MHPAEA submitted to Tri-Departments on May 17, 2023, which was also incorporated into ABHW's public comment letter on the Proposed Rule.

Concerns about the new interpretation regarding cross-over benefits are particularly significant for prescription drug benefits. Many prescription drugs are prescribed to treat a variety of different diagnoses, yet health plan claims and authorization systems are not designed to marry diagnosis and prescription drug information. Our members share that there is no accurate way to link the two or to set up pharmacy systems to ingest such information. Since providers are not required to submit diagnostic information to pharmacies, there will always be a gap in the ability of pharmacies to report this information to health plans. Notably, in recent Medicaid rules, CMS did not finalize the inclusion of diagnosis into their analysis because that data is difficult for pharmacists to obtain.<sup>2</sup>

The preamble to the Final Rules acknowledges "the particular challenges with respect to prescription drug benefits due to the lack of diagnostic information on claims for reimbursement" but offers no solution to the problem that the Departments have created by requiring plans to identify every claim and authorization as either an MH/SUD benefit or a M/S benefit based on the condition being treated. The preamble asserts that "these final rules, similar to the 2013 final regulations, provide plans and issuers enough flexibility to make decisions about how to classify items and services, including prescription drugs, as either mental health benefits, substance use disorder benefits, or medical/surgical benefits," but does not explain what "flexibility" the rules offer given the clarification that such classification must be made according to the condition being treated. Perhaps the Departments mean that plans can characterize prescription drugs as "M/S drugs" or "MH/SUD drugs" based on the condition they are most commonly prescribed to treat. If this "flexibility" is available for prescription drugs, is it also available for benefits for inpatient, outpatient, and emergency services? If the asserted "flexibility" for prescription drug benefits is not available for other types of benefits, what is the basis for such difference? The fact that the Departments appear to seek to "fudge" their interpretation as applied to prescription drug benefits underscores the extent to which the proposal is under-considered and misguided.

Finally, the Tri-Departments definition for "Mental Health Benefits" confirms that plans must define MH benefits to include all covered conditions that fall under any of the diagnostic categories listed in the mental, behavioral, and neurodevelopmental disorders chapter of the most current version of the International Classifications of Diseases (ICD) or that are listed in the current Diagnostic and Statistical Manual of Mental Disorders (DSM). The rule thus defines intellectual and neurodevelopmental disorders, including dementia and

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<sup>&</sup>lt;sup>2</sup> CMS, Medicaid Drug Rebate Program Final Rule, <a href="https://www.federalregister.gov/documents/2024/09/26/2024-21254/medicaid-program-misclassification-of-drugs-program-administration-and-program-integrity-updates">https://www.federalregister.gov/documents/2024/09/26/2024-21254/medicaid-program-misclassification-of-drugs-program-administration-and-program-integrity-updates</a>

autism spectrum disorder, as MH conditions, even if applicable state laws define these conditions as M/S conditions. This overrides state law definitions for MH/ SUD benefits, which creates confusion and is difficult to implement. For example, some states, such as Ohio and New Mexico, currently classify autism as an M/S benefit. Historically, intellectual and neurodevelopment disorders have not been considered MH conditions. This also diverges from the Centers for Medicare and Medicaid Services (CMS) guidance for Medicaid and CHIP, under which many state Medicaid agencies have defined benefits for intellectual and developmental disabilities to be M/S benefits.

#### **Recommendation:**

ABHW urges the Departments to withdraw and revise the definition of "Mental Health Benefits." We reiterate that the reasonable and practical definition of MH/SUD conditions is benefits for treatments and services that are generally delivered to treat MH/SUD conditions and that all other benefits are M/S benefits.

## II. New Requirements for NQTL Comparative Analyses (Effective January 1, 2025):

The requirements for NQTL comparative analyses in the Final Rules depart significantly from both the statute and previous guidance.

From a purely structural perspective, the Final Rules significantly reconfigure the 5-part test set forth in statute to become a 6-part test in the regulations. For example, step 2 of the statute requires plans to identify the NQTL "factors," and step 3 of the statute requires plans to identify the evidentiary standards that are used for each factor, but the Final Rules address both factors and evidentiary standards in step 2. Conversely, step 4 of the statute addresses both "as written" and "in operation" comparisons, whereas the Final Rules address the "as written" comparison in step 4 and the "in operation" comparison in step 5. The Departments provide no justification for this arbitrary departure from the clearly delineated structure of the statute.

