# SUPPORTING STATEMENT FOR PAPERWORK REDUCTION ACT 1995: MENTAL HEALTH PARITY INFORMATION COLLECTION

**This ICR seeks approval for a revision of an existing control number.**

## A. JUSTIFICATION

### 1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the 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 (MH) benefits and medical/surgical benefits, and codified those provisions in section 712 of ERISA, section 2705 of the PHS Act, and section 9812 of the Code.[1] The changes made by MHPAEA are codified in these same sections and include provisions to apply the mental health parity requirements to substance use disorder (SUD) benefits and impose additional requirements for financial requirements and treatment limitations for group health plans and health insurance coverage offered in connection with a group health plan. MHPAEA does not apply to small employers that have between two and 50 employees. The changes made by MHPAEA became generally effective for plan years beginning on or after October 3, 2009. The Departments of Labor, Health and Human Services (HHS), and the Treasury (the Departments) issued interim final rules to implement MHPAEA on February 2, 2010,[2] and final rules on November 13, 2013.[3]

Additionally, the HHS final regulation[4] regarding essential health benefits (EHB) under the Affordable Care Act (ACA) requires non-grandfathered health insurance coverage in the individual and small group markets (generally coverage offered by employers with 50 or fewer employees) to comply with the requirements of MHPAEA and its implementing regulations in order to satisfy the requirement to cover EHB. This information collection has been revised to include these added burdens.

1 The Patient Protection and Affordable Care Act extended MHPAEA to apply to individual health insurance coverage and redesignated MHPAEA in the PHS Act as section 2726.
2 75 FR 5410 (Feb. 2, 2010).
3 78 FR 68240 (Nov. 13, 2013).
4 See 45 CFR 147.150 and 156.115 (78 FR 12834, February 25, 2013).

MHPAEA and the 2013 final regulations (29 CFR 2590.712(d)) require plan administrators to provide two disclosures regarding MH/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 29 CFR 2590.712(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 Labor, however, is not proposing that plans or issuers use a specific form.

***Claims Denial Disclosure under MHPAEA***

MHPAEA and the 2013 final regulations (29 CFR 2590.712(d)(2)) provide that the reason for any denial under a group health plan (or health insurance coverage offered in connection with such plan) of reimbursement or payment for services with respect to MH/SUD benefits in the case of any participant or beneficiary must be made available by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary in a form and manner consistent with the DOL claims procedure regulation (29 CFR 2560.503-1). The claims procedure regulation 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 claims procedure 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 2013 final regulations provide that ERISA-covered plans (and health insurance coverage offered in connection with such plans) must make the reason for any denial available by the plan administrator (or health insurance issuer offering such coverage) to the participant or beneficiary in a form and manner consistent with the requirements of 29 CFR 2560.503-1.

***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.[5] The Cures Act requires the Departments to make this feedback publicly available by December 13, 2017.[6] 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 nonquantitative treatment limitations (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 considered those comments in making changes to the model form. OMB then received an additional five comments in response to the 30-day notice on the revised model notice.

***The Consolidated Appropriations Act of 2021***

The Consolidated Appropriations Act (CAA, 2021) was enacted on December 27, 2020.[7] 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 CAA, 2021, on February 10, 2021, 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;

5 Cures Act section 13001(c)(1).
6 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).
7 Pub. L. 116-260 (Dec. 27, 2020).

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 this section.[8]

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. In instances in which one of the Departments concludes that the plan or issuer has not submitted sufficient information to review the comparative analyses requested, the Department shall specify to the plan or issuer the information they must submit to be responsive to the request. If, after review of a comparative analysis, one of the Departments determines that the plan or issuer is not in compliance with MHPAEA, the plan or issuer shall specify to the Department the actions the plan or issuer will take to come into compliance and provide additional comparative analyses that demonstrate compliance not later than 45 days after the initial determination of noncompliance. If the Departments make a final determination that the plan or issuer still is not in compliance with MHPAEA, not later than 7 days after such determination, the plan or issuer shall notify all individuals enrolled in the plan or applicable health insurance coverage that the plan or issuer has been determined to be not in compliance with MHPAEA.

The CAA, 2021 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.

