Supporting Statement – Part A
Non-Quantitative Treatment Limitation Analyses and Compliance Under MHPAEA
(CMS-10773/OMB control number 0938-NEW)

A. Background

Enacted on October 3, 2008, the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), Public Law 110-343, amended the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Service Act (PHS Act), and the Internal Revenue Code of 1986 (Code). MHPAEA expanded existing parity requirements between medical and surgical benefits and mental health benefits and also extended parity requirements to substance use disorder benefits. The law generally requires that group health plans and group health insurance issuers offering both medical/surgical and mental health or substance use disorder (MH/SUD) benefits do not apply more restrictive financial requirements (e.g., co-pays, deductibles) and/or treatment limitations (e.g., visit limits, prior authorization) to MH/SUD benefits than those requirements and/or limitations applied to substantially all medical/surgical benefits.

The Patient Protection and Affordable Care Act, Pub. L. 111-148, was enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152, was enacted on March 30, 2010. These statutes are collectively known as the "Affordable Care Act." The Affordable Care Act reorganizes, amends, and adds to the provisions of part A of Title XXVII of the PHS Act relating to group health plans and health insurance issuers in the group and individual markets. The Affordable Care Act added section 715(a)(1) to ERISA and section 9815(a)(1) to the Code to incorporate the provisions of part A of Title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The Affordable Care Act extended MHPAEA to apply to the individual health insurance market and redesignated MHPAEA as section 2726 of the PHS Act.[1] Additionally, section 1311(j) of the Affordable Care Act applies section 2726 of the PHS Act to qualified health plans (QHPs) in the same manner and to the same extent as such section applies to health insurance issuers and groups health plans. Additionally, the Department of Health and Human Services (HHS) final regulation regarding essential health benefits (EHB) requires health insurance issuers offering non-grandfathered health insurance coverage in the individual and small group markets, through an Exchange or outside of an Exchange, to comply with the requirements of the MHPAEA regulations in order to satisfy the requirement to cover EHB.[2]

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1 MHPAEA requirements apply to both grandfathered and non-grandfathered health plans. See section 1251 of the Affordable Care Act and its implementing regulations at 26 CFR 54.9815-1251T, 29 CFR 2590.715-1251, and 45 CFR 147.140. Under section 1251 of the Affordable Care Act, grandfathered health plans are exempted only from certain Affordable Care Act requirements enacted in Subtitles A and C of Title I of the Affordable Care Act. The provisions extending MHPAEA requirements to the individual market, and requiring that qualified health plans comply with MHPAEA were not part of these sections.

2 See 45 CFR §§147.150 and 156.115 (78 FR 12834, February 25, 2013).

The MHPAEA final regulations require that a group health plan or health insurance issuer may not impose a non-quantitative treatment limitation (NQTL) with respect to MH/SUD benefits in any classification unless, under the terms of the plan (or health insurance coverage) as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the NQTL to MH/SUD benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation to medical/surgical benefits in the same classification.[3] Under this analysis, the focus is not on whether the final result is the same for MH/SUD benefits as for medical/surgical benefits, but rather on whether the underlying processes, strategies, evidentiary standards, and other factors are in parity. These processes, strategies, evidentiary standards, and other factors must be comparable and applied no more stringently for MH/SUD benefits than for medical/surgical benefits.

The Consolidated Appropriations Act, 2021 (the Appropriations Act) was enacted on December 27, 2020.[4] The Appropriations Act amended MHPAEA to provide important new protections. The Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury (collectively, "the Departments") have jointly prepared a Frequently Ask Questions (FAQ) document to help stakeholders understand these amendments.[5]

Under the Appropriations Act, group health plans and health insurance issuers offering group or individual health insurance coverage must now document and be prepared to submit their comparative analysis with respect to each NQTL imposed when requested by any of the Departments or applicable state authority. For an analysis to be treated as sufficient under the Appropriations Act, it must contain a detailed, written, and reasoned explanation of the specific plan terms and practices at issue, and include the bases for the plan's or issuer's conclusion that the NQTLs comply with MHPAEA. At a minimum, sufficient analyses must include a robust discussion of all of the following elements:

