

Internal Revenue Service
SUPPORTING STATEMENT
TD 9640
(Notice of Medical Necessity Criteria
under the Mental Health Parity and Addiction Equity Act of 2008)
OMB Control Number 1545-2165

1. CIRCUMSTANCES NECESSITATING COLLECTION OF INFORMATION

The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) was enacted on October 3, 2008 as sections 511 and 512 of the Tax Extenders and Alternative Minimum Tax Relief Act of 2008 (Division C of Public Law 110-343). MHPAEA amends the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Service Act (PHS Act), and the Internal Revenue Code of 1986 (the Code). In 1996, Congress enacted the Mental Health Parity Act of 1996, which required parity in aggregate lifetime and annual dollar limits for mental health benefits and medical and surgical benefits. Those mental health parity provisions were codified in section 712 of ERISA, section 2705 of the PHS Act, and section 9812 of the Code. The changes made by MHPAEA are codified in these same sections and consist of additional requirements as well as amendments to several of the existing mental health parity provisions applicable to group health plans and health insurance coverage offered in connection with a group health plan. MHPAEA and the interim final regulations did not apply to small employers who have between two and 50 employees. The changes made by MHPAEA are generally effective for plan years beginning after October 3, 2009.

On April 28, 2009, the Departments of the Treasury, Labor, and HHS (collectively, the Departments) published in the Federal Register (74 FR 19155) a request for information (RFI) soliciting comments on the requirements of MHPAEA. After consideration of the comments received in response to the RFI, the Departments published interim final regulations. These regulations generally become applicable to plans and issuers for plan years beginning on or after July 1, 2010.

The Departments published final regulations in November 2013. In general, the final regulations incorporate clarifications issued by the Departments through subregulatory guidance since the issuance of the interim final regulations and provide new clarifications on issues such as nonquantitative treatment limitations (NQTLs) and the increased cost exemption. Additionally, the Department of Health and Human Services (HHS) final regulation regarding essential health benefits (EHB) requires qualified non-grandfathered health plans and health insurance issuers in the individual and small group markets (plan with less than 50 participants) to comply with the requirements of MHPAEA and its implementing regulations in order to satisfy the requirement to cover EHB.¹ This information collection has been revised to include these added burdens.

¹ See 45 CFR 147.150 and 156.115 (78 FR 12834, February 25, 2013).

MHPAEA and the final regulations (29 CFR 2590.712(d)) require plan administrators to provide two disclosures regarding Mental Health (MH)/substance use disorder (SUD) benefits--one providing criteria for medical necessity determinations (medical necessity disclosure) and the other providing the reason for denial of claims reimbursement (claims denial disclosure). These disclosures are information collection requests for purposes of the Paperwork Reduction Act and are discussed below.

Medical Necessity Disclosure under MHPAEA

MHPAEA and section 26 CFR 54.9812-1(d)(1) require a plan administrator to provide, upon request, the criteria for medical necessity determinations made with respect to MH/SUD benefits to current or potential participants, beneficiaries, or contracting providers. Accordingly, any plan that receives a request from a current or potential plan participant, beneficiary, or contracting health care provider must provide that party with a Medical Necessity Disclosure under MHPAEA. The Department of Treasury (IRS), however, is not proposing that plans or issuers use a specific form.

Claims Denial Disclosure under MHPAEA

MHPAEA and these final regulations (26 CFR 54.9812-1(d)(2)) also provide that the reason for any denial under a group health plan (or health insurance coverage) of reimbursement or payment for services with respect to MH/SUD benefits in the case of any participant or beneficiary must be made available upon request or as otherwise required by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary. The Department of Labor's ERISA claims procedure regulation (29 CFR 2560.503-1) requires, among other things, plans to provide a claimant who is denied a claim with a written or electronic notice that contains the specific reasons for denial, a reference to the relevant plan provisions on which the denial is based, a description of any additional information necessary to perfect the claim, and a description of steps to be taken if the participant or beneficiary wishes to appeal the denial. The regulation also requires that any adverse decision upon review be in writing (including electronic means) and include specific reasons for the decision, as well as references to relevant plan provisions. Therefore, the final regulations provide that ERISA-covered plans (and health insurance coverage offered in connection with such plans) will be deemed to satisfy the MHPAEA claims denial disclosure requirement if they comply with the ERISA claims procedure regulation.

Requirements in the 21st Century Cures Act Related to MHPAEA Disclosures

Among its provisions, the Cures Act required the Departments, by June 13, 2017, to solicit feedback from the public on how the disclosure request process for documents containing information that health plans and health insurance issuers are required under Federal or State law to disclose to participants, beneficiaries, contracting

providers or authorized representatives to ensure compliance with existing mental health parity and addiction equity requirements can be improved while continuing to ensure consumers' rights to access all information required by Federal or State law to be disclosed.² The Cures Act requires the Departments to make this feedback publicly available by December 13, 2017.³ As part of this public outreach process, the Departments solicited comments on a draft model form that participants, enrollees, or their authorized representatives could use to request information from their health plan or issuer regarding NQTLs that may affect their MH/SUD benefits, or to obtain documentation after an adverse benefit determination involving MH/SUD benefits to support an appeal. The Departments received 19 comments and used those comments to make changes to the model form.

The Consolidated Appropriation Act of 2021

The Consolidated Appropriations Act (CAA, 2021) was enacted on December 27, 2020.⁴ 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, 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 benefit 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; 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
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

² Cures Act section 13001(c)(1).