More troublingly, the Final Rules add new requirements that are not addressed by the statute. First, the Final Rules substantively transform the text that identifies what types of "factors" to analyze. The statute requires plans to analyze the factors and evidentiary standards that are "used to determine that the NQTLs will apply to mental health or substance use disorder benefits and medical or surgical benefits," but the Final Rules require plans to analyze the factors and evidentiary standards "used to design or apply the NQTL." This "design or apply" language is explained to separately address "strategies" and

"processes," thus creating two types of factors where the statute only identifies one type of factor.

Second, the Final Rules add a new step 3 that does not exist in the statute, requiring plans to provide a "description of how factors are used in the design and application of the nonquantitative treatment limitation." (As noted above, the Final Rules combine statutory steps 2 and 3; the Final Rules then insert this wholly new step 3 that has no basis in the statute.) The Departments make no attempt to identify any statutory basis for this new requirement.

Third, the Final Rules create a new requirement for plans to provide documentation of each factor, including, as relevant, documentation of evidence of whether MH/SUD and M/S benefits met or did not meet any applicable threshold in the evidentiary standard and records documenting the consideration and application of all factors and evidentiary standards, as well as the results of their application.

Thus, for example, for prior authorization requirements for prescription drugs, the Final Rules require health plans to provide evidence to demonstrate why each prior authorization factor was or was not met for every covered drug. With thousands of covered drugs on most commercial formularies, the volume of documentation that these Final Rules require plans to create for a single NQTL type in a single classification is immense. However, the Final Rules require plans to create such documentation for every NQTL type applied in every classification.

This interpretation departs significantly from both the statute and previous guidance. Where the statute requires plans to develop analyses that evaluate the comparability of their strategies and processes, the regulations require plans to implement new business processes for documenting their day-to-day work. Many plans do not currently create and maintain documentation of all of the evidentiary support for every decision they make. The absence of documentation should be expected where health plan professionals appropriately rely on their professional training, experience, knowledge, and judgment to evaluate NQTL factors. Yet these Final Rules impose burdensome make-work requirements for industry professionals to develop written documentation to justify their every decision instead of aligning with the statute to require analysis of the comparability of the types of processes, strategies, evidentiary standards, and other factors that the plan applies to its decision-making.

In addition to our members' concerns about the addition of these new extra-statutory requirements, our members continue to find that many aspects of the documentation requirements are exceedingly ambiguous. Our concerns about the continuing lack of clarity

about the Departments' expectations for comparative analyses are heightened by the fact that the Departments continue to assert that not a single comparative analysis they have reviewed to date meets their expectations (as stated in the 2023 Report to Congress on MHPAEA), coupled with the fact that the Departments have yet to create a model comparative analysis that would satisfy their expectations.

#### **Recommendation:**

ABHW urges the Departments to withdraw the regulatory requirements for comparative analyses and revise them to align with the statutory requirements. Specific revisions should include alignment with the 5-step framework of the statute, elimination of the new requirement to analyze "process" factors, elimination of the new step 3 to analyze how factors are used in the design and application of the NQTL, and elimination of the new requirement to create documentation to demonstrate the application of every factor to every service in every classification for every NQTL.

ABHW also recommends the development of a federal advisory committee comprised of diverse stakeholders to create model examples of completed NQTL comparative analyses, including industry representatives with expertise and experience creating and implementing health plan policies and operations regarding the applicable NQTL for each model analysis.

### III. Absence of a Defined List of NQTL Types for Analysis:

The Final Rules continue to require plans and issuers to proactively create comparative analyses for "all" NQTL types, to be provided within ten days of a regulator's request while leaving the list of NQTL types that regulators can demand explicitly unbounded. Given that regulators can determine that <u>any</u> aspect of plan design or operations constitutes an NQTL, this interpretation of the statute is arbitrary and capricious.

This interpretation also puts plan fiduciaries in an untenable position. Plan fiduciaries must certify that they have selected and monitored service providers to develop the required comparative analyses, but given the unbounded definition, plan fiduciaries have no way to determine whether they have fully complied with their duties.