1. A clear description of the specific NQTL, plan terms, and policies at issue.
2. Identification of the specific MH/SUD and medical/surgical benefits to which the NQTL applies within each benefit classification, and a clear statement as to which benefits identified are treated as MH/SUD and which are treated as medical/surgical.
3. Identification of any factors, evidentiary standards or sources, or strategies or processes considered in the design or application of the NQTL and in determining which benefits, including both MH/SUD benefits and medical/surgical benefits, are subject to the NQTL. Analyses should explain whether any factors were given more weight than others and the reason(s) for doing so, including an evaluation of any specific data used in the determination.
4. To the extent the plan or issuer defines any of the factors, evidentiary standards, strategies, or processes in a quantitative manner, it must include the precise definitions used and any supporting sources.

3 26 CFR 54.9812-1(c)(4)(i); 29 CFR 2590.712(c)(4)(i); and 45 CFR 146.136(c)(4)(i) and 147.160.
4 Pub. L. 116-260 (Dec. 27, 2020).
5 See Appendix I

5. The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between MH/SUD and medical/surgical benefits and, if so, describe the process and factors used for establishing that variation.
6. If the application of the NQTL turns on specific decisions in administration of the benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s).
7. If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both MH/SUD and medical/surgical benefits.
8. A reasoned discussion of the plan's or issuer's findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, factors, and sources identified above within each affected classification, and their relative stringency, both as applied and as written. This discussion should include citations to any specific evidence considered and any results of analyses indicating that the plan or coverage is or is not in compliance with MHPAEA.
9. The date of the analyses and the name, title, and position of the person or persons who performed or participated in the comparative analyses.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act (PRA), The Centers for Medicare & Medicaid Services (CMS) has submitted the following for emergency review to the Office of Management and Budget (OMB). We are requesting emergency review and approval in order to implement provisions requiring group health plans and health insurance issuers offering group or individual health insurance coverage that offer both medical/surgical benefits and MH/SUD benefits and that impose NQTLs on MH/SUD benefits to perform and document their comparative analyses of the design and application of NQTLs, and to make their comparative analyses available to the Departments or applicable state authorities, upon request. In accordance with 5 CFR 1320.13(a)(2)(iii), we believe that if the normal, non-emergency clearance procedures are followed, CMS will be unable to conduct the statutorily required reviews of the NQTL analyses and submit to Congress, and make publicly available, a report on the conclusions of the reviews in 2021.

B. Justification

1. Need and Legal Basis

Section 203 of Title II of Division BB of the Appropriations Act amended MHPAEA, in part, by expressly requiring group health plans and health insurance issuers offering group or individual health insurance coverage that offer both medical/surgical benefits and MH/SUD benefits and that impose NQTLs on MH/SUD benefits to perform and document their comparative analyses of the design and application of NQTLs. Further, beginning 45 days after the date of enactment of the Appropriations Act, these plans and issuers must make their

comparative analyses available to the Departments or applicable state authorities, upon request, including the following information:

1. The specific plan or coverage terms or other relevant terms regarding the NQTLs and a description of all MH/SUD and medical or surgical benefits to which each such term applies in each respective benefits classification;
2. The factors used to determine that the NQTLs will apply to MH/SUD benefits and medical or surgical benefits;
3. The evidentiary standards used for the factors identified, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTLs to MH/SUD benefits and medical or surgical benefits;
4. The comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to MH/SUD 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/surgical benefits in the benefits classification; and
5. The specific findings and conclusions reached by the plan or issuer, including any results of the analyses that indicate that the plan or coverage is or is not in compliance with the MHPAEA requirements.[6]

2. Information Users

CMS will request the comparative analyses from self-funded non-federal governmental plans and issuers offering group and individual health insurance coverage in direct enforcement states for MHPAEA for reviews related to potential violations of MHPAEA or complaints regarding noncompliance with MHPAEA that concern NQTLs, and any other instances deemed appropriate.

The Appropriations Act also requires the Departments, after review of the comparative analyses, to share information on findings of compliance and noncompliance with the state where the plan is located or the state where the issuer is licensed to do business.

Additionally, not later than one year after enactment of the Appropriations Act and annually by October 1 thereafter, the Departments must submit to Congress and make publicly available a report as described in item 10 below.

3. Use of Information Technology

Plans and issuers must submit all information electronically to CMS.