***2024 Final Rules***

These final rules amend the regulations implementing MHPAEA and add new regulations implementing the NQTL comparative analysis requirements under MHPAEA, as amended by the CAA, 2021. Specifically, these final rules amend the existing NQTL standard to prohibit plans and issuers from using NQTLs to place greater restrictions on access to MH/SUD benefits as compared to medical/surgical benefits. As part of these changes, these final rules require plans and issuers to collect and evaluate relevant data in a manner reasonably designed to assess the impact of NQTLs on relevant outcomes related to access to MH/SUD benefits and medical/surgical benefits. The final

8 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).

rules also require plans and issuers to take reasonable action, as necessary, to ensure compliance with MHPAEA, where the relevant data suggest that an NQTL contributes to material differences in access to MH/SUD benefits as compared to medical/surgical benefits in a classification. Additionally, these final rules specify that if a plan or issuer receives a final determination from the relevant Secretary that the plan or issuer is not in compliance with the rules for comparative analyses, the Secretary may direct the plan or issuer not to impose the NQTL with respect to MH/SUD benefits, unless or until the plan or issuer demonstrates to the Secretary compliance with the requirements or takes appropriate action to remedy the violation. These final rules also amend existing examples and add new examples on the application of the rules for NQTLs to clarify and illustrate the requirements of MHPAEA. Additionally, these final rules set forth the content requirements for NQTL comparative analyses and specify how plans and issuers must make these comparative analyses available to the Departments, as well as to an applicable State authority, and to participants, beneficiaries, and enrollees.

**2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.**

***Medical Necessity Disclosure***

As discussed above, MHPAEA and the 2013 final regulations require plans and issuers to provide Medical Necessity Disclosure. Receiving this information will enable potential and current participants and beneficiaries to make more informed decisions when choosing their plans and hopefully result in better treatment of their MH conditions and SUDs. MHPAEA also requires plan 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 physicians and institutions to structure available resources to provide the most efficient MH/SUD 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 Appropriations 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. The Departments are required by statute to request a certain number of comparative analyses per year and, once requested, review the analyses to determine whether NQTL that is the subject of each analysis violates MHPAEA. Additionally, the final rules permit a participant or beneficiary (including a provider or other person acting as a participant's or beneficiary's authorized representative) who has received an adverse benefit determination related to MH/SUD benefits to request a copy of a comparative analysis, so the participant and beneficiary has the information necessary to determine whether to appeal the adverse benefit determination. This provision allows all participants and beneficiaries in plans and issuers subject to ERISA to request a copy of any comparative analysis, consistent with the general requirement under ERISA section 104 that entitles participants and beneficiaries to copies of instruments under which a plan is established or operated. ***2024 Final Rules***

These final rules amend existing regulatory definitions and add new definitions of key terms, including "factors," "processes," "strategies," and "evidentiary standards." They also add more specificity as to what conditions or disorders plans and issuers must treat as MH conditions and SUDs, and clarify that the way a plan or issuer defines MH benefits and SUD benefits for purposes of MHPAEA must be consistent with generally recognized independent standards of current medical practice. These final rules also clarify the way the parity requirements apply to NQTLs, including by prohibiting discriminatory factors and evidentiary standards, and provide additional examples of the application of MHPAEA to NQTLs to improve the understanding and ability of the regulated community to comply with the law. Additionally, these final rules require that plans and issuers provide meaningful benefits for covered mental health conditions and substance use disorders in each classification in which in which medical/surgical benefits are provided.

Under these final rules, plans and issuers will be required to collect and evaluate relevant data in a manner reasonably designed to assess the impact of the NQTL on relevant outcomes related to access to MH/SUD benefits and medical/surgical benefits. Where the relevant data suggest that the NQTL contributes to material differences in access to MH/SUD benefits as compared to medical/surgical benefits in a classification, the plan or issuer must take reasonable action, as necessary, to address the material differences to ensure compliance with MHPAEA.

These final rules provide guidance for how to comply with the relevant data evaluation requirements in limited circumstances where data is temporarily unavailable for new and newly imposed NQTLs and where no data exists that can reasonably measure any relevant impact of an NQTL on access to MH/SUD benefits and medical/surgical benefits. Where relevant data is temporarily unavailable for new or newly imposed NQTLs, the plan or issuer must provide a detailed explanation of the lack of relevant data, the basis for the plan's or issuer's conclusion that there is a lack of relevant data, and when and how the data will become available and be collected and analyzed. For an NQTL for which no data exists that can reasonably assess any relevant impact on access to MH/SUD benefits and medical/surgical benefits, the plan or issuer must provide a reasoned justification as to the basis for the conclusion that there are no data that can reasonably assess the NQTL's impact, why the nature of the NQTL prevents the plan or issuer from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure that the NQTL complies with MHPAEA.

Additionally, these final rules specify that if a plan or issuer receives a determination from the relevant Secretary that the plan or issuer is not in compliance with the rules for comparative analyses, the Secretary may direct the plan or issuer not to impose the NQTL with respect to MH/SUD benefits.

