

October 12, 2023

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Room N-5653
U.S. Department of Labor
200 Constitution Avenue NW
Washington, DC 20210
Attention: 1210-AC11

Via Regulations.gov

To Whom it May Concern:

Thank you for the opportunity to comment on the proposed Requirements Related to the Mental Health Parity and Addiction Equity Act (MHPAEA) published in the Federal Register on August 3, 2023. These comments are submitted on behalf of the members of the National Association of Insurance Commissioners (NAIC), which represents the chief insurance regulators in the 50 states, the District of Columbia, and the United States territories.

State insurance regulators share responsibility with EBSA, CMS, and IRS in enforcing federal mental health parity requirements. And many states have implemented their own mental health parity requirements on health insurers. In reviewing health insurers' parity documentation and practices, state regulators have observed many deficiencies in parity compliance and reporting similar to those outlined in the preamble to the proposed rule and in recent Reports to Congress. State regulators appreciate the Departments' stepped-up enforcement efforts and work to update, enhance, and clarify regulations under MHPAEA. We submit the following comments with the goal of streamlining enforcement for both health insurers and state regulators and ultimately improving access to timely, high quality mental health and substance use disorder (MH/SUD) services.

In general, state regulators encourage the Departments to use the final rule to recognize state enforcement authority to the greatest possible extent. A number of states have developed robust parity enforcement practices and have years of experience in working with health insurers to bring about greater compliance. We believe federal regulations should serve as a floor for parity standards, not a ceiling. State rules that are more protective of consumer access to services should not be limited by federal standards. The final rule should clarify that insurers must comply with applicable state and federal requirements. Federal standards should not preempt state standards that require greater consumer protection and meeting federal standards should not allow an issuer to be deemed in compliance with a

state standard, including with regard to the Department's proposed exceptions for independent clinical standards and fraud, waste, and abuse prevention.

More specifically, the Departments request comment on whether the requirements for submission of comparative analyses detailed in proposed 45 CFR 146.137(d) should apply when the comparative analysis is requested by a state authority. We believe the final rule should explicitly recognize states' authority to enforce the requirements of paragraph (d), including those related to timeline, insufficiency, noncompliance, required action, corrective action plans, and notification. Allowing state authorities to make findings of insufficiency and noncompliance recognizes states' valid enforcement authority and significantly extends enforcement capacity. Some states, though, have their own laws and regulations in these areas. The federal rule should expand, not restrict, state authority. We recommend that the final rule allow states to apply either the federal requirements or applicable state requirements related to comparative analyses that are more stringent than federal requirements, at the state's option. Further, we believe that the language in proposed 45 CFR 146.137(b) should explicitly state that comparative analyses must be made available to the applicable state authority upon request. One, this aligns with the statutory text in Public Health Service Act Section 2726(a)(8)(A). In fact, the statutory text emphasizes "the applicable state authority" and only mentions the Secretary parenthetically. Two, while the proposed 45 CFR 146.137(e) establishes that an issuer must provide "a copy of the comparative analysis" to the applicable state authority, we believe this weakens the request power for states established by the statute.

Definitions

State regulators appreciate the Departments' attention to definitions in the proposed rule. Unclear or ambiguous terms have been a challenge in states' parity enforcement. Regulators support the explicit inclusion of the Diagnostic and Statistical Manual of Mental Disorders and the International Classification of Diseases in the definitions of mental health benefits and substance use disorder benefits. These references will help ensure that conditions like autism are consistently identified as mental health conditions.

State regulators have observed several instances where issuers incorrectly fail to apply MHPAEA protections to benefits that can be used for both MH/SUD conditions and medical/surgical conditions. Specifically, issuers are using the methodology from a Medicaid FAQ regarding long-term services and supports to argue that any benefit that is used more than 50% of the time for medical/surgical conditions may be considered to be a medical/surgical benefit 100% of the time and is therefore not protected by MHPAEA. For example, issuers have argued that, because nutritional counseling is used more than 50% of the time to treat medical conditions, it is therefore always a medical benefit and not subject to the predominant test for allowable cost sharing, even when it is used for mental health conditions like eating disorders. Defining benefits based on the condition or disorder being treated is a foundational piece of MHPAEA. When an issuer incorrectly defines a benefit based on the benefit's potential to treat other patients for medical/surgical conditions, the issuer uses inaccurate expected plan payments to calculate the predominant and substantially all tests. This can result in misidentifying the predominant level of cost sharing

for financial requirements. It also facilitates misuse regarding MHPAEA's NQTL and disclosure requirements.