³ Cures Act section 13001(c)(2). The Departments must also share this feedback with the National Association of Insurance Commissioners (NAIC) to the extent the feedback includes recommendations for the development of simplified information disclosure tools to provide consistent information to consumers. Such feedback may be taken into consideration by the NAIC and other appropriate entities for the voluntary development and voluntary use of common templates and other sample standardized forms to improve consumer access to plan information. See Cures Act section 13001(c)(3).

⁴ Pub. L. 116-260 (Dec. 27, 2020).

- 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 this section.⁵

The CAA, 2021 also provides that the Departments shall request that a group health plan or issuer submit the comparative analyses for plans that involve potential violations of MHPAEA or complaints regarding noncompliance with MHPAEA that concern NQTLs, and any other instances in which the Departments determine appropriate.

The Appropriations Act further 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.

2023 Proposal

The Departments are proposing amendments to regulations implementing MHPAEA and proposes new regulations for the comparative analyses required under MHPAEA, as amended by the CAA, 2021. Specifically, this rule would amend existing and add new definitions, amend the existing NQTL standard to prevent plans and issuers from using NQTLs to place greater limits on access to MH/SUD benefits as compared to medical/surgical benefits, and add additional examples on the application of NQTLs to clarify and safeguard the protections of MHPAEA. Additionally, these proposed rules would set forth the content requirements for the comparative analyses and specify how plans and issuers must make these comparative analyses available to the Departments, any applicable State authority, and to participants, beneficiaries, and enrollees.

2. USE OF DATA

Medical Necessity Disclosure

As discussed above, MHPAEA and the final regulations require plans and issuers to provide a Medical Necessity Disclosure. Receiving this information will enable potential and current participants and beneficiaries to make more informed decisions regarding the choices available to them under their plans and hopefully result in better treatment of their MH/SUD conditions. MHPAEA also requires plans administrators to provide the Medical Necessity Disclosure to current and potential contracting health care providers. Because medically necessary criteria generally indicate appropriate treatment for certain illnesses in accordance with standards of good medical practice, this information should enable

⁵ 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).

physicians and institutions to structure available resources to provide the most efficient mental health care for their patients.

Claims Denial Disclosure

MHPAEA and the final regulations require plans and issuers to explain the reason that a specific claim is denied. Most practically, participants and beneficiaries need this information to determine whether they agree with the decision and, if not, whether to pursue an appeal.

Disclosure Request Form

Group health plan participants, beneficiaries, covered individuals in the individual market, or persons acting on their behalf, may use the model form to request information from plans regarding NQTLs that may affect patients' MH/SUD benefits or that may have resulted in their coverage being denied. The form aims to simplify the process of requesting relevant disclosures for patients and their authorized representatives.

The Consolidated Appropriation Act of 2021

As discussed above, under the CAA, 2021, plans and issuers must now 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 CAA, 2021, 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, 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, would be subject to the NQTL. Analyses should explain whether any factors were given more weight than others and the reason(s) for doing so, including evaluating any specific data used in the determination.
4. To the extent the plan or issuer defined any of the factors, evidentiary standards, strategies, or processes in a quantitative manner, it must include the precise definitions used and any supporting sources.
5. Documented analyses 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 or issuer relies on any experts, documented analyses should include an assessment of the expert's qualifications and the extent to which the plan or issuer ultimately relied upon the expert 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 in writing. 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 addition, the Departments are proposing that plan and issuers include certain data requirements to the comparative analysis allowing for additional calculations and explanations in the analysis for certain NQTLs.

Finally, not later than one year after enactment of the CAA, 2021, and annually by October 1 thereafter, the Departments 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;
2. The Departments' conclusions as to whether each plan or issuer submitted sufficient information for the Departments to review the comparative analyses requested;
3. For each plan or issuer that submitted sufficient information for the Secretary to review the comparative analyses requested, the Departments' conclusion as to whether and why the plan or issuer is in compliance with the disclosure requirements of MHPAEA;
4. The Departments' specifications for each plan or issuer that did not submit sufficient information for the Departments to review the comparative analyses for compliance; and
5. The Departments' 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.

2023 Proposal

The proposed amendments to the existing MHPAEA regulations would add new definitions, amend existing definitions, clarify the rules for NQTLs, amend the existing NQTL standard to prevent plans and issuers from using NQTLs to place greater limits on access to mental health and substance use disorder benefits as compared to medical/surgical benefits. As part of these changes, these proposed rules would require plans to collect and evaluate relevant data in a manner reasonably designed to assess the impact of NQTLs on access to mental health and substance use disorder benefits, and would set forth a special rule with regard to network composition.

These proposed rules would also amend existing examples and add new examples on the application of the rules for NQTLs to clarify and illustrate the protections of MHPAEA. Additionally, these proposed rules would set forth the content requirements for NQTL comparative analyses, and specify how plans must make these comparative analyses available to the Departments, as well as to an applicable State authority, and participants, beneficiaries, and enrollees.

3. USE OF IMPROVED INFORMATION TECHNOLOGY TO REDUCE BURDEN

The regulation does not restrict plans or issuers from using electronic technology to provide either disclosure. The Department of Labor's regulations under 29 C.F.R. § 2520.104b-1(b) provides that, "where certain material, including reports, statements, notices and other documents, is required under Title I of the Act, or regulations issued thereunder, to be furnished either by direct operation of law or on individual request, the plan administrator shall use measures reasonably calculated to ensure actual receipt of the material by plan participants, beneficiaries and other specified individuals". Section 29 CFR 2520.104b-1(c) establishes the manner in which disclosures under Title I of ERISA made through electronic media will be deemed to satisfy the requirement of § 2520.104b-1(b). Section 2520-107-1 establishes standards concerning the use of electronic media for maintenance and retention of records. Under these rules, all pension and welfare plans covered under Title I of ERISA may use electronic media to satisfy disclosure and recordkeeping obligations, subject to specific safeguards.