These final rules also set forth specific content requirements for comparative analyses required by the CAA, 2021, and outline the process for plans and issuers to provide their comparative analyses to the Departments or an applicable State authority upon request:

1. A description of the NQTL, including identification of the NQTL, identification of all benefits to which the NQTL applies and a description of what benefits are included in the classification;
2. Identification and definition of the factors and evidentiary standards used to design or apply the NQTL, including identification of every factor, as well as the evidentiary standards considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived, a definition of each factor and a description of any steps the plan or issuer has taken to correct, cure, or supplement any information, evidence, sources, or standards that would otherwise have been considered biased or not objective;
3. Description of how factors are used in the design and application of the NQTL, including a detailed explanation of how each factor identified and defined is used to determine which mental health or substance use disorder benefits and which medical/surgical benefits are subject, and an explanation of the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors or relied upon in designing and applying the NQTL;
4. Demonstration of comparability and stringency as written, including documentation of each factor identified and defined was applied, a comparison of how the NQTL, as

written, is designed and applied to mental health or substance use disorder benefits and to medical/surgical benefits, documentation demonstrating how the factors are comparably applied, as written, and an explanation of the reasons for any deviations or variations in the application of a factor;

5. Demonstration of comparability and stringency in operation, including a comprehensive explanation of how the plan or issuer evaluates whether, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL, identification of the relevant data collected and evaluated, documentation of the outcomes that resulted and a detailed explanation of any material differences in access and discussion of the actions that have been or are being taken by the plan or issuer to mitigate any material differences in access; and
6. Findings and conclusions, including any findings that the plan is or is not (or might or might not be) in compliance, a reasoned discussion of such findings, citations to any additional specific information, and a certification by one or more named fiduciaries that they have engaged in a prudent process to select one or more qualified service providers to perform and document a comparative analysis and have satisfied their duty to monitor those service providers.

Additionally, in these final rules, HHS finalizes regulatory amendments to implement a provision in the CAA, 2023 that sunsets the election option for sponsors of self-funded non-Federal governmental plans to opt out of requirements under MHPAEA.

**3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration for using information technology to reduce burden.**

The regulation does not restrict plans or issuers from using electronic technology to provide the required disclosures. 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. However, in order to ensure access for those participants and beneficiaries who may lack the ability to access electronic media, in order to meet the conditions of 29 CFR 2520.104b-1(c), all

disclosures must be provided in paper form upon request. Additionally, to notify all participants and beneficiaries of a final determination of noncompliance, the plan may make the required notice available electronically if the format is readily accessible; the notice is provided in paper form free of charge upon request; and, in a case in which the electronic form is an internet posting, the plan or issuer timely notifies the participant or beneficiary in paper form (such as a postcard or email), that the documents are available on the internet, provides the internet address, and notifies the participant or beneficiary that the documents are available in paper form upon request.

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. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.**

MHPAEA amended ERISA and the Code in addition to the PHS Act. The required disclosures are specific to MHPAEA. The Department of Health and Human Services, The Department of the Treasury, and the Department of Labor have worked together on rulemaking to ensure there will be no duplication. Also, the regulations provide that ERISA-covered plans (and health insurance coverage offered in connection with such plans) must make the reason for any denial available by the plan administrator (or health insurance issuer offering such coverage) to the participant or beneficiary in a form and manner consistent with the requirements of 29 CFR 2560.503-1.

**5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.**

While MHPAEA does not apply to plans sponsored by employers with 50 or fewer employees, the ACA EHB Regulation requires non-grandfathered fully-insured plans in the small group market sponsored by employers with 50 or fewer employees) to comply with MHPAEA in order to satisfy the requirement to provide EHB. To help minimize burden, the regulations provide that ERISA-covered plans (and health insurance coverage offered in connection with such plans) must make the reason for any denial available by the plan administrator (or health insurance issuer offering such coverage) to the participant or beneficiary in a form and manner consistent with the requirements of 29 CFR 2560.503-1.

**6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.**

Part of this information collection arises in connection with the occurrence of individual claims for benefits and consists of third-party notices and disclosures. If the plans and issuers do not provide the 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 MH conditions and SUDs. The required disclosures make it easier to determine whether plans are making decisions about MH/SUD conditions in parity to those made regarding medical/surgical conditions.

The Department will use the comparative analyses of the design and application of NQTLs to help enforce the requirements of MHPAEA and to provide a required report to Congress.

**7. Explain any special circumstances that would cause an information collection to be conducted in a manner:**

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;**
- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
- **requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

There are no special circumstances in this information collection.

**8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.**

**Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.**

**Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years -- even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.**

The Departments' notice required by 5 CFR 1320.8(d), which provided the public with 60 days to comment on the information collection under the proposed rules, was published in the Federal Register on August 3, 2023 (88 FR 51552).

DOL received comments on the proposed rules (https://www.federalregister.gov/documents/2023/08/03/2023-15945/requirements-related-to-the-mental-health-parity-and-addiction-equity-act). Many commenters expressed concern that the Departments underestimated the burden of collecting the required data, the burden required in conducting the substantially all and predominant variation analysis, the number of NQTLs that would need to be analyzed for each plan and issuer, and the amount of time that it would take to conduct those analyses. The Departments reviewed these public comments in developing the paperwork burden analysis discussed here.