We urge the Departments to clarify that this methodology used by issuers is not acceptable under MHPAEA, and that any benefits intended to treat a diagnosed mental health condition or substance use disorder are protected by MHPAEA.

Further, we urge the Departments to assure that definitions such as those for MH/SUD benefits are applicable to both group health plans and health insurance coverage to which parity requirements apply. For instance, definitions in proposed 146.136 include the language "a group health plan (or health insurance coverage offered by an issuer in connection with a group health plan)," which, by excluding individual insurance coverage, is more limited than the language used in Public Health Service Act Section 2726, "a group health plan or a health insurance issuer offering group or individual health insurance coverage." Since paragraph (e)(4) and the regulations on essential health benefits apply parity standards to non-grandfathered individual insurance coverage, the definitions should also be inclusive of such coverage.

Predominant and Substantially All Tests

The Departments propose to extend the predominant and substantially all tests to NQTLs. While we support the intent of this proposed requirement to align with the purpose of ensuring access to care, state regulators caution that this amendment may be problematic in practice. We request that the Departments issue extensive, detailed clarification on how to apply and interpret this requirement. Even with more clarification, some state regulators are concerned that applying these tests stringently to NQTLs would add significant complexity and burden to MHPAEA compliance without proportional benefits in consumer access to care.

The predominant and substantially all tests, as currently constructed, require the issuer to determine its expected plan payments (essentially allowable amounts for claims) for the plan year. It is unclear how this process would be handled for limitations that occur outside of the claims process and do not have specific payments or allowable amounts associated, such as denied prior authorizations or exclusion of experimental or investigational services.

The Departments provide examples for applying the tests, such as considering auto-adjudication versus manual review and the number of levels of review when determining the predominant variation of an NQTL. However, issuer processes for functions such as utilization management are extremely complex and nuanced, and finding the predominant variation of an NQTL may be unworkable in many real-life situations. For example, we have noted the following variations of prior authorization or concurrent review: An admission that requires notification but no clinical review; a non-clinical review based on predetermined standards (called "Fast Certification" by multiple carriers); a first-level or nurse clinical review; a second-level or physician clinical review; and a peer-to-peer clinical review. Within each of these categories some processes may be automated vs. manual, some may be handled by vendors vs. directly by the issuer, and some may have multiple utilization management systems within all of the aforementioned categories. Determining how to combine all of these

elements to arrive at the predominant variation of an NQTL for prior authorization or concurrent review may be infeasible for issuers and regulators without additional clarification.

State regulators have observed that a significant challenge in reviewing comparative analyses is that issuers describe processes, strategies, evidentiary standards, and other factors in extremely broad terms and commonly omit material information altogether. Enforcing the predominant test means that issuers may only describe what they have identified as the predominant variation of an NQTL and omit all of the other information, which would be problematic if the issuer misidentifies the predominant variation.

Exceptions for Independent Standards and Fraud, Waste, and Abuse

The proposed rule would create two exceptions to allow plans and issuers to apply more restrictive treatment limitations when the limitation arises from independent professional medical or clinical standards or prevents fraud, waste, and abuse. Such exceptions are likely necessary, but state regulators believe it is important for the Departments to establish clear and effective guardrails for their use. We request that the Departments elaborate on the permitted parameters of these exceptions, as they are currently written broadly enough that issuers may attempt to misuse them and claim the exceptions in situations where they are not intended to apply. The prohibition on deviations from independent standards is an important protection. It should be further specified, for example, that if medical necessity denial rates of prior authorization requests are not comparable between medical and surgical benefits and MH/SUD benefits, the issuer may not use the “independent professional medical or clinical standards” exception simply because prior authorization involves the application of medical necessity criteria. The issuer may not be applying the independent standards correctly, there may be discretion applied by physician reviewers that is not specified in standards, or the development of an issuer’s internal criteria may not be compliant with MHPAEA.