The Government Paperwork Elimination Act (GPEA) requires agencies to allow customers the option to submit information or transact with the government electronically, when practicable. Where feasible, and subject to resource availability and resolution of legal issues, EBSA has implemented the electronic acceptance of information submitted by customers to the federal government.

4. EFFORTS TO IDENTIFY DUPLICATON

MHPAEA amended ERISA and the Code in addition to the PHS Act. Accordingly, the Departments require plans and issuers to provide, upon request, medical necessity and claims denial disclosures. There will be no duplication of effort with HHS and Treasury, however, because only the Department of Labor oversees ERISA-covered group health plans. Also, the final regulations provide that ERISA-covered plans (and health insurance coverage offered in connection with such plans) will be deemed to satisfy the MHPAEA claims denial disclosure requirement if they comply with the ERISA claims procedure regulation.

5. METHODS TO MINIMIZE BURDEN ON SMALL BUSINESSES OR OTHER SMALL ENTITIES

While MHPAEA does not affect plans with less than 50 participants, the ACA Essential Health Benefits Regulation requires non-grandfathered plans with less than 50 participants to comply with MHPAEA. To help minimize burden, the final regulations provide that ERISA-covered plans (and health insurance coverage offered in connection with such plans) will be deemed to satisfy the MHPAEA claims denial disclosure requirement if they comply with the ERISA claims procedure regulation.

6. CONSEQUENCES OF LESS FREQUENT COLLECTION ON FEDERAL PROGRAMS OR POLICY ACTIVITIES

The information collection arises in connection with the occurrence of individual claims for benefits and consists of third-party notices and disclosures. While no information is reported to the Federal government, if the plans and issuers do not provide the two disclosures or provide those disclosures less frequently, the Federal policy goals underlying MHPAEA would be impeded. Access to information about reasons for denials and medical necessity criteria enables participants, beneficiaries, and health care providers to better utilize health care resources which in turn may result in better treatment for mental health/substance use disorder conditions. At the very least, these disclosures make it easier to determine whether plans are making decisions about mental health/substance use disorder conditions in parity to those made regarding medical/surgical conditions.

7. SPECIAL CIRCUMSTANCES REQUIRING DATA COLLECTION TO BE INCONSISTENT WITH GUIDELINES IN 5 CFR 1320.5(d)(2)

There are no special circumstances requiring data collection to be inconsistent with Guidelines in 5 CFR 1320.5(d)(2).

8. CONSULTATION WITH INDIVIDUALS OUTSIDE OF THE AGENCY ON AVAILABILITY OF DATA, FREQUENCY OF COLLECTION, CLARITY OF INSTRUCTIONS AND FORMS, AND DATA ELEMENTS

Proposed regulations (REG-120727-21) published 08/03/2023 at 88 FR 51552, requested public comments and recommendations on the information collections. Any comments

received on the information collections will be addressed within the Final Rule submission.

9. EXPLANATION OF DECISION TO PROVIDE ANY PAYMENT OR GIFT TO RESPONDENTS

No payment or gift will be provided to any respondents.

10. ASSURANCE OF CONFIDENTIALITY OF RESPONSES

Generally, tax returns and tax return information are confidential as required by 26 USC 6103.

11. JUSTIFICATION OF SENSITIVE QUESTIONS

A privacy impact assessment (PIA) has been conducted for information collected under this request as part of the “Business Master File (BMF)” system and a Privacy Act System of Records notice (SORN) has been issued for this system under IRS 24.046-Customer Account Data Engine Business Master File. The Internal Revenue Service PIA’s can be found at <https://www.irs.gov/uac/Privacy-Impact-Assessments-PIA>.

Title 26 USC 6109 requires inclusion of identifying numbers in returns, statements, or other documents for securing proper identification of persons required to make such returns, statements, or documents and is the authority for social security numbers (SSNs) in IRS systems.

12. ESTIMATED BURDEN OF INFORMATION COLLECTION

Notices under the Mental Health Parity and Addiction Equity Act of 2008

As discussed in item 1 above, MHPAEA and the regulations (26 CFR 54.9812(d)) contain two disclosure provisions for group health plans and health insurance coverage offered in connection with a group health plan. The Claims Denial Disclosure (26 CFR 54.9812-1(d)(2)) requires the reason for any denial under a group health plan (or health insurance coverage) of reimbursement or payment for services with respect to mental health or substance use disorder benefits in the case of any participant or beneficiary to be made available upon request or as otherwise required by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary.

The Department of Labor’s ERISA claims procedure regulation (29 CFR 2560.503-1) requires, among other things, provides a claimant who is denied a claim with a written or electronic notice that contains the specific reasons for denial, a reference to the relevant plan provisions on which the denial is based, a description of any additional information necessary to perfect the claim, and a description of steps to be taken if the participant or

beneficiary wishes to appeal the denial. The regulation also requires that any adverse decision upon review be in writing (including electronic means) and include specific reasons for the decision, as well as references to relevant plan provisions. Therefore, the final regulations (26 CFR 54.9812-1(d)(2)) provide that ERISA-covered plans (and health insurance coverage offered in connection with such plans) will be deemed to satisfy the MHPAEA claims denial disclosure requirement if they comply with the ERISA claims procedure regulation. This ICR does not apply to the claims denial notice, because the costs and burdens associated with complying with the claims denial disclosure requirement already are accounted for under the Department of Labor's Employee Benefit Plan Claims Procedure under ERISA regulation (OMB Control Number 1210-0053).