In response to commenters' concerns that the Departments underestimated the number of NQTLs that each plan or issuer would need to create comparative analyses for, and that plans and issuers would on average have the same number NQTLs, the Departments have revised their assumptions to 10 NQTLs for both plans and issuers. One commenter proposed the average number of NQTLs should be more than 15 at a minimum,[9] while another noted that there were at least 15 NQTLs referenced in the proposed rules and

9 *See* comment from ABHW (Oct. 17, 2023), last accessed at https://www.regulations.gov/comment/EBSA-2023-0010-0236.

other guidance.[10] However, given that the number of NQTLs vary by issuer and plan, that most plans will not have every NQTL identified in regulations and guidance (although some might have more), and that NQTLs can be counted as an umbrella group, the Departments assume 10 NQTLs.

The Departments assume that collecting the data, and reviewing and revising the comparative analyses would require 60 hours per NQTL in the first year and 12 hours per NQTL in subsequent years. While plans and issuers can use other professionals to fulfill their requirements, for purposes of developing the wage estimate, the Departments assume that it will take a team of data analysts, actuaries, and attorneys to collect the data and prepare the comparative analyses, and have estimated a composite wage rate of $167.48.[11]

**9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.**

There are no payments or gifts in this information collection.

**10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.**

There are no questions of sensitive nature in this information collection, and thus there is no assurance of confidentiality provided to respondents.

**11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.**

There are no questions of sensitive nature in this information collection.

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10 *See* comment from BCBSA (Oct. 17, 2023), last accessed at https://www.regulations.gov/comment/EBSA-2023-0010-0237.

11 The wage rate of an attorney, actuary, and data analyst is, respectively, $165.71, $177.11, and $159.61. (Internal DOL calculation based on 2024 labor cost data. For a description of DOL's methodology for calculating wage rates, see EBSA, *Labor Cost Inputs Used in the Employee Benefits Security Administration, Office of Policy and Research's Regulatory Impact Analyses and Paperwork Reduction Act Burden Calculations* (June 2019), https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf.) The composite wage rate is estimated in the following manner: [$165.71 × (1 ÷ 3) + $159.61 × (1 ÷ 3) × $177.61 × (1 ÷ 3) = $167.48].

**12. Provide estimates of the hour burden of the collection of information. The statement should:**

- **Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.**
- **If this request for approval covers more than one form, provide separate hour burden estimates for each form.**
- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 14.**
- **The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 14.**

Group health plans sponsored by employers with 50 or more employees that offer mental health and substance use disorder benefits are generally required to comply with MHPAEA. Although MHPAEA includes a small employer exemption, group health plans sponsored by employers with less than 50 employees who purchase non-grandfathered small group coverage are required to comply with MHPAEA under the EHB requirements of the ACA. In this analysis, plan size is used as a proxy for employer size to determine if a plan is affected. Evidence suggests that most large plans offer MH/SUD benefits, and nearly all participants in such plans have behavioral health coverage.[12]

The following wage rates were used in this analysis: $57.10 (medical secretary), $159.61 (data analyst), $165.71 (legal professional), $177.11 (actuary), and $216.39 (physician).[13]

12 Dominic Hodgkin, Constance M. Horgan, Maureen T. Stewart, Amity E. Quinn, Timothy B. Creedon, Sharon Reif, & Deborah W. Garnick, *Federal Parity and Access to Behavioral Health Care in Private Health Plans*, 69(4) Psychiatric Services pp. 396-402 (2018), https://ps.psychiatryonline.org/doi/pdf/10.1176/appi.ps.201700203; Department of Labor, *Selected Medical Benefits: A Report from the Department of Labor to the Department of Health and Human Services*, (April 15, 2011), https://www.bls.gov/ebs/additional-resources/selected-medical-benefits-a-report-from-dol-to-hhs.pdf; & Constance Horgan, Dominic Hodgkin, Maureen T. Stewart, Amity Quinn, Elizabeth L. Merrick, Sharon Reif, Deborah W. Garnick, & Timothy B. Creedon, *Health Plans' Early Response to Federal Parity Legislation for Mental Health and Addiction Services*, Psychiatric Services 67(2), (February 1, 2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4738051/pdf/nihms737198.pdf.