To maintain independence, generally recognized professional medical or clinical standards should be those promulgated by non-profit professional associations for the relevant clinical specialty or recognized by government bodies. Fraud, waste, and abuse prevention practices should be closely examined under the design and application requirements as well as through outcomes data to assure they are not being used to limit treatment inappropriately. Fraud, waste, and abuse risk is a common factor for determining which services will be subject to NQTLs. However, this does not mean that issuers can broadly claim exceptions from MHPAEA’s requirements for NQTLs simply because this risk is a component or factor of the NQTL. Additional guidance from the Departments would potentially deter misuse of these exceptions. In particular, the Departments should provide a very narrow definition for “waste.” In theory, the entire purpose of utilization management is to prevent “waste.” Therefore, it is very easy to imagine plans and issuers claiming exemption for a broad range of NQTLs under the “prevent waste” category. To prevent overuse of the exceptions, all three terms—fraud, waste, and abuse—require much greater definitional clarity that is narrow and tailored in scope.

The final rule should also clarify the role of states in granting or disallowing an exception. States would appreciate certainty that when they make a determination that a treatment

limitation does or does not qualify for an exception, the decision will not be reconsidered at the federal level.

Outcomes Data

The proposal would establish detailed requirements for plans and issuers to collect and analyze data on access to MH/SUD benefits and to take action when the data show differences in outcomes compared to medical and surgical benefits. State regulators generally support these requirements for data collection, analysis, and reasonable action. In several states' experiences, issuers frequently lack the data to show parity compliance or they may submit extensive data without performing their own analysis. We believe the law is clear that the obligations of measuring and assessing compliance fall with plans and insurance issuers, not regulators. Establishing this requirement in federal regulation will help prevent plans and issuers from submitting un-analyzed data and reduce reliance on complaints to identify parity issues.

Nonetheless, both federal and state regulators will need to enforce standards for the validity of plan and issuer outcome data. To do so successfully, clearer data definitions will be helpful. Plans and issuers may not measure claims outcomes in a consistent way, particularly with regard to partial approvals and partial denials. The proposed rule language is unclear as to whether "claims denials" is broadly meant to include denials taking place as part of utilization management functions (including prior authorization, concurrent review, and retrospective review). In states' experience, denial numbers and percentages provided without the correct context may not be the best indicators of MHPAEA compliance. We request that, in the final regulation or in future guidance as allowed for in the proposed rule, the Departments clarify the following:

- Issuers should be performing and documenting internal audits to ensure that reviewers are adhering to medical necessity criteria and correctly applying the permitted discretion/clinical judgment.
- Issuers must account for situations where lower levels of care are being approved or a lower number of days/visits is being approved as an alternative to the originally submitted request. For example, if the provider submits an authorization for an inpatient residential treatment stay, but the issuer authorizes only outpatient partial hospitalization as medically necessary, this should be accounted for in any metrics submitted and clearly denoted for regulator review.
- Issuers should provide data that contemplates facets such as the frequency of peer-to-peer reviews and the number of requests that were referred to physician review.

A critical component of parity compliance is parity in operation. Examining outcomes data is the best way to understand the results of plans' and issuers' operations. While disparities in outcomes do not, by themselves, prove parity violations, they do provide regulators an important cue for where to examine treatment limitations that could be affecting access to care. State regulators agree that material differences in outcomes data should be strong indicators of parity violations.

