ABHW
Advancing Health Care Policy
for Mental Health and Addiction

August 16, 2021

William N. Parham, III
CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development
Room C4-26-05
Attention: Document Identifier/OMB Control Number: 0938-1393
7500 Security Boulevard
Baltimore, Maryland 21244–1850

Ali Khawar
Acting Assistant Secretary
Employee Benefits Security Administration
U.S. Department of Labor
Room N-5647
Attention: Document Identifier/OMB Control Number: 1210-0138
200 Constitution Ave, NW
Washington, DC 20210

Dear Mr. Parham and Mr. Khawar,

On behalf of the Association for Behavioral Health and Wellness (ABHW) we appreciate the opportunity to provide comments with respect to the following two Information Collection Requests (ICRs):

- The U.S. Department of Health and Human Services' (HHS) Non-Quantitative Treatment Limitation Analyses and Compliance Under Mental Health Parity and Addiction Equity Act (MHPAEA) of 2008 (CMS-10773) (OMB Control Number 0938-1393) and

- An amendment to the Department of Labor's (DOL) Notice of Medical Necessity Criteria under MHPAEA (OMB Control Number 1210-0138)

Both the amendment to DOL's ICR 1210-0138 and this new information collection under HHS' ICR 0938-1393 aim to codify new information collections envisioned under the Consolidated Appropriations Act (CAA), which began as an initial request under emergency clearance earlier this year. We submit the following comments for your consideration.

1. ***Protecting confidential information.***

We thank the agencies for clarifying that the collection will not include Personally Identifiable Information or Proprietary and Confidential Information. We request that the agencies validate these parts of their ICRs. If correct, we suggest instituting appropriate safeguards to protect against the inadvertent collection of Personally Identifiable Information or Proprietary or Confidential Information.

2. Clarify the discrepancies between DOL and HHS ICRs.

When MHPAEA was first enacted in 2008, only two requirements and related disclosure obligations were identified by Congress: (1) Claims Denial Disclosure and (2) Medical Necessity Disclosure. The initial ICR for 1210-0138 promulgated in 2010 reflects this intent and established those information collections. However, these new ICRs by DOL and HHS are creating confusion. First and foremost, we request clarification regarding the discrepancy between the information collections. DOL modifies one ICR and adds one new ICR[1] while HHS adds five new ICRs.[2] The CAA does not appear to support such a wide variance in the total number of information collections between the two agencies. Aligning the information collections between the agencies would help clarify the scope of the anticipated information collections and establish uniformity amongst the agencies.

Second, we note that FAQ 45 published by Centers for Medicare and Medicaid Services (CMS) and attached to each of the five information collections in 0938-1393 includes a disclaimer stating that its contents do not have the force or effect of law.[3] However, DOL's version of FAQ 45, does not include this disclaimer.[4] This introduces ambiguity as to express or implied requirements derived from the FAQs and the relation to the proposed information collection, as well as the cost and burden estimates associated with the collection. We request that this ambiguity be clarified and that the disclaimers be aligned between the agencies. To the extent other supporting documents do not impose information collection obligations on third parties, such as the Compliance Assistance Guide, we ask that those similar disclaimers be attached.

3. Proactively promote uniformity between state and federal requirements.

Given the significant costs and burdens associated with evaluating MHPAEA compliance, our members support efforts aimed at establishing consistency and uniformity as it pertains to MHPAEA compliance examinations. Disparate approaches taken to date by different regulators at both the federal and state level confuse the regulatory landscape and impact the ability to effectively scale compliance initiatives. The public would be well

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[1] Office of Information and Regulatory Affairs, Information Collection List, https://www.reginfo.gov/public/do/PRAICList?ref_nbr=202103-1210-004, last visited June 18, 2021.
[2] Office of Information and Regulatory Affairs, Information Collection List, https://www.reginfo.gov/public/do/PRAICList?ref_nbr=202104-0938-001, last visited June 18, 2021.
[3] CCIIO: FAQs About Mental Health and Substance Use Disorder Parity Implications and the Consolidated Appropriations Act, 2021 Part 45, pg. 1. https://www.reginfo.gov/public/do/DownloadDocument?objectID=110493001, last visited June 18, 2021.
[4] DOL: FAQs About Mental Health and Substance Use Disorder Parity Implementation and the Consolidated Appropriations Act, 2021 Part 45, https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-45.pdf, last visited June 18, 2021.

served by establishing a uniform information collection program amongst federal regulators that in turn, is also adopted at the state level.

Since the enactment of MHPAEA, DOL, HHS, the National Association of Insurance Commissioners (NAIC), and various states have all codified different requirements, proposed different suggestions, or developed different methodologies for performing analyses imposing significant operational costs on plans and issuers.

In fact, a recent issue brief published by the Medicaid and CHIP Payment and Access Commission (MACPAC) strongly supports the need for uniformity. Specifically, the issue brief makes the following observations:[5]

- "Providers continue to be challenged by vastly different NQTLs across Managed Care Organizations (MCOs), and availability of information (i.e., criteria for medical necessity determinations regarding behavioral health benefits) remains a problem within Medicaid, particularly as it relates to services for children and youth. **Making federal parity requirements more transparent would help stakeholders and patients identify parity violations**."