ABHW does not seek to limit the Departments' ability to identify new NQTL types or to require plans to ensure that any NQTL type that regulators may identify in the course of an investigation comply with MHPAEA. ABHW merely requests the Departments to provide leadership to create common expectations for federal regulators, state regulators, plan fiduciaries, and plan members about what types of comparative analyses should be developed

proactively and made available upon request. This list can and should be regularly updated to align with evolving plan and, coverage designs and enforcement findings.

#### **Recommendation:**

ABHW recommends that the Departments provide a defined list of NQTL types to guide plan fiduciaries and state regulators regarding the appropriate scope of documentation to require and to exercise enforcement discretion with regard to the timing of requests for any NQTL type not identified on the standard list.

#### IV. Material Difference (Effective January 1, 2026):

Where a health plan's data measures demonstrate outcomes that are materially different for MH/SUD benefits than for M/S benefits, the plan must determine whether the numerical difference is "material" and whether the differences are attributable to the NQTL. If the plan uncovers material differences in data outcomes measures, they are required to take "reasonable actions" to address any material differences as necessary to ensure compliance.

The Departments fail to acknowledge that despite taking appropriate action, the relevant data may nevertheless continue to reveal material differences in access. The health plan might, for example, be unable to improve network composition because of provider shortages, as opposed to its business or operational decisions. In such a case, the health plan should not be cited for non-compliance, provided, of course, that the plan is able to document actions taken to attempt to address the differences.

The Departments do not propose a definition or standard for materiality or reasonable action, making these provisions ambiguous and difficult to implement. The Final Rules provide examples of plans taking "reasonable" actions and thereby achieving compliance, but these examples posit that the plan implements a virtual smorgasbord of nearly every possible action that could be imagined and makes no attempt to define a realistic *threshold* for compliance. This deliberate obscuring of the demarcation between compliance and noncompliance is a textbook case of an agency taking the "terrify first and clarify later" approach to rulemaking that was specifically prohibited by the 5<sup>th</sup> Circuit in *Career Colleges and Schools of Texas v. United States Department of Education.*<sup>3</sup>

#### **Recommendation:**

<sup>&</sup>lt;sup>3</sup> Career Colleges and Schools of Texas v. United States Department of Education, No. 23-50491 (5th Cir. 2024)

ABHW recommends that this provision, along with the corresponding examples and discussion, be withdrawn. We urge that the Departments convene a federal advisory committee comprised of diverse stakeholders to create model data measures and define specific standards for determining thresholds for "material differences" for the model measures.

#### V. Prohibition on Discriminatory Factors (effective January 1, 2026):

Health plans must now determine whether factors and evidentiary standards are somehow discriminatory. Proving the absence of discrimination will be incredibly challenging and labor-intensive. Moreover, this requirement creates a new standard for compliance that is not found in the statute. The Departments fail to explain why a new standard is needed or justified, and the example of a "discriminatory factor" would clearly fail the existing statutory requirement for factors to be comparable and applied no more stringently. Thus, these complex and ambiguous new requirements are not only unsupported by the statute, but they are also unnecessary.

#### **Recommendation:**

ABHW urges the Departments to withdraw the new regulatory prohibition on discriminatory factors, which exceeds the statutory authority.

#### VI. NQTL Cease and Desist Provision (Effective January 1, 2025):

A new enforcement provision in the Final Rules authorizes federal and state regulators to prohibit health plans from applying an NQTL if the plan's comparative analysis does not adequately demonstrate compliance. For example, if the plan's comparative analysis for its provider network design falls short of the new regulatory requirements, regulators could require the plan to cover all out-of-network benefits on an in-network basis and/or to reimburse all out-of-network providers on an in-network basis. (Exactly how this would work in practice is not discussed.) This new enforcement power claimed in the Final Rules lacks specific statutory authorization in MHPAEA.

One section of the statute that the Departments identify as the basis for this new authority (Code section 9812(a)(3)(A), ERISA section 712(a)(3)(A), and PHS Act section 2726(a)(3)(A)) states only that plans or issuers must ensure that their MH and SUD benefits' treatment limitations and financial requirements are not more restrictive than those for

medical or surgical benefits. This language does not provide the Departments with the authority to impose new enforcement strategies.