13 Internal DOL calculation based on 2024 labor cost data. For a description of DOL's methodology for calculating

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

As discussed in item 1 above, MHPAEA and the regulations (29 CFR 2590.712(d) and 29 CFR 2590.712-1) contain disclosure provisions for group health plans and health insurance coverage offered in connection with a group health plan. The Claims Denial Disclosure (29 CFR 2590.712(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 by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary in a form and manner consistent with the Department's ERISA claims procedure regulation (29 CFR 2560.503-1). This regulation requires, among other things, a plan administrator 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. 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 (29 CFR 2590.712(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.[14] The Department estimates that 410,581 ERISA-covered health plans with 50 or more participants[15] and 1,718,935 ERISA-covered health plans with less than 50 participants[16]

wage rates, see https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf.

14 78 FR 68240 (11/13/2013)

15 Estimates are based on data from the 2022 Medical Expenditure Survey Insurance Component.

16 The Departments estimate that there are 2,465,483 ERISA-covered group health plans with less than 50 participants based on data from the 2022 Medical Expenditure Panel Survey – Insurance Component and the 2020 County Business Patterns from the Census Bureau. The Departments also estimate that 83 percent of group health plans with less than 50 participants are fully insured based on data from the 2022 Medical Expenditure Panel Survey Insurance Component (MEPS-IC) and the 2020 County Business Patterns from the Census Bureau. The 2020 Kaiser

that are not grandfathered are affected by this medical necessity disclosure, resulting in a total of 2,129,516 requests.[17] Please see Table 1 for calculations and burden totals.

***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. The Department estimates that approximately 498,015 requests will be made using the model form.[18] The Department estimates that it will take a provider approximately 5 minutes to review clinical records and complete this form. Please see Table 1 for calculations and burden totals.

To meet the PRA requirement, the Department estimated the burden associated with completing the Model Disclosure Request Form. Under the MHPAEA regulations, participants have the right to request information regarding NQTLs. The Department notes, 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.

**Table 1. Hour Burden of Medical Necessity Disclosures and Model Disclosure Request Forms**

| | Number of Entities | Number of Hours per Entity | Total Hour Burden | Wage Rate | Hour Equivalent of Cost Burden |
|---|---|---|---|---|---|
| | (A) | (B) | (C) | (D) | (A x B x C x D) |
| Medical secretaries prepare Medical Necessity Criteria Disclosures | 2,129,516 | 0.083 | 177,460 | $57.10 | $10,132,946 |
| Medical providers review | 498,015 | 0.083 | 41,501 | $216.39 | $8,980,455 |

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 Departments have calculated the number of fully insured, non-grandfathered plans with less than 50 participants in the following manner: 2,465,483 small ERISA-covered group health plans x 83% x (100% minus 16%) = 1,718,935

17 410,581 large ERISA-covered health plans with 50 or more participants + 1,718,935 ERISA-covered health plans with less than 50 participants = 2,129,516 requests.

18 The Department estimates that the total number of health claims denied is 199,206,000. The Department assumes that the percent of total claims that are MH/SUD claims is 10 percent. The Department also assumes that the percent of denials resulting in a request for explanation is 10 percent. Finally, the Department assumes that 25 percent of group health plan participants, beneficiaries, and covered individuals in the individual market will request disclosures from plans and that providers will complete the form as authorized representatives and submit the form electronically, at minimal cost, to the plan. Thus, the number of requests will be made using the model form is calculated in the following manner: 199,206,000 health claims x 10 percent x 10 percent x 25 percent = 498,015.

| | | | | | |
|---|---|---|---|---|---|
| and complete Model Disclosure Request Forms | | | | | |
| **Total** | **2,627,531** | **-** | **218,961** | **-** | **$19,113,401** |

***Requirements under the Consolidated Appropriations Act of 2021***

*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.

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-insured group health plans. While there are ERISA 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 ERISA-covered self-insured group health plans, which are under jurisdiction of the Department.

Based on its prior experience and current funding, DOL expects to request 20 comparative analyses each year. 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 10 plans, will be required to spend additional time to produce additional documentation. Please see Table 2 for calculations and burden totals.

***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 must respond to the initial determination by the Secretary and specify the actions the plan or issuer will take to bring the plan or coverage into compliance (a corrective action plan). The plan or issuer also must submit additional comparative analyses that demonstrate compliance not later than 45 days after the initial determination of noncompliance.

The Department does not have a good estimate of the number of plans that will be

compliant. As documented in the 2022 MHPAEA Report to Congress,[19] the Department found that none of the comparative analyses reviewed by the Departments under the first year of the CAA, 2021, contained sufficient information and documentation from plans and issuers upon initial receipt and nearly all were found to be similarly deficient for the 2023 MHPAEA Comparative Analysis Report to Congress.[20] While the Department believes that most plans and issuers are not currently complying with the CAA, the Department believes that the number of plans and issuers currently complying with the CAA is more than zero. With these final rules, the Department believes that plans and issuers will better understand and fulfill their obligations under MHPAEA; and will have greater clarity regarding differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits. Thus, the Department assumes that following these final rules, 40 percent of plans, or 8 plans, will be found to be noncompliant and will have to submit additional comparative analyses. Please see Table 2 for calculations and burden totals.