4. Duplication of Efforts

6 Internal Revenue Code (Code) section 9812(a)(8)(A)(i)-(iv), ERISA Section 712(a)(8)(A)(i)-(iv) and PHS Act section 2726(a)(8)(A)(i)-(iv).

MHPAEA amended ERISA and the Code in addition to the PHS Act. Accordingly, both DOL and the Treasury may require plans and issuers to provide the information as well. However, only CMS oversees non-Federal governmental health plans and issuers of individual and group health coverage, therefore there will be no duplication of effort with DOL and the Treasury.

States may require issuers to provide the information as well. However, no duplication should occur because CMS will only request information from issuers when CMS has direct enforcement responsibility for MHPAEA in a state.[7]

5. Small Businesses

Small businesses are not significantly affected by these information collection requirements (ICRs).

6. Less Frequent Collection

This collection is required to fulfill the statutory requirements in the Appropriations Act. CMS will not be able to conduct reviews of the NQTL analyses and ensure regulatory compliance without collecting the information from plans and issuers. CMS will also need to perform the comparative analyses reviews, submit the report to Congress, and make it available to the public as required by statute.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

CMS is seeking emergency clearance in accordance with the emergency review procedures set forth under 5 CFR 1320.13 and waiver of the notice requirement under the emergency clearance as set forth in 5 CFR 1320.13(d). After emergency clearance is obtained the ICRs will be submitted for review under the normal PRA procedures allowing for public review and comment.

9. Payments/Gifts to Respondents

No payments or gifts are associated with these ICRs.

10. Confidentiality

7 CMS is responsible for enforcement of MHPAEA with regard to issuers in Missouri, Texas, and Wyoming.

The Appropriations Act requires the Departments, after review of the comparative analyses, to share information on findings of compliance and noncompliance with the state where the group health plan is located or the state where the issuer is licensed to do business. Additionally, not later than one year after enactment of the Appropriations Act, and annually by October 1 thereafter, the Secretary of HHS must submit to Congress and make publicly available a report that contains:

1. A summary of the comparative analyses requested, including the identity of each plan or issuer that is determined not to be in compliance after a final determination by the Secretary;
2. The Secretary's conclusions as to whether each plan or issuer submitted sufficient information for the Secretary to review the comparative analyses requested for compliance with MHPAEA;
3. For each plan or issuer that submitted sufficient information for the Secretary to review the comparative analyses requested, the Secretary's conclusion as to whether and why the plan or issuer is in compliance with MHPAEA;
4. The Secretary's specifications with respect to the additional information that each plan or issuer that did not submit sufficient information must submit for the Secretary to review the comparative analyses for compliance with MHPAEA; and
5. The Secretary's specifications of the actions each plan or issuer that the Secretary determined is not in compliance must take to be in compliance with MHPAEA, including the reason the Departments determined the plan or issuer was not in compliance.

11. Sensitive Questions

These ICRs involve no sensitive questions.

12. Burden Estimates (Hours & Wages)

The burden estimates below have been updated based on recent data on individual market issuers and labor and mailing costs. We generally used data from the Bureau of Labor Statistics[8] to derive average labor costs (including 100 percent fringe benefits) for estimating the burden associated with the ICRs. Table 1 below presents the mean hourly wage, the cost of fringe benefits and overhead, and the adjusted hourly wage.

TABLE 1: Adjusted Hourly Wages Used in Burden Estimates

Occupation Title	Occupational Code	Mean Hourly Wage ($/hr.)	Fringe Benefits and Overhead ($/hr.)	Adjusted Hourly Wage ($/hr.)
Business Operations Specialist	13-1198	$38.57	$38.57	$77.14
General and Operations Manager	11-1021	$59.15	$59.15	$118.30

8 May 2019 National Occupational Employment and Wage Estimates United States found at https://www.bls.gov/oes/current/oes_nat.htm.