Medical Necessity Disclosure

MHPAEA and the final regulations (26 CFR 54,9812-1(d)(1)) also require plan administrators to make the plan's medical necessity determination criteria available upon request to potential participants, beneficiaries, or contracting providers. The Department is unable to estimate with certainty the number of requests for medical necessity criteria disclosures that will be received by plan administrators; however, the Department has assumed that, on average, each plan affected by the rule will receive one request. The Department estimates that 409,822 ERISA-covered health plans with 50 or more participants⁶ and 1,488,476 ERISA-covered health plans with less than 50 participants⁷ that are not grandfathered are affected by this medical necessity disclosure, resulting in a total of 1,898,298 requests.⁸

The Department assumes that it will take a medically trained clerical staff member five minutes to respond to each request at a wage rate of \$45.39 per hour. This results in an annual hour burden of 175,215 hours and an associated equivalent cost of \$7,953,004 for the 2,102,579 requests.

Model Disclosure Request Form

Group health plan participants, beneficiaries, covered individuals in the individual market, or their authorized representatives may use the model form to request disclosures from plans. Use of this form is optional. For this analysis, the Department assumes that 25

⁶ Estimates are based on data from the 2021 Medical Expenditure Survey Insurance Component.

⁷ The Department estimates that there are 2,134,934 ERISA-covered group health plans with less than 50 participants based on data from the 2021 Medical Expenditure Survey - Insurance Component (MEPS-IC). The Department also estimates that 83 percent of group health plans with less than 50 participants are fully insured based on data from the 2021 MEPS-IC. The 2020 Kaiser Employer Health Benefits Survey reported that in 2020, 16 percent of firms offering health benefits offered at least one grandfathered health plan (Kaiser Employer Health Benefits Survey (Source: KFF. 2020 Kaiser Employer Health Benefits Survey. <https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf>). Thus, the Department has calculated the number of fully insured, non-grandfathered plans with less than 50 participants in the following manner: 2,134,934 small ERISA-covered group health plans x 83% x (100% minus 16%) = 1,488,476. The Department has not identified what share of plans with 50 or more participants offer mental health or substance use disorder benefits and so has assumed that all of these plans offer them.

⁸ 409,822 large ERISA-covered health plans with 50 or more participants + 1,488,476 ERISA-covered health plans with less than 50 participants = 1,898,298 requests

percent of the claims denial disclosure requests will be made using this model form and that providers will complete the form as authorized representatives and submit the form electronically, at minimal cost, to the plan. The Department estimates that it will take a provider approximately 5 minutes to review clinical records and complete this form. Therefore, approximately 498,015 requests will be made using the model form. The burden per response will be 5 minutes at a labor rate of \$208.07 per hour). The total burden will be 41,501 hours, with an equivalent cost of approximately \$8,635,165.⁹

To meet the PRA requirement, the Department estimated the burden associated with completing the Model Disclosure Request Form, because it is a new ICR. Under the MHPAEA regulations, participants previously had the right to request information regarding NQTLs, but a formalized process was not established to do so. Thus, the Department's estimate results in a burden increase for the ICR. The Department notes however, that the availability of the form is likely to reduce the overall burden imposed on plan participants to request the information, because it provides a simplified process to do so. Also, because use of the form is voluntary, the Department assumes that participants only will use the form if it reduces their burden to request the information.

Requirements under the Consolidated Appropriations Act of 2021 and the MHPAEA FAQ 45

Content Requirement Under the CAA, 2021

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.

The Department estimates that 249,991 self-insured group health plans with more than 50 participants are affected by this rule.¹⁰ For the purpose of this analysis, it is assumed that health insurance issuers will fulfill the requirements for fully-insured group health plans, and group health plans themselves will fulfill the requirements for self-insure group health plans. While there are group health plans that are fully-insured, and are under the Department's jurisdiction, as HHS has jurisdiction over issuers, HHS is accounting for this portion of the burden in their analysis, in addition to non-federal government group health plans. Accordingly, this analysis, considers only the burden associated with self-insured group health plans, which are under jurisdiction of the Department.

⁹ The burden is estimated as follows: 498,015 notices × 5 minutes = 41,501 hours. A labor rate of \$208.07 is used for physician. The labor rates are applied in the calculation as: 498,015 notices × 5 minutes x \$208.07 = \$8,635,165.

¹⁰ The Department has not identified what share of plans with 50 or more participants offer mental health or substance use disorder benefits and so has assumed that all of these plans offer them. Based on the 2021 Medical Expenditure Survey, 61 percent of ERISA-covered group health plans with 50 or more participants are self-insured. Thus, the Department calculates the number of self-insured group health plans based on the following manner: 409,822 ERISA-covered group health plans with 50 or more participants x 61% = 249,991.