***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 a good estimate for the number of plans what will receive a final determination of noncompliance. In order to have a sense of the cost, the Department assumes five plans that will not be in compliance. Please see Table 2 for calculations and burden totals.

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.

**Table 2. Hour Burden of the Requirements under Consolidated Appropriations Act of 2021 and the MHPAEA FAQ 45**

19 *2022 MHPAEA Report to Congress*, https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf.
20 *2023 MHPAEA Comparative Analysis Report to Congress*, www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf.

| | Number of Entities | Number of Hours per Entity | Total Hour Burden | Wage Rate | Hour Equivalent of Cost Burden |
|---|---|---|---|---|---|
| | (A) | (B) | (C) | (D) | (A x B x C x D) |
| General operation managers correcting incorrect comparative analyses | 10 | 1 | 10 | $137.67 | $1,377 |
| Business operation specialists correct incorrect comparative analyses | 10 | 4 | 40 | $114.36 | $4,574 |
| General operation managers submit additional comparative analyses | 8 | 8 | 64 | $137.67 | $8,811 |
| Business operation specialists submit additional comparative analyses | 8 | 120 | 960 | $114.36 | $109,786 |
| Lawyers draft notice that the coverage is determined to be noncompliant with MHPAEA | 5 | 1 | 5 | $165.71 | $829 |
| **Total** | **23** | **-** | **1,079** | **-** | **$125,376** |

***2024 Final Rules***

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

These final rules amend existing definitions and add new definitions of key terms, including “factors,” “processes,” “strategies,” and “evidentiary standards.” They as to what conditions or disorders plans and issuers must also add more specificity as to what conditions or disorders plans and issuers must treat as MH conditions and SUDs, and clarify that the way a plan or issuer defines MH benefits and SUD benefits for purposes of MHPAEA must be consistent with generally recognized independent standards of current medical practice. These final rules also clarify the way the parity requirements apply to NQTLs, including by prohibiting discriminatory factors and evidentiary standards, amend and provide additional examples of the application of MHPAEA to NQTLs, to improve the understanding and ability of the regulated community to comply with the law. Additionally, these final rules require that plans and issuers provide meaningful benefits for covered MH conditions or SUDs in each classification in which meaningful medical/surgical benefits are provided.

Under these final rules, plans and issuers will be required to collect and evaluate relevant data in a manner reasonably designed to assess the impact of the NQTL on relevant outcomes related to access to MH/SUD benefits and medical/surgical benefits. Where the relevant data suggest that the NQTL contributes to material differences in access to MH/SUD benefits as compared to medical/surgical benefits in a classification, the plan or issuer must take reasonable action, as necessary, to address the material differences to

ensure compliance, in operation, with MHPAEA.

These final rules provide guidance for how to comply with the relevant data evaluation requirements in limited circumstances where data is temporarily unavailable for new and newly imposed NQTLs and where no data exists that can reasonably measure any relevant impact of an NQTL on access to MH/SUD benefits and medical/surgical benefits. Where relevant data is temporarily unavailable for a newly imposed NQTL, the comparative analysis must include a detailed explanation of the lack of relevant data, the basis for the plan's or issuer's conclusion that there is a lack of relevant data, and when and how the data will become available and be collected and analyzed. For an NQTL for which no data exists that can reasonably assess any relevant impact on access to mental health and substance use disorder benefits and medical/surgical benefits, the plan or issuer must provide a reasoned justification as to the basis for the conclusion that there are no data that can reasonably assess the NQTL's impact, why the nature of the NQTL prevents the plan or issuer from reasonably measuring its impact, an explanation of what data was considered and rejected, and document any additional safeguards or protocols used to ensure that the NQTL complies with MHPAEA. In the instances where there is a temporary data lag for a newly imposed NQTL or no data exists that can reasonably assess any relevant impact of an NQTL, providing this justification is likely to be less expensive than the estimated burden for doing an analysis when there is data. However, the Departments are of the view that nearly all NQTLs will have some relevant data to collect and evaluate; therefore, the Departments estimate the burden as if every plans and issuers everyone performs the data analysis.

Additionally, these final rules specify that if a plan or issuer receives a determination from the relevant Secretary that the plan or issuer is not in compliance with the rules for comparative analyses, the Secretary may direct the plan or issuer not to impose the NQTL with respect to MH/SUD benefits.

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

These final rules set forth specific content requirements for comparative analyses required by the CAA, 2021, and outline the process for plans and issuers to provide their comparative analyses to the Departments or an applicable State authority upon request.