To ensure that this standard can be successfully implemented, we recommend the Departments provide additional clarification regarding when differences in outcomes become material differences that trigger actions to ensure compliance. We expect that outcome measures will have some variation due to differences in patients who seek MH/SUD benefits, differing professionals and facilities who provide them, and differing treatments for behavioral health conditions. The examples provided in the proposed rule will be very helpful for issuers and regulators, but more examples and additional clarification would be useful. We do not believe that a single numerical threshold will always be appropriate for judging a difference to be material. Nonetheless, should regulators enforcing the rule generally consider a 10% difference in access measures to be material? Under what circumstances would a smaller difference be material? And what considerations should a regulator use in allowing a larger difference without corrective action? We support the requirement for reasonable action to address material differences in outcome measures and believe it allows appropriate flexibility. Reasonable actions to address a large difference in outcomes may be significantly different than reasonable actions to address a smaller, but still material difference.

Along with the proposed rule, the Departments published a Technical Release that seeks comment on network composition data the Departments may collect to assess access to behavioral health care. State regulators support the extra attention to network composition. Challenges in accessing in-network behavioral health providers are widely reported by consumers to state insurance regulators. We suggest that the Departments align provider network data collection as directly as possible with existing provider network data requirements, such as those for Qualified Health Plan certification and state network adequacy review. We also support the principle outlined in the Technical Release that states should be permitted, but not required, to apply the enforcement safe harbor related to network composition. Some states have concern with the two-year length of the proposed safe harbor—giving states the option to alter or refrain from using the safe harbor builds in needed flexibility.

Improving Mental Health and Substance Use Disorder Benefits Through Other Consumer Protection Laws

The Departments solicit comments on how behavioral health crisis services fit within the existing categories for either MHPAEA or the essential health benefits (EHB). State regulators welcome guidance and direction from the Departments on these topics. Specifically, we point out that mobile crisis response units and residential crisis stabilization units are core emergency treatments for mental health conditions and substance use disorders. Therefore, these services should be covered in order to provide meaningful MH/SUD benefits that are comparable to medical and surgical benefits in the emergency classification. As such, we urge the Departments to allow the emergency components of these services to be considered EHB and to specify that these services should be placed in the emergency classification for MHPAEA purposes. Currently, very few plans and issuers cover behavioral health crisis services, introducing an NQTL by making them excluded benefits. It is very unlikely that plans and issuers exclude any common service types in the medical/surgical emergency classification of benefits. By clearly establishing that behavioral health crisis services should be classified in the emergency classification of benefits, the Departments

would strengthen MHPAEA protections for these critical services and prevent plans and issuers from excluding coverage for them, regardless of their inclusion as EHBs.

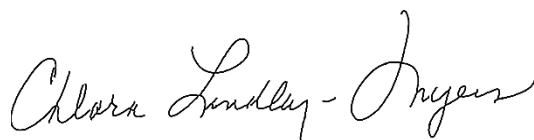
Federal Funding for State Enforcement Costs

As stated already, states play a crucial role in the enforcement of the federal MHPAEA, and this is appropriate. However, ensuring compliance with these complicated rules is time-consuming and costly to states - and the Departments are, by this proposed rule, seeking to increase that burden. States request federal funds to assist states in their enforcement efforts.

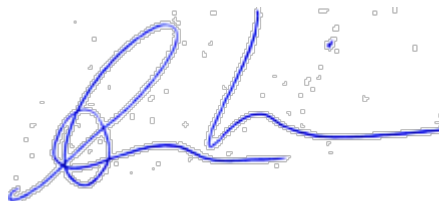
Just last year, Congress authorized grants to states for enforcement of federal mental health parity laws through section 1331 of the Consolidated Appropriations Act (CAA) of 2023. However, these funds have yet to be appropriated. In fact, the Senate's Labor, Health and Human Services, and Education, and Related Agencies Appropriations report approved by the committee says: "The Committee encourages the Secretary to support State insurance departments for the implementation of mental health parity as authorized in Public Law 117-328." Given that the clear intent of Congress is that these funds be made available to states, we ask that HHS move quickly to implement the parity enforcement grants authorized by Congress last year.

Thank you for the opportunity to comment on the NPRM. States share the goals of improving coverage of and access to MH/SUD services and look forward to continued collaboration with federal officials in this area.

Sincerely,



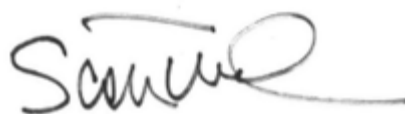
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