Based on the Departments' prior experience, the Departments expect 100 comparative analyses each year to be requested. The Department assumes that 50 percent of plans will be able to provide all of the appropriate documentation in their first attempt. The other 50 percent, or 50 plans, will be required to spend additional time to produce additional documentation. The Department estimates it will take a total of five hours, one of a general or operations manager and four of a business operations specialist. The Department estimates that a general or operations manager will have an hourly labor cost of \$132.38 and a business operations specialist will have an hourly labor cost of \$109.96.¹¹ This results in a total hour burden of 250 hours with an equivalent cost burden of \$28,611 in each year.¹²

Corrective Action Plan

In instances where the Department has reviewed the comparative analyses and any other materials submitted upon request from a plan or issuer and determined that the plan or issuer is not in compliance with MHPAEA, the CAA, 2021 requires the plan or issuer to specify to the Department the actions the plan or issuer will take to come into compliance (a corrective action plan). Specifically, the plan or issuer must submit additional comparative analyses that demonstrate compliance not later than 45 days after the initial determination of noncompliance. The Department does not have an estimate of the number of plans that will be compliant; to account for burden the Department assumes that 40 percent of plans will be found to be noncompliant and will have to submit additional comparative analyses. The Department estimates that it will take a total of 128 hours, eight hours of a general or operations manager and 120 hours of a business operations specialist. The Department estimates that a general or operations manager will have an hourly labor cost of \$132.38 and a business operations specialist will have an hourly labor cost of \$109.96. This results in a total hour burden of 5,120 hours with an equivalent cost burden of \$570,170 in each year.¹³

Notice to Participants of Noncompliance

The CAA, 2021 requires that if the Department makes a final determination that the plan or issuer is still not in compliance following the 45-day corrective action period, the plan or issuer must notify all individuals enrolled in the plan or coverage, not later than 7 days after such determination, that the coverage is determined to be noncompliant with MHPAEA. The Department does not have an estimate for the number of plans what will still be out of compliance; to account for this burden the Department uses the number of 10 plans that

¹¹ *Ibid.*

¹² The burden is estimated as follows: 50 plans × 1 hours for general manager + 50 plans × 4 hours for operation manager = 250 hours. A labor rate of \$132.38 is used for general manager and a labor rate of \$109.96 is used for operation manager. The labor rates are applied in the calculation as: 25 plans × 1 hours × \$132.38 for general manager + 50 plans × 4 hours × \$109.96 for operation manager = \$28,611.

¹³ The burden is estimated as follows: 40 plans × 8 hours for general manager + 40 plans × 120 hours for operation manager = 5,120 hours. A labor rate of \$132.38 is used for general manager and a labor rate of \$109.96 is used for operation manager. The labor rates are applied in the calculation as: 40 plans × 8 hours × \$132.38 for general manager + 40 plans × 120 hours × \$109.96 for operation manager = \$570,170.

will not be in compliance. The Department estimates it will take one hour per plan for a legal professional to draft the notice resulting in a burden of 10 hours with an equivalent cost of \$1,593.¹⁴

Lastly, plans and issuers are required to make their comparative analyses of the design and application of NQTLs available to applicable State authorities upon request. The Department does not have information on how often such requests are likely to occur from State authorities; however, the Department expects that the comparative analyses and associated documentation plans and issuers prepare for the Department will be used to comply with the requests from State authorities. To provide State authorities with their comparative analyses and associated documentation, the Department assumes that plans and issuers will incur a de minimis cost.

Summary of Requirements under CAA, 2021

The total annual hour burden for these requirements is 5,380 hours and equivalent cost of \$600,374.

2023 Proposal

Amendment to Existing MHPAEA Regulations (29 CFR 2590.712; 26 CFR 54.9812-1)

The proposed amendments to the existing MHPAEA regulations would add new definitions, amend existing definitions, specify new requirements related to NQTLs, amend existing examples of NQTLs, and add new examples of NQTLs, providing clarity to the regulated community. The proposed amendments would also specify that mental health and substance use definitions must be consistent with generally recognized standards of care and would add more specificity as to what conditions or disorders plans and issuers would be required to treat as mental health and substance use conditions or disorders. The proposed amendments also require plans and issuers to evaluate relevant outcomes data and address any material differences in the data between mental health and substance use disorder benefits and medical/surgical benefits.

New Regulation (29 CFR 2590.712-1; 26 CFR 54.9812-2)

These proposed rules set more specific content and data requirements for the NQTL comparative analyses required by MHPAEA as amended by the CAA, 2021, clarify when the comparative analyses need to be performed, and outline the timeframes and process for plans and issuers to provide their comparative analyses to the Departments or applicable State authority upon request. These proposed rules would also require plans and issuers to collect and evaluate relevant data as part of each comparative analysis, including but not limited to claims denials, data relevant to NQTLs as required by State law or private

¹⁴ The burden is estimated as follows: 10 plans x 1 hour = 10 hours. A labor rate of \$159.34 is used for a legal professional. The labor rate is applied in the calculation as: 10 plans x 1 hour x \$159.34 for a legal professional = \$1,593.

accreditation standards, utilization rates, network adequacy metrics, and provider reimbursement rates, in fulfillment of the existing requirement that they evaluate and document their evaluation as part of the analysis of the application of NQTLs related to network composition and provider reimbursement.

For the purpose of this analysis, it is assumed that health insurance issuers would fulfill the data request for fully insured group health plans. This burden is accounted for under HHS' OMB Control number 0938-1393. It is also assumed that TPAs and other service providers would fulfill the requirements for the vast majority of self-insured group health plans.

Burden Estimates for Both Existing Requirements and Proposed Requirements

The Departments estimate that there are approximately 250,000 ERISA self-insured group health plans with 50 or more participants that are affected by these proposed rules.¹⁵ The Departments are of the view that the number of self-insured group health plans that actually perform the analysis themselves and incur the full estimated compliance costs may be much smaller. The Departments analyzed 2020 Form 5500 Schedule C (Service Provider Information) filings of self-insured health plans and determined that 89 percent of those plans indicated that they contracted with a TPA.¹⁶ Self-insured group health plans could fulfill the requirements, with the help of TPAs and other service providers.