Occupation Title	Occupational Code	Mean Hourly Wage ($/hr.)	Fringe Benefits and Overhead ($/hr.)	Adjusted Hourly Wage ($/hr.)
Lawyer	23-1011	$69.86	$69.86	$139.72

NQTL analysis documentation and recordkeeping:

The Appropriations Act requires plans and issuers to perform and document comparative analyses for all NQTLs imposed. For an analysis to be treated as sufficient under the Appropriations Act, it must contain a detailed, written, and reasoned explanation of the specific plan terms and practices at issue, and include the bases for the plan's or issuer's conclusion that the NQTLs comply with MHPAEA. We expect that plans and issuers were already conducting NQTL analyses as best practice when creating benefit packages to ensure that the NQTLs are imposed in a manner that is compliant with MHPAEA. Therefore, we are only estimating the burden to comply with the additional requirements of the Appropriations Act.

Issuers offering individual or group health insurance coverage usually have multiple products offered in multiple 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. The total burden for each issuer in the first year will be 80 hours on average, with an equivalent cost of $6,500. In subsequent years, issuers will only need to update the documentation as needed. We estimate that for each issuer, a business operations specialist will need 36 hours (at an hourly labor cost of $77.14) and a senior manager will need 4 hours (at an hourly labor cost of $118.30) on average to document and keep records of the changes. The total annual burden for each issuer in subsequent years will be 40 hours on average, with an equivalent cost of approximately $3,200.

We estimate a total of 473 issuers offering individual and group health coverage nationwide, with 1,553 issuer/state combinations offering coverage in multiple states. We estimate that for all issuers in all states, the total burden in the first year will be 124,240 hours with an equivalent cost of approximately $10 million. In subsequent years, we estimate the total annual burden for all issuers will be 62,120 hours, with an equivalent cost of approximately $5 million. We estimate the average burden over 3 years will be approximately 82,827 hours, with an equivalent cost of approximately $6.7 million.

Sponsors of self-funded non-federal governmental plans are responsible for performing and documenting their analyses. We estimate that for each plan sponsor, a business operations specialist will need 32 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 their plan, keep records, and prepare the documentation for submission to HHS or state

authorities upon request. We estimate the total burden for each plan sponsor in the first year will be 40 hours on average, with an equivalent cost of approximately $3,400. In subsequent years, plan sponsors will only need to update the documentation as needed. We estimate that for each plan sponsor, a business operations specialist will need 16 hours (at an hourly labor cost of $77.14) and a senior manager will need 4 hours (at an hourly labor cost of $118.30) on average to document and keep records of the changes. We estimate the total annual burden for each issuer in subsequent years will be 20 hours on average, with an equivalent cost of approximately $1,700.

We estimate that there are 34,879 self-funded non-federal governmental plans. We estimate that for all plan sponsors, the total burden in the first year will be 1,395,160 hours with an equivalent cost of approximately $119 million. In subsequent years, we estimate the total annual burden for all plan sponsors will be 697,580 hours, with an equivalent cost of approximately $59.6 million. We estimate the average burden over 3 years will be approximately 930,100 hours, with an equivalent cost of approximately $79.4 million

TABLE 2: Annual Burden for Issuers related to NQTL analysis documentation and recordkeeping

Year	Number of Respondents	Number of Responses	Total Estimated Annual Burden (Hours)	Total Estimated Labor Cost
2021	1,553	1,553	124,240	$10,095,245
2022	1,553	1,553	62,120	$5,047,623
2023	1,553	1,553	62,120	$5,047,623
3 year Average	1,553	1,553	82,827	$6,730,164

TABLE 3: Annual Burden for Self-Insured Non-Federal Governmental Plans related to NQTL analysis documentation and recordkeeping

Year	Number of Respondents	Number of Responses	Total Estimated Annual Burden (Hours)	Total Estimated Labor Cost
2021	34,879	34,879	1,395,160	$119,107,600
2022	34,879	34,879	697,580	$59,553,800
2023	34,879	34,879	697,580	$59,553,800
3 year Average	34,879	34,879	930,107	$79,405,066

Review of comparative analysis:

Under the Appropriations Act, plans and issuers must submit their comparative analysis with respect to each NQTL imposed when requested by CMS. CMS will only request this information from issuers in states where CMS has direct enforcement responsibility for MHPAEA. The cost of submitting the information to CMS electronically will be minimal.