The Departments also cite section (a)(8)(B)(iv)(V) of the statute to order the removal of the NQTL. However, this, too, is insufficient authority. This section of the statute discusses the Secretary's annual report to Congress but does not have language saying that the Secretary has the authority to prohibit the imposition of the NQTL. What the section does require is that the Secretary must include the specifications described in clause (iii), which gives the Secretary the authority to review the comparative analyses and, upon a finding of noncompliance, requires *the plan or issuer* to specify to the Secretary the actions it will take to ensure compliance.

Finally, the Departments argue that the statute provides an *implicit* authority to prohibit the application of an NQTL as a consequence of a violation. However, this argument is undercut by the fact that the statute sets forth an *explicit* authority for enforcement: specifically, the statute provides that if the Secretary makes a final determination of noncompliance, the plan or issuer must notify participants and beneficiaries of the Secretary's findings.

The asserted new authority for federal regulators to prohibit the application of an NQTL based solely on the plan's failure to document a comparative analysis that satisfies the regulator's expectations is especially concerning given that regulators to date have found that <u>all</u> initial documentation submitted is insufficient. In a context where all investigated health plans are failing to satisfy the Departments' expectations, imposing draconian penalties on some plans is the very definition of arbitrary and capricious enforcement.

Our members' concerns are further exacerbated by the highly subjective nature of interpreting the exceedingly ambiguous new regulations and the near certainty that different federal and state regulators will arrive at differing conclusions about the sufficiency of plans' analyses. Indeed, federal and state investigations to date have already arrived at different conclusions, with plans that operate in multiple markets submitting virtually identical documentation to different regulators and receiving findings of non-compliance from some and no findings from others. This is especially problematic given that the Departments have not adopted ABHW's recommendation to create an appeals process to provide a formal review process. Health plans and insurers should have the opportunity to be heard at a meaningful time and in a meaningful manner. Substantial procedural protections are required here, as the consequences following a final determination of noncompliance are severe.

#### **Recommendation:**

ABHW requests the Departments to withdraw the regulatory section that authorizes regulators to prohibit the application of an NQTL that the regulator finds to violate MHPAEA.

#### VII. Meaningful Benefits (Effective January 1, 2026):

The Final Rules create a new provision that requires health plans to cover "meaningful benefits" for each covered MH/SUD condition in each benefit classification. The Final Rules further stipulate that "whether the benefits provided are meaningful benefits is determined in comparison to the benefits provided for medical conditions and surgical procedures in the classification" and that the plan does not provide "meaningful benefits" for a given condition unless it provides benefits for at least one "core treatment" for that condition.

The "meaningful benefits" requirement expands on the requirement to offer coverage in every classification. The statute explicitly says it cannot be construed to require plans to provide "any" mental health or substance use disorder benefits. The preamble of the Final Rules responds to concerns about *specific* mental health and substance use disorder services not being considered meaningful benefits, but this misses the point that the statute prohibits regulators from interpreting it to require coverage for any MH/SUD benefits, and this new requirement would clearly require coverage for certain MH/SUD benefits.

The threshold for compliance with the new "meaningful benefits" requirement is also extremely ambiguous, including how to compare whether the MH/SUD benefits provided are "meaningful benefits" relative to the benefits provided for medical conditions and surgical procedures in the classification. Although the Final Rules provide some examples of MH/SUD services that would or would not meet the minimum threshold of being a "core treatment," they provide no examples of how to determine "whether the benefits provided are meaningful benefits ... in comparison to the benefits provided for medical conditions and surgical procedures in the classification." For example, even if MH/SUD services that are growing in popularity, such as treatment with ketamine or in a wilderness therapy program, may not be "core treatments," it is unclear how to determine the impact of excluding coverage for these services on the comparison to the scope of covered M/S benefits in the classification. This new mandate to cover meaningful benefits for every MH/SUD diagnosis may also cause special complications in conjunction with the new requirement to define intellectual and neurodevelopmental disabilities as mental health conditions.

#### **Recommendation:**

We urge the Departments to withdraw the regulatory requirements for plans to cover meaningful benefits for every covered MH/SUD condition in every classification in order to avoid the direct conflict of this requirement with the MHPAEA statute.