To the extent self-insured plans use plan designs provided by TPAs or service providers responsible for nearly identical fully insured plans, those TPAs or service providers could utilize the analysis already performed for those fully insured plans, while helping these self-insured plans comply with the requirements. The Department assumes that most self-insured health plans would utilize service providers to perform the analysis and that only 11 percent¹⁷ (27,499) of the affected self-insured group health plans, primarily the largest, would need to conduct the analyses themselves for their plan specific design.¹⁸ The Department requests comments on the percent of self-insured group health plans that would rely on analyses that TPAs and other service providers have already performed for their other plans, thus reducing estimated burden on plans.

15 Employers with 50 or more employees are required to comply with MHPAEA. Employers with less than 50 participants are required to comply with MHPAEA as part of the Essential Health Benefits requirements of the ACA. The Departments have not identified what share of plans with 50 or more participants offer MH/SUD benefits and has therefore assumed that all of these plans offer them. Based on the 2021 Medical Expenditure Survey, 61 percent of ERISA-covered group health plans with 50 or more participants are self-insuring. Thus, the Departments calculates the number of ERISA self-insured group health plans with 50 or more participants based on the following manner: 409,822 ERISA group health plans with 50 or more participants x 61% = 249,991.

16 Because many plans are exempt from filing a Form 5500, the Departments only identified 37,934 self-insured health plan filings for 2020. Of these, only 5,537 plans (or roughly 15 percent) attached a Schedule C. Of those plans, 4,920 (or roughly 89 percent) indicated they paid compensation, either directly or indirectly, of at least \$5,000 for either 12) claims processing, 13) contract administrator, or both.

17 Based on the 2020 Form 5500, 89 percent of self-insured plans filed a Schedule C and indicated using either a Claims Processor, Contract Administrator, or both.

18 The Departments assume only large plans, defined as a plan with 50 or more participants would self-administer. 249,991 self-funded ERISA plans with 50 or more participants x 11 percent of plans that self-administer = 27,499.

The Department expects that these numbers may overestimate the number of self-insured plans that would perform the analysis themselves, without assistance from TPAs or service providers. For example, in the review of comparative analyses by the Departments, which has focused on self-funded plans, the reliance on insurance companies, TPAs, and other service providers for much or all of the work has been nearly universal. As noted above, this is not surprising because of the outsized role insurance companies, TPAs and other service providers tend to play in designing the plans, administering the networks, managing claims, providing plan services, maintaining and holding the data relevant to the comparative analyses, and driving MHPAEA compliance or noncompliance.

Non-grandfathered, fully insured group health plans with less than 50 participants who are subject to MHPAEA under the Essential Health Benefits requirements of the ACA, are likely to have their issuers prepare the comparative analysis. Issuers can take advantage of economies of scale by preparing the required documents for those plans purchasing coverage. HHS has jurisdiction over insurance issuers and therefore HHS is accounting for this portion of the burden in their analysis, in addition to non-federal government group health plans. Accordingly, this analysis considers only the burden associated with ERISA self-insured group health plans, which are under the jurisdiction of the Departments of Labor and the Treasury.

These proposed rules require that plans document actions that have been or are being taken by the plan or issuer to mitigate any material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, as required in the demonstration of comparability and stringency in operation requirement in section 54.9812-2(c)(5)(iv) of these proposed rules. To meet the format, content, data, and documentation requirements for the comparative analysis, the Department expects that plans preparing their own comparative analyses will on average annually perform four NQTL analyses and assumes that each NQTL analysis would require 20 hours in the first year, 4 hours for a general or operations manager and 16 hours for a business operations specialist.¹⁹ In the first year, this results in a total hour burden of 2,199,921 hours with an equivalent cost burden of \$251,767,736.²⁰ Once the comparative analyses are performed or documented, plans would need to update the analyses when making changes to the terms of the plan or coverage, including changes to the way NQTLs are applied to mental health and substance use disorder benefits. In subsequent years, the Department estimates it would take a total of 10 hours annually per NQTL to update the analyses, 2 hours for a general or operations manager and 8 hours for a business operations specialist. In

¹⁹ The estimated hour burden is consistent with the hour burden estimated in the previous PRA supporting statement for 1210-0138. In the PRA supporting statement, the Department estimated that it would take a total of 20 hours for plans to update each comparative analysis as required by the CAA, 2021 (<https://omb.report/icr/202108-1210-015/doc/114767500>). This estimate differs by accounting for plans needing to evaluate multiple NQTLs.

²⁰ The burden is calculated as follows: (27,499 ERISA self-insured group health plans x 4 NQTLs x 4 hours for a general or operations manager) + (27,499 ERISA self-insured group health plans x 4 NQTLs x 16 hours for a business operations specialist) = 2,199,921 hours. A labor rate of \$132.38 is used for a general or operations manager and a labor rate of \$109.96 is used for a business operations specialist. The labor rate is applied in the calculation as: (27,499 ERISA self-insured group health plans x 4 NQTLs x 4 hours for a general or operations manager x \$132.38) + (27,499 ERISA self-insured group health plans x 4 NQTLs x 16 hours for a business operations specialist x \$109.96) = \$251,767,736.

subsequent years, this results in a total hour burden of 1,099,960 hours with an equivalent cost burden of \$125,883,822.²¹