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

***Burden Estimates for Final Requirements***

The final rules will affect self-funded plans and MEWAs. The Departments estimate that 709 self-funded plans with 500 or more participants will prepare the comparative analysis and data themselves. The Departments also estimate that 4,076 self-funded plans with 500 or more participants will receive a generic comparative analysis from their TPA or other service provider, which they will subsequently customize to suit their specific needs. Finally, the Departments estimate that 132 plan MEWAs and 21 non-plan MEWAs that are not fully-insured will provide assistance to plans in collecting and analyzing the data, and generating the comparative analyses. For more information on how the number of each type of entity is estimated, please refer to the Affected Entities, of the regulatory impact analysis.

Non-grandfathered, fully insured ERISA plans with less than 50 participants that are subject to MHPAEA under the EHB requirements of the ACA are likely to have their issuers prepare their comparative analyses. Issuers can take advantage of economies of scale by preparing the required documents for those plans purchasing coverage. HHS has jurisdiction over issuers in States that substantially fail to enforce MHPAEA's requirements and therefore is accounting for this portion of the burden in its analysis, in addition to the burden related to non-Federal governmental plans. Accordingly, this analysis considers only the burden associated with ERISA self-funded group health plans, which are under the jurisdiction of the DOL and the Treasury.

These final rules require that a plan or issuer discuss in its comparative analysis the 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 of these final rules. In the proposed rules, the Departments estimated that, on average, plans would need to analyze four separate NQTLs and issuers would need to analyze eight NQTLs to satisfy their additional comparative analysis requirements. The Departments further estimated that plans and issuers preparing their own comparative analyses would incur a burden of 20 hours per NQTL in the first year, with 4 hours for a general or operations manager to review the requirements and outline the changes needed for the comparative analyses and 16 hours for a business operations specialist to prepare the comparative analyses. Once the comparative analyses are performed and documented, the Departments estimated that plans and issuers 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 Departments estimated plans would incur a burden of 10 hours annually per NQTL to update the analyses, with 2 hours for a general or operations manager and 8 hours for a business operations specialist.

In response to commenters' concerns that the Departments underestimated the number of NQTLs that each plan or issuer would need to create comparative analyses for, and that

plans and issuers would on average have the same number NQTLs, the Departments have revised their assumptions to 10 NQTLs for both plans and issuers. One commenter proposed the average number of NQTLs should be more than 15 at a minimum, while another noted that there were at least 15 NQTLs referenced in the proposed rules and other guidance. However, given that the number of NQTLs vary by issuer and plan, that most plans will not have every NQTL identified in regulations and guidance (although some might have more), and that NQTLs can be counted as an umbrella group, the Departments assume 10 NQTLs.

The Departments assume that collecting the data, and reviewing and revising the comparative analyses would require 60 hours per NQTL in the first year and 12 hours per NQTL in subsequent years. While plans and issuers can use other professionals to fulfill their requirements, for purposes of developing the wage estimate, the Departments assume that it will take a team of data analysts, actuaries, and attorneys to collect the data and prepare the comparative analyses, and have estimated a composite wage rate of $167.48.[21] Please see Table 3 for calculations and burden totals.

**Table 3. Hour Burden to Fulfill the Data Requirements and Prepare the Comparative Analyses**

| | Number of Entities | Number of NQTLs per Entity | Number of Hours per NQTL for Data and Comparative Analysis | Total Hour Burden | Hourly Wage | Equivalent Cost of Hour Burden |
|---|---|---|---|---|---|---|
| | (A) | (B) | (C) | (A × B × C) | (D) | (A × B × C × D) |
| ***First Year*** | | | | | | |
| TPAs | 103 | 10 | 60 | 61,800 | $167.48 | $10,350,264 |
| Self-funded plans with more than 500 participants that will conduct the comparative | 709 | 10 | 60 | 425,400 | $167.48 | $71,245,992 |

21 The wage rate of an attorney, actuary, and data analyst is, respectively, $165.71, $177.11, and $159.61. (Internal DOL calculation based on 2024 labor cost data. For a description of DOL's methodology for calculating wage rates, see EBSA, *Labor Cost Inputs Used in the Employee Benefits Security Administration, Office of Policy and Research's Regulatory Impact Analyses and Paperwork Reduction Act Burden Calculations* (June 2019), https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf.) The composite wage rate is estimated in the following manner: [$165.71 × (1 ÷ 3) + $159.61 × (1 ÷ 3) × $177.61 × (1 ÷ 3) = $167.48].