If the Departments do not eliminate this requirement entirely, at minimum, we request that this provision be more clearly limited to requiring coverage for at least one core treatment for each covered condition in each classification and that the Departments eliminate the requirement to determine "whether the benefits provided are meaningful benefits [...] in comparison to the benefits provided for medical conditions and surgical procedures in the classification." Nevertheless, the mandate to cover a core treatment still presents a conflict with the requirements of the MHPAEA statutory language.

#### VIII. Relevant Data Evaluation Requirements (Effective January 1, 2026):

The Final Rule requires health plans to "collect and evaluate relevant data" when conducting an NQTL comparative analysis. The Tri-Departments do not specify the specific measures required for specific NQTL types. Significant ambiguity remains about how these requirements will be interpreted and enforced, leading to a very high likelihood of inconsistent interpretation and enforcement across markets and courts in the absence of federal leadership. Moreover, the focus on the impact or outcome of the NQTL clearly exceeds the statutory requirement for comparability of design and application and departs without legal justification from previous guidance that clearly stipulated that disparity of results did not indicate disparity of design or application.

#### **Recommendation:**

While the "relevant data evaluation" requirements come into effect on January 1, 2026, there is an immediate need for further sub-regulatory guidance from the Departments, as was noted in the Final Rules. Additional guidance must provide more detail on the relevant data points that will need to be operationalized on a systematic basis so that plans and issuers are able to efficiently review and analyze the relevant data and respond to data requests by health plans working to meet their obligations under MHPAEA. ABHW recommends that the Departments convene a federal advisory committee comprised of diverse stakeholders to create model data measures and to perform reliability and validity testing for identified measures. Federal advisory committee members should include industry representatives with expertise and experience implementing health plan policies and operations regarding the applicable NQTL for each measure set and members with expertise in creating and testing data measures for managed care.

In closing, we again urge the Departments to delay the Final Rules for re-examination and to ensure that the application and enforcement are practical, effective, and efficient.

We thank you for your efforts and for considering our comments on the Final Rules. ABHW welcomes the opportunity to meet with the Departments to discuss our response and suggestions. If you have questions, please contact Kathryn Cohen, Senior Director of Regulatory Affairs, at <a href="mailto:cohen@abhw.org">cohen@abhw.org</a>.

Sincerely,

Debbie Witchey

President and CEO

APPENDIX A - ABHW Proposal on Definitions for Benefits Under MHPAEA submitted to Tri-Departments on May 17, 2023

# RE: PROPOSED AMENDMENTS TO REGULATORY DEFINITIONS FOR "BENEFITS" UNDER THE MENTAL HEALTH PARITY AND ADDICTION EQUITY ACT(MHPAEA)

We request that the Tri-Departments add the underlined language below to the regulatory definitions for "Mental health benefits," "SUD benefits," and "Medical/Surgical benefits":

"Medical/surgical benefits means benefits with respect to items or services for medical conditions or surgical procedures, as defined under the terms of the plan or health insurance coverage and in accordance with applicable Federal and State law, but does not include mental health or substance use disorder benefits. The plan or issuer must define items or services to be "for" medical conditions or surgical procedures according to a reasonable method, such as by determining:

- Whether the treatment or service is most commonly delivered to treat medical/surgical conditions,
- Whether the treatment or service is most commonly delivered by medical or surgical providers and/or
- Whether administration of claims or coverage for the treatment or service is provided through a vendor that is contracted to administer medical/surgical benefits.

Any condition defined by the plan or coverage as being or as not being a medical/surgical condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), the most current version of the ICD, or State guidelines)."

"Mental health benefits means benefits with respect to items or services for mental health conditions, as defined under the terms of the plan or health insurance coverage and in accordance with applicable Federal and State law. The plan or issuer must define items or services to be "for" mental health conditions according to a reasonable method, such as by determining:

• Whether the treatment or service is most commonly delivered to treat mental health conditions,

- Whether the treatment or service is most commonly delivered by mental health treatment providers and/or
- Whether administration of claims or coverage for the treatment or service is provided through a vendor that is contracted to administer medical/surgical benefits.

Any condition defined by the plan or coverage as being or as not being a mental health condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), the most current version of the ICD, or State guidelines)."

Substance use disorder benefits means benefits with respect to items or services for substance use disorders, as defined under the terms of the plan or health insurance coverage and in accordance with applicable Federal and State law. The plan or issuer must define items or services to be for substance use disorders according to a reasonable method, such as by determining:

- Whether the treatment or service is most commonly delivered to treat substance use disorders,
- Whether the treatment or service is most commonly delivered by substance use disorder treatment providers, and/or
- Whether administration of claims or coverage for the treatment or service is provided through a vendor that is contracted to administer medical/surgical benefits.