The proposed rules require that group health plans offering group health insurance coverage must make a comparative analysis available upon request by the Department. The CAA, 2021 requires the Departments to collect no less than 20 comparative analyses per year, but it also provides that the Departments shall request that a group health plan or issuer submit the comparative analyses for plans that involve potential MHPAEA violations or complaints regarding noncompliance with MHPAEA that concern NQTLs, and any other instances in which the Departments determine appropriate. Based on its prior experience, Departments expect to request 100 comparative analyses each year. To provide the Department with their comparative analyses and associated documentation, the Department estimates, based on internal discussion, it will take a total of five hours for plans, one of a general or operations manager and four of a business operations specialist. This would result in a total hour burden of 500 hours with an equivalent cost burden of \$57,222 in each year.²²

These proposed rules would also require plans and issuers to make the comparative analyses and other applicable information required by the CAA, 2021 available upon request to participants and beneficiaries in plans subject to ERISA and to participants, beneficiaries, and enrollees in all non-grandfathered group health plans and non-grandfathered group or individual health insurance coverage upon request in connection with an appeal of an adverse benefit determination. The Department estimates that each plan will receive one request per covered health plan annually and that plans would annually incur a burden of five minutes for a clerical worker to prepare and send the comparative analyses to each requesting participant or beneficiary. This results in an hour burden of 158,192 hours with an equivalent cost of \$10,037,282.²³

Recordkeeping Requirement

The Department posits that plans and issuers already maintain records as part of their regular business practices. Further, in ERISA sections 107 and 413 includes a general six-year

21 The burden is calculated as follows: (27,499 ERISA self-insured group health plans x 4 NQTLs x 2 hours for a general or operations manager) + (27,499 ERISA self-insured group health plans x 4 NQTLs x 8 hours for a business operations specialist) = 1,099,960 hours. A labor rate of \$132.38 is used for a general or operations manager and a labor rate of \$109.96 is used for a business operations specialist. The labor rate is applied in the calculation as: (27,499 ERISA self-insured group health plans x 4 NQTLs x 2 hours for a general or operations manager x \$132.38) + (27,499 ERISA self-insured group health plans x 4 NQTLs x 8 hours for a business operations specialist x \$109.96) = \$125,883,822.

22 The burden is calculated as follows: (100 ERISA self-insured group health plans x 1 hour for a general or operations manager) + (100 ERISA self-insured group health plans x 4 hours for a business operations specialist) = 500 hours. A labor rate of \$132.38 is used for a general or operations manager and a labor rate of \$109.96 is used for a business operations specialist. The labor rate is applied in the calculation as: (100 ERISA self-insured group health plans x 1 hour for a general or operations manager x \$132.38) + (100 ERISA self-insured group health plans x 4 hours for a business operations specialist x \$109.96) = \$57,222.

23 The hour burden is estimated as: (1,488,476 fully-insured, non-grandfathered plans with less than 50 participants + 409,822 ERISA-covered group health plans with 50 or more participants) x 5 minutes = 158,192 hours. A labor rate of \$63.45 is used for a clerical worker. The labor rate is applied in the calculation as: (1,488,476 fully-insured, non-grandfathered plans with less than 50 participants + 409,822 ERISA-covered group health plans with 50 or more participants) x 5 minutes x \$63.45 = \$10,037,282.

retention requirement. For these reasons the Department estimates a minimal additional burden. The Department estimates that, on average, any additional recordkeeping requirements will take clerical personnel five minutes annually. This results in an hour burden of 158,192 hours with an equivalent cost of \$10,037,282.²⁴

Summary of Both Existing Requirements and Proposed Requirements

In summary, the total annual hour burden in the first year for these requirements is 2,516,804 hours and equivalent cost of \$271,899,431. The total annual hour burden in the subsequent years for these requirements is 1,416,844 hours and equivalent cost of \$146,015,609. The three-year average burden is 1,783,497 hours and equivalent cost of \$187,976,883.

Overall Summary

In summary, in the first year, the total hour burden associated with this information collection is 2,721,878 hours and equivalent cost of \$289,819,684. In subsequent years, the total hour burden associated with this information collection is 1,673,418 hours and equivalent cost of \$184,916,498. The three-year average hour burden is 1,883,110 hours and an equivalent cost of \$205,897,135. The annual cost burden is \$2,182,094.

Because the Department of Labor and the Department of the Treasury share enforcement jurisdiction of group health plans and employers under the MHPAEA provisions (see section 712 of ERISA and section 9812 of the Internal Revenue Code), the aggregate paperwork burden of this information collection is divided equally between those two Departments. Therefore, the portion of the burden allocated to the Department of Labor is half of the total hours or 108,358 hours with an associated equivalent cost of \$7,526,311. These burden hours, along with the cost burden discussed in question 13, are assessed on half of the total respondents or 1,300,297 respondents, and half of the total responses or 1,300,297 responses.

Authority	Description	# of Respondents	# Responses per Respondent	Annual Responses	Hours per Response	Total Burden	Equivalent Cost
TD 9640	Technical Amendment to External Review for Multi-State Plan Program	1,323,153	1	1,323,153	0.7116	941,555	\$1,091,047
		1,323,153		1,323,153		941,555	\$1,091,047

²⁴ The hour burden is estimated as: (1,488,476 fully-insured, non-grandfathered plans with less than 50 participants + 409,822 ERISA-covered group health plans with 50 or more participants) x 5 minutes = 158,192 hours. A labor rate of \$63.45 is used for a clerical worker. The labor rate is applied in the calculation as: (1,488,476 fully-insured, non-grandfathered plans with less than 50 participants + 409,822 ERISA-covered group health plans with 50 or more participants) x 5 minutes x \$63.45 = \$10,037,282.