- "States, MCOs and others noted that they underestimated the scope of federal requirements when initiating their parity analyses, perhaps due to lack of prior expertise. One state noted that it took significant time for staff to understand the specificity and depth of what was required."

- "Another challenge noted by interviewees was that NQTLs were assessed and interpreted differently within and across states. For example, one state noted that MCOs, stakeholders, and state staff had different opinions on what constituted a non-quantitative treatment limitation. It took time and resources, including the assistance of hired consultants, to develop a shared understanding of what MHPAEA required."

- "Analysis of NQTLs can be particularly complicated if payment methodologies for behavioral and medical and surgical benefits differ. For example, many inpatient medical and surgical services may be paid using diagnostic related groups (DRGs) with payment based on factors such as diagnosis, treatment, and age. Hospitals are then paid a fixed amount regardless of the total cost and time needed to treat the patient. Under DRG-based payment methodologies, hospitals are incentivized to reduce the average length of stay and associated service costs. By contrast, inpatient behavioral health treatment is often paid through a per-diem rate. Per diem payments promote longer inpatient stays, and concurrent reviews may be appropriate to ensure services provided are medically necessary.[6] However, services that are paid under DRGs do not require concurrent review because hospitals are paid the same rate, no matter how long the patient is in the hospital.

[5] Implementation of the Mental Health Parity and Addiction Equity Act in Medicaid and CHIP, MACPAC, Issue Brief, July 2021.
[6] Berenson et al. 2016, MACPAC 2011.

> In this example, the use of concurrent review for inpatient psychiatric stays may be viewed as a parity violation if it is considered a more restrictive policy when compared to non-quantitative treatment limitations used for medical and surgical services. However, one MCO noted that this difference in payment structures necessitates an additional level of review for behavioral health services."

Our hope is to collaborate with the agencies to develop a uniform MHPAEA examination process in order to address disparate approaches to collecting information, performing an analysis, and determining compliance. To that end, we strongly urge the agencies to promulgate regulations to codify the CAA's requirements and provide clear rules and promote uniformity for the examination process.

4. ***Rules for MHPAEA examinations should be established using the normal notice and comment process.***

To the extent that the ICRs attempt to establish procedural rules for examinations established pursuant to the CAA, we question the appropriateness of using the ICR process for that purpose. Since the CAA clearly requires a new examination process, agencies should follow the normal notice and comment process for codifying rules of procedure under the code of federal regulations.

Ultimately, issuers and plans are responsible for achieving compliance with mental health parity and proving the same by documenting the analyses that demonstrate compliance. In attempting to meet these requirements, issuers and plans continue to strive to understand expectations with respect to parity compliance, most of which are centered around NQTLs. Accordingly, we appreciate that the CAA affords parity stakeholders an opportunity for further clarifications by requiring that the DOL, HHS, and Department of Treasury (collectively "the tri-Departments") promulgate regulations on NQTL analyses and compliance. Under such rulemaking efforts, we urge the tri-Departments to consider the following actions to comply with the CAA mandate and help issuers and plans better understand the regulators' expectations with respect to NQTLs:

- **Define a set of standard or "core" NQTLs that issuers and plans must analyze and document and provide a best-practice example analysis for each**. It is not possible for plans and issuers to develop 5-step analyses for "all" NQTLs proactively (i.e., in advance of a specific request and available on demand) without guidance to establish which NQTLs must be analyzed and documented. The current definition of an NQTL can conceivably involve almost any aspect of plan design and operations. The final rules define "Treatment limitations" to be "limits on the scope or duration of treatment," and define NQTLs somewhat circularly to be treatment limits that "otherwise limit the scope or duration of benefits for treatment under a plan or coverage."[7] However, no guidance has been provided to define or provide any

[7] "Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of

boundaries to what can constitute a "limit on the scope or duration of treatment," and the NQTL types that regulators have focused on for enforcement have varied over time.

ABHW members appreciate the clarity and specificity of FAQ 45, Q8, in which the tri-Departments identify the four specific NQTLs they intend to focus on for the near future. In the long term, ABHW reiterates its request for regulators to define a set of NQTLs on which issuers and plans are expected to have documented analyses prepared for submission within a very short timeframe upon request.[8] Defining such a list will facilitate plans' responsiveness to regulator requests for information relating to the core NQTLs, particularly upon short notice, and would in no way prevent regulators from requesting documentation on other non-core NQTLs should a complaint or specific compliance concern arise.