Any disorder defined by the plan as being or as not being a substance use disorder must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the DSM, the most current version of the ICD, or State guidelines)

#### Rationale

The MHPAEA regulations currently state that "*Mental health benefits* means benefits with respect to items or services for mental health conditions, as defined under the terms of the plan or health insurance coverage and in accordance with applicable Federal and State law. Any condition defined by the plan or coverage as being or as not being a mental health condition must be defined to be consistent with generally recognized independent standards of current medical practice." Parallel definitions are provided for SUD benefits and for M/S benefits.

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<sup>&</sup>lt;sup>4</sup> 29 CFR 2590.712(a)

Neither the MHPAEA regulations nor any FAQ or other federal guidance directly addresses the proper application of parity to benefits for treatments and services that can be delivered to care for both MH/SUD and M/S conditions. However, in making compliance determinations, regulators are taking the position that parity applies to claims for benefits with a primary diagnostic code that has been defined by the plan to be a MH or SUD condition. This position creates a number of sweeping downstream consequences that will be extremely burdensome and legally challenging to address.

Under this interpretation, treatment limits or cost-sharing requirements for the same service rendered by the same provider may differ solely based on the condition being treated. For example, if a plan applies a higher copay to x-rays than to other outpatient services and that higher copay does not meet the predominant test, then the higher copay may not be applied when the provider indicates a MH or SUD diagnosis code for the x-ray (e.g. to screen a person with tobacco use disorder for lung cancer). The practical result of this interpretation can therefore be to require that benefits for members with MH/SUD conditions be <u>more</u> generous than benefits for members with M/S conditions, in contradiction to the plain text of the statute, which merely requires <u>parity</u>.

## Key considerations include:

The scope of the parity protection may be arbitrary in practice, given relatively arbitrary current practices for determining which diagnosis to list as "primary" in the context of comorbid conditions and/or complex etiologies. There is little formal guidance or consistency in practice about how providers should determine which diagnosis is "primary" and whether the claim should be properly considered to be "for" the MH/SUD condition or the M/S condition. The question can be complex in practice. For example, the ranking of diagnoses may be essentially arbitrary for urgent care, office visits, and other services to treat a patient with co-morbid depression, tobacco use disorder, obesity, hyperlipidemia, and chronic obstructive pulmonary disorder. The ranking of diagnoses may also be unclear for patients who need treatment for physical injuries that result from MH or SUD conditions (e.g., self-harm) or for patients with MH and SUD conditions that result from M/S conditions (e.g., psychosis caused by HIV). In these and other situations, parity enforcement may also create incentives for providers to inappropriately prioritize MH/SUD diagnoses over M/S diagnoses in claims coding to avoid treatment limits and/or to reduce patient cost-sharing obligations. It is unwise to base the parity compliance determinations on such ambiguous and unreliable foundations.

- This interpretation will require many payors to make costly investments to update their claims systems to account for diagnostic codes when processing and adjudicating claims. The scope of services for which a provider may list an MH or SUD diagnosis code is uncertain and difficult to predict. A wide range of emergency services, urgent care services, office visits and therapy services, and screening and diagnostic services are commonly delivered to treat patients with both M/S and MH/SUD conditions. In addition, for the reasons described above, providers may assign MH/SUD diagnoses to claims for services that are rarely delivered to treat MH/SUD conditions. In this context, a parity compliance strategy cannot rely on a defined set of MH/SUD service codes; instead, the only practical way for Plans to ensure that cost-sharing and limits comply with parity is to differentiate claims adjudication based on the primary diagnosis code for all services. Unfortunately, many claims systems are not currently set up to differentiate cost-sharing or treatment limits by diagnosis code.
- Plans will have to update their actuarial projections of spending by benefit for the purposes of evaluating compliance with the "predominant" and "substantially all" tests. Regulators, in some instances, have determined that a Plan's actuarial testing methodology for parity compliance was insufficient where the Plan failed to remove claims for services with an MH or SUD diagnosis code from the dataset used to project spending on M/S benefits. Unfortunately, many claims platforms are not currently set up to systematically account for diagnosis codes.
- This interpretation will require many Plans to make costly investments to update their utilization management platforms to account for diagnostic codes when processing authorization requests and appeals. Regulators, in some instances, have determined that a Plan's methodology for analyzing denial and appeal rates for its comparative analyses of relevant NQTLs was insufficient where the Plan failed to assign all authorization requests to the MH/SUD or M/S datasets based on the diagnosis code rather than the service or provider type. Unfortunately, many utilization management platforms are not currently set up to systematically account for diagnosis codes.
- Where the parity test requires that a cost-sharing requirement or treatment limit for a service be adjusted regarding the treatment of MH/SUD conditions, making the MH/SUD coverage more generous than coverage for M/S conditions, the differential coverage may be interpreted to discriminate against