13. ESTIMATED TOTAL ANNUAL COST BURDEN TO RESPONDENTS

The Department calculated the cost to deliver the requested medical necessity criteria disclosures (regardless of whether the disclosure is prepared in-house or by service providers). Many insurers and plans already may have the information prepared in electronic form, and the Departments assume that 58.2 percent of requests will be delivered electronically resulting in a de minimis cost.²⁵ The Departments estimate that the cost burden associated with distributing the 1,898,298²⁶ medical necessity criteria disclosures sent by paper will be \$682,400.²⁷ This estimate is based on an average document size of four pages, five cents per page material and printing costs, and 66 cents postage costs.

Because the Department of Treasury/IRS and the Department of Labor share enforcement jurisdiction with respect to group health plans and employers under the MHPAEA provisions (see section 712 of ERISA and section 9812 of the Internal Revenue Code), the aggregate paperwork burden of this information collection is divided equally between those two Departments. Therefore, the portion of the cost burden allocated to the Department of Treasury/IRS is \$329,579.

14. ESTIMATED ANNUALIZED COST TO THE FEDERAL GOVERNMENT

Because the Department of Labor and the Department of the Treasury/IRS share enforcement jurisdiction of group health plans and employers under the MHPAEA provisions (see section 712 of ERISA and section 9812 of the Internal Revenue Code), the aggregate paperwork burden of this information collection is divided equally between those two Departments. Therefore, the portion of the burden allocated to the Department of Treasury/IRS is a total of \$98,392,320 spread across four years for an average annual cost of \$24,598,080 to request, review, and make a compliance determination for 200 comparative analyses spread across four years (or 50 comparative analyses spread across four years (or 50 comparative analyses per year). These costs include 648 FTEs (average 162 FTEs per year) and \$9,260,000 in additional expenses (average of \$2,315,000 per year), which include contracts with subject matter experts and costs to amend EBSA electronic case

²⁵ According to data from the National Telecommunications and Information Agency (NTIA), 40.0 percent of individuals age 25 and over have access to the Internet at work. According to a Greenwald & Associates survey, 84 percent of plan participants find it acceptable to make electronic delivery the default option, which is used as the proxy for the number of participants who will not opt-out of electronic disclosure that are automatically enrolled (for a total of 33.6 percent receiving electronic disclosure at work). Additionally, the NTIA reports that 40.4 percent of individuals age 25 and over have access to the internet outside of work. According to a Pew Research Center survey, 61.0 percent of internet users use online banking, which is used as the proxy for the number of internet users who will affirmatively consent to receiving electronic disclosures (for a total of 24.7 percent receiving electronic disclosure outside of work). Combining the 33.6 percent who receive electronic disclosure at work with the 24.7 percent who receive electronic disclosure outside of work produces a total of 58.2 percent who will receive electronic disclosure overall.

(1-0.582)*[177,822 large plans+ 338,503 plans between 50-100 participants + 1,586,254 non-grandfathered plans with less than 50 participants]

²⁶ 409,822 ERISA-covered group health plans with 50 or more participants + 1,488,476 non-grandfathered plans with less than 50 participants = 1,898,298 medical necessity criteria disclosures

²⁷ [409,822 ERISA-covered group health plans with 50 or more participants x (1- 58.2%) x (\$0.66 + \$0.05 x 4 pages)] + [1,488,476 non-grandfathered plans with less than 50 participants x (1- 58.2%) x (\$0.66 + \$0.05 x 4 pages)] = \$682,400

management system in order to track the requests and their review. The number of FTEs estimated were based on review of resources required to review NQTL analyses in prior investigations. The annual government cost is \$26,913,080 (\$24,598,080 + \$2,315,000=\$26,913,080).

15. REASONS FOR CHANGE IN BURDEN

The Departments are proposing amendments to regulations implementing MHPAEA and proposes new regulations for the comparative analyses required under MHPAEA, as amended by the CAA, 2021. Specifically, this rule would amend existing and add new definitions, amend the existing NQTL standard to prevent plans and issuers from using NQTLs to place greater limits on access to MH/SUD benefits as compared to medical/surgical benefits, and add additional examples on the application of NQTLs to clarify and safeguard the protections of MHPAEA. Additionally, these proposed rules would set forth the content requirements for the comparative analyses and specify how plans and issuers must make these comparative analyses available to the Departments, any applicable State authority, and to participants, beneficiaries, and enrollees.

In addition, the data inputs, mailing costs, and wage rates have been updated. As a result, the number of responses has decreased by 90,267, the hour burden has decreased by 909,981 hours, and the cost burden has decreased by \$-3,905,731.

16. PLANS FOR TABULATION, STATISTICAL ANALYSIS AND PUBLICATION

There are no plans for tabulation, statistical analysis, and publication.

17. REASONS WHY DISPLAYING THE OMB EXPIRATION DATE IS INAPPROPRIATE

IRS believes that displaying the OMB expiration date is inappropriate because it could cause confusion by leading taxpayers to believe that this regulation sunsets as of the expiration date. Taxpayers are not likely to be aware that the IRS intends to request renewal of the OMB approval and obtain a new expiration date before the old one expires.

18. EXCEPTIONS TO THE CERTIFICATION STATEMENT

There are no exceptions to the certification statement.

Note: The following paragraph applies to all of the collections of information in this submission:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long

as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103