- **Provide a clear, comprehensive example of an NQTL analysis for each NQTL on the core list.** The CAA requirement to document the plan's compliance analysis is new.[9] Moreover, the 5-step framework mandated by the CAA differs materially from existing guidance in the DOL Self Compliance Guide,[10] and guidance in FAQ 45 on the documentation requirements of the CAA expands substantially on the substantive compliance considerations set forth previous guidance. No example is available of a complete NQTL analysis that the tri-Departments would consider to comply with the CAA requirements. When ABHW and its members met with the tri-Departments in March, the regulators informed us that, to-date, they had not seen what they would consider a model NQTL analysis. Significant ambiguity remains about the actual breadth and depth of details and supporting documentation required for each component of the CAA's five-step analyses. Model NQTL analyses would help clarify expectations, promote uniformity, and ultimately improve parity compliance. Accordingly, for each NQTL on the core list, we believe the tri-Departments should also provide at least one complete example of a compliant analysis. This would help clarify expectations, promote uniformity, and improve parity compliance.

- **Define a standard by which NQTL analyses are evaluated and a process by which examinations are pursued.** In FAQ 45, Q2 and Q4, the tri-Departments

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coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under a plan or coverage. (See paragraph (c)(4)(ii) of this section for an illustrative list of nonquantitative treatment limitations.) A permanent exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of this definition." 29 CFR § 2590.712(a), 45 CFR § 146.136(a), and 26 CFR § 54.9812-1(a).

[8] *See* Implications of parity documentation requirements and examination processes and standards under CAA, ABHW, March 3, 2021.

[9] *See* attached Appendix A: Timeline of Federal Guidance Regarding a Step-Wise Approach to MHPAEA Compliance.

[10] See Implications of parity documentation requirements and examination processes and standards under CAA, ABHW, March 3, 2021, p. 4-5.

address the information plans and issuers must make available to regulators and the types of documents issuers and plans should be prepared to submit in support of a given NQTL analysis. In practice, however, ABHW's members have found that the back and forth with the regulators during examinations can be confusing due to the lack of a defined process for NQTL documentation requests. As such, we hope to work with regulators to outline a process to better MHPAEA compliance.

5. The cost burden estimate proposed in the ICRs are not comprehensive.

In terms of cost and burden estimates, the ICRs include many unrealistic assumptions which flow from a conclusion that plans and issuers have operationalized what the agencies refer to as "best practices." "Best practices," appears to correlate with the DOL's suggested approach under its Compliance Assistance Guide which, for the first time, is now attached as a supporting document to ICR 1210-0138. This document is not attached to ICR 0938-1393. This disconnect introduces yet another ambiguity.

Until the enactment of the CAA, plans and issuers were able to perform an analysis in any reasonable manner so long as it was consistent with MHPAEA's final regulation. HHS, the NAIC, and state regulators, likewise, were free to propose and, in fact, actively used varying means for performing a MHPAEA compliance analysis. As a result, many regulators, plans and issuers will have to revamp their compliance initiatives in order to come into alignment with the CAA's prescriptive approach.

Both ICR estimates assume two individuals, an operations manager and a business operations specialist, can complete these analyses in less than 80 hours. In the case of HHS, it presumes this timeframe is reasonable to conduct an analysis for all products, keep records, and prepare documentation to HHS or state authorities.[11] While DOL's analysis is more practical in that it attributes its estimate to the plan level ("an average of 20 hours per plan to make any updates, 16 hours of a business operations specialist and four hours of a general or operations manager."), our members do not believe these estimates to be realistic.[12] Furthermore, plans and issuers are already assuming significant costs attempting to implement CAA's requirements without the benefit of proposed or final regulations given the CAA provided only 45 days to come into compliance.

It is prudent to also note that there is additional complexity for employer pans that have to obtain information from their behavioral health and medical/surgical vendors for review. The time estimate in the ICR seems to presuppose that the information is readily available for review but in practice, the plan or issuer must decide what information is needed, obtain if from vendors and then do the analysis. Additionally, for managed behavioral health organizations, they must participate in reviews with each customer and the lack of

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[11] HHS states: "We estimate that in the first year, for each issuer, a business operations specialist will need 72 hours (at an hourly labor cost of $77.14) and a senior manager will need 8 hours (at an hourly labor cost of $118.30) on average to document the analyses for all products, keep records, and prepare the documentation for submission to HHS or state authorities upon request." CMS-10773 NQTL Analysis Review Supporting Statement - Emergency.docx at 7.

[12] *See* OMB Control Number 1210-0138 MHPAEA Supporting Statement at 13.

uniformity among regulators requires a significant amount of time for each review because the information is not scalable from one assessment to the next even if the process for different plans is the same.

While we disagree on the accuracy of burden estimates in the ICRs, we support the aim of this request for comment. This information collection exercise helps "assess the impact of its information collection requirements and minimize the reporting burden on the public and helps the public understand the Department's information collection requirements and provide the requested data in the desired format."[13]

6. Conclusion.

We appreciate the opportunity to comment on these ICRs, and look forward to working with the agencies regarding the CAA's examination process. Please do not hesitate to contact Deepti Loharikar at loharikar@abhw.org or 202-505-1834 with any questions or concerns. We appreciate your time and efforts on this important issue and look forward to continuing to be a strong partner as we all move forward.

Sincerely,

Pamela Greenberg

Pamela Greenberg, MPP
President and CEO

[13] See Federal Register / Vol. 86, No. 76 / Thursday, April 22, 2021 / Notices 21349. 13