individuals with disabilities based on a M/S condition that needs the service for the treatment of their M/S condition. Such discrimination may violate the terms of the Americans with Disabilities Act (ADA).

For all of these reasons, the current approach to interpreting the ambiguous regulatory language is unnecessarily complex and burdensome. In addition, the current enforcement approach contravenes the language of the MHPAEA rules, which offer broad flexibility for plans and issuers to define their benefits under the terms of the plan or coverage (constrained only by federal and state law).<sup>5</sup>

Fortunately, the language of the MHPAEA regulations suggests a more straightforward and common-sense solution. The most reasonable and practical interpretation of the final rule is that benefits "for" MH/SUD conditions are benefits for treatments and services that are generally delivered to treat MH/SUD conditions and that all other benefits are M/S benefits. This approach would align with standard plan and coverage terms as currently designed and set forth in the MH/SUD sections of the standard plan description, plan contract or coverage policy, and related plan or coverage materials and would align with standard claims processing procedures as currently operated.

This approach would also align with guidance issued by the Centers for Medicare & Medicaid Services ("CMS") regarding the application of parity to long-term services and support for Medicaid and CHIP enrollees. The CMS guidance allows Plans to define benefits that can be used to treat either medical or behavioral conditions by means of a reasonable method, such as looking at the services and treatment spent and determining whether the service is predominantly used for a medical diagnosis or a mental health/substance use disorder diagnosis and defining it accordingly.<sup>6</sup>

<sup>&</sup>lt;sup>5</sup> The clear deference to plans and issuers to create their own definitions for "MH benefits," "SUD benefits," and "M/S benefits" under the terms of the plan or coverage stands in contrast to the narrow instruction for plans and issuers to use "generally recognized independent standards of medical practice" to define "MH conditions," "SUD conditions," and "M/S conditions."

<sup>&</sup>lt;sup>6</sup> Centers for Medicare and Medicaid Services, *Frequently Asked Questions: Mental Health and Substance Use Disorder Parity Final Rule for Medicaid and CHIP*, October 11, 2017, Q4. <a href="https://www.medicaid.gov/federal-policy-guidance/downloads/faq101117.pdf">https://www.medicaid.gov/federal-policy-guidance/downloads/faq101117.pdf</a>:

<sup>&</sup>quot;A variety of LTSS benefits, such as personal care and respite care, could be defined as either MH/SUD or medical/surgical (M/S), depending on the condition of the beneficiary being treated. For these benefits, the state may define the benefit as MH/SUD or M/S for the entire beneficiary population using a reasonable method, such as whether the service is most commonly or frequently provided due to a MH/SUD or M/S condition. For example, if more than 50% of spending on personal care is for beneficiaries who are receiving the service due to M/S conditions, the state may reasonably define personal care services as a M/S benefit for the purposes of the parity analysis."

Explicit guidance is critically needed to clarify whether it is necessary for Plans to make the significant capital investments that would be needed to update software platforms and data systems to identify every claim and authorization as either an "MH/SUD benefit" or a "M/S benefit." As noted above, many utilization management and claims adjudication platforms are not currently equipped to do so. To the extent that the Departments decide to formalize the interpretation that services must be covered as "MH/SUD benefits" or "M/S benefits" based on the condition being treated, the economic impact and paperwork burden of this guidance should be assessed pursuant to Executive Orders 12866 (Regulatory Planning and Review, September 30, 1993) and 13563 (Improving Regulation and Regulatory Review, February 2, 2011).