We assume that upon review, 10 plans and issuers will be found to have not submitted sufficient documentation and will have to provide additional documentation. We estimate that for each such plan or issuer, a business operations specialist will need 4 hours (at an hourly labor cost of $77.14) and a senior manager will need 1 hour (at an hourly labor cost of $118.30) on average to gather and submit the documents to CMS. We estimate the total burden for each plan or issuer will be 5 hours, with an equivalent cost of approximately $427. For 10 plans or issuers, we estimate the total annual burden will be 50 hours, with an equivalent cost of approximately $4,270.

TABLE 4: Annual Burden for Self-Insured Non-Federal Governmental Plans and Issuers related to Review of Comparative Analysis

Number of Respondents	Number of Responses	Total Estimated Annual Burden (Hours)	Total Estimated Labor Cost
20	20	50	$4,269

In instances where CMS, upon review of documentation submitted, determines that the plan or issuer is not in compliance with MHPAEA, the Appropriations Act requires the plan or issuer to specify the actions the plan or issuer will take to come into compliance and submit additional comparative analyses that demonstrate compliance not later than 45 days after the initial determination of noncompliance. We expect that no more than 2 issuers and 6 plan sponsors will be found to be non-compliant with the MHPAEA NQTL requirements and will need to complete corrective actions to bring the NQTL into compliance. We estimate that for each such issuer, a business operations specialist will need 36 hours (at an hourly labor cost of $77.14) and a senior manager will need 4 hours (at an hourly labor cost of $118.30) on average to prepare and submit documentation demonstrating compliance to CMS. We estimate the total burden for each issuer will be 40 hours, with an equivalent cost of approximately $3,250 and for 2 issuers, the total burden will be 80 hours with an equivalent cost of approximately $6,500. We estimate that for each such plan sponsor, a business operations specialist will need 16 hours (at an hourly labor cost of $77.14) and a senior manager will need 4 hours (at an hourly labor cost of $118.30) on average to prepare and submit documentation demonstrating compliance to CMS. We estimate the total burden for each plan sponsor will be 20 hours, with an equivalent cost of approximately $1,700. We estimate the total cost for 6 plan sponsors will be 120 hours with an equivalent cost of approximately $10,200. For all 8 plan sponsors or issuers, we estimate the total burden will be 200 hours, with an equivalent cost of approximately $16,700.

TABLE 5: Annual Burden for Self-Insured Non-Federal Governmental Plans and Issuers related to Corrective Action Plans

Type of Respondent	Number of Respondents	Number of Responses	Total Estimated Annual Burden (Hours)	Total Estimated Labor Cost
Issuer	2	2	80	$6,500
Plan Sponsor	6	6	120	$10,245
Total	8	8	200	$16,745

Following the 45-day corrective action period, if CMS makes a final determination that the plan or issuer is still not in compliance, not later than 7 days after such determination, the plan or issuer must notify all individuals enrolled in the plan or coverage that the coverage is determined to be noncompliant with MHPAEA. We anticipate that issuers and plan sponsors will take corrective action to become compliant with MHPAEA NQTL requirements. If a plan or issuer is still not in compliance, we estimate that it will take a lawyer (at an hourly labor cost of $139.72) 1 hour to prepare the required notice for a cost of approximately $140.

TABLE 6: Annual Burden for Self-Insured Non-Federal Governmental Plans and Issuers related to Notification of Non-compliance

Number of Respondents	Number of Responses	Total Estimated Annual Burden (Hours)	Total Estimated Labor Cost
1	1	1	$140

Submission to states upon request:

Under the Appropriations Act, plans and issuers must be prepared to submit their comparative analysis with respect to each NQTL imposed when requested by the applicable state authority. Of the 47 states and the District of Columbia that enforce MHPAEA, we are unable to estimate how many states will request this information and how often. However, the cost of submitting the information to state authorities electronically will be minimal.

14. Cost to Federal Government

CMS estimates that the cost of each review will be approximately $100,000, with a total cost of $2 million for all 20 reviews annually.

15. Changes to Burden

This is a new collection of information.

16. Publication/Tabulation Dates

CMS is required to publish reports using review results as described in item 10 above.

17. Expiration Date

There are no instruments associated with these ICRs.

APPENDIX I

FAQS ABOUT MENTAL HEALTH AND SUBSTANCE USE DISORDER PARITY IMPLEMENTATION AND THE CONSOLIDATED APPROPRIATIONS ACT, 2021 PART 45