| | Number of Entities | Number of NQTLs per Entity | Number of Hours per NQTL for Data and Comparative Analysis | Total Hour Burden | Hourly Wage | Equivalent Cost of Hour Burden |
|---|---|---|---|---|---|---|
| | **(A)** | **(B)** | **(C)** | **(A × B × C)** | **(D)** | **(A × B × C × D)** |
| analysis themselves | | | | | | |
| Self-funded plans with more than 500 participants that will receive generic comparative analyses from the TPA, and will then customize it | 4,076 | 10 | 30 | 1,222,800 | $167.48 | $204,794,544 |
| Plan MEWAs that are not fully insured | 132 | 10 | 60 | 79,200 | $167.48 | $13,264,416 |
| Non-Plan MEWAs that are not fully insured | 21 | 10 | 60 | 12,600 | $167.48 | $2,110,248 |
| **First-year Total** | **5,041** | **-** | **-** | **1,801,800** | **-** | **$301,765,464** |
| ***Subsequent Years*** | | | | | | |
| TPAs | 103 | 10 | 12 | 12,360 | $167.48 | $2,070,053 |
| Self-funded plans with more than 500 participants that will conduct the comparative analysis themselves | 709 | 10 | 12 | 85,080 | $167.48 | $14,249,198 |
| Self-funded plans with | 4,076 | 10 | 6 | 244,560 | $167.48 | $40,958,909 |

| | Number of Entities | Number of NQTLs per Entity | Number of Hours per NQTL for Data and Comparative Analysis | Total Hour Burden | Hourly Wage | Equivalent Cost of Hour Burden |
|---|---|---|---|---|---|---|
| | **(A)** | **(B)** | **(C)** | **(A × B × C)** | **(D)** | **(A × B × C × D)** |
| more than 500 participants that will receive generic comparative analyses from the TPA, and will then customize it | | | | | | |
| Plan MEWAs that are not fully insured | 132 | 10 | 12 | 15,840 | $167.48 | $2,652,883 |
| Non-Plan MEWAs that are not fully insured | 21 | 10 | 12 | 2,520 | $167.48 | $422,050 |
| **Subsequent Years Total** | **5,041** | **-** | **-** | **360,360** | **-** | **$60,353,093** |
| **Total (Three-year average)** | **5,041** | **-** | **-** | **840,840** | **-** | **$140,823,883** |

These final rules also require that group health plans offering group health insurance coverage must make a comparative analysis available upon request by DOL. The CAA, 2021 requires the Departments to collect no fewer 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 determines appropriate. Based on its prior experience and current funding, DOL expects to request 20 comparative analyses each year. To provide the Department with their comparative analyses and associated documentation, DOL 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. Please see Table 4 for calculations and burden totals.

These final rules also require plans and issuers to make the comparative analyses and other applicable information required by the CAA, 2021 available upon request to ERISA and to participants, beneficiaries, and enrollees in all non-grandfathered group health plans and non-grandfathered group or individual health insurance coverage (including a provider or other person acting as a participant's, beneficiary's, or enrollee's authorized representative) in connection with an adverse benefit determination, as well as to participants and beneficiaries in plans subject to ERISA. The Departments estimate that each plan will receive one request per covered health plan annually and that plans will annually incur a burden of 5 minutes for a clerical worker to prepare and send the comparative analyses to each requesting participant or beneficiary. Please see Table 4 for calculations and burden totals.

***Recordkeeping Requirement***

The Departments posit that plans and issuers already maintain records as part of their regular business practices. Further, ERISA section 107 includes a general 6-year retention requirement. For these reasons, the Departments estimate a minimal additional burden. The Departments estimate that, on average, any additional recordkeeping requirements will take clerical personnel 5 minutes annually. Please see Table 4 for calculations and burden totals.

**Table 4. Hour Burden of Other Requirements**

| | Number of Responses | Number of Hours per Response | Total Hour Burden | Wage Rate | Hour Equivalent of Cost Burden |
|---|---|---|---|---|---|
| | **(A)** | **(B)** | **(A × B)** | **(C)** | **(A × B × C)** |
| Business operations specialists prepare comparative analysis for audits | 20 | 1 | 20 | $137.67 | $2,753 |
| General operation managers prepare comparative analysis for audits | 20 | 4 | 80 | $114.36 | $9,149 |
| Clerical workers prepare comparative analyses upon participant request | 2,129,516 | 0.083 | 177,460 | $65.99 | $11,710,585 |
| Clerical workers maintain recordkeeping | 2,129,516 | 0.083 | 177,460 | $65.99 | $11,710,585 |
| **Total** | **2,129,536** | **-** | **355,020** | **-** | **$23,433,073** |

***Overall Summary***

Because the Department of Labor and the Department of the Treasury 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. Please see Table 5 for burden totals.

**Table 5. Total Hour Burden**

| | **Total for All Agencies** | **DOL Total** |
|---|---|---|
| | **(A)** | **(B)** |
| Total Hour Burden (First Year) | 2,376,862 | 1,188,431 |
| Total Equivalent Cost of Hour Burden (First Year) | $344,437,316 | $172,218,658 |
| Total Hour Burden (Subsequent Years) | 1,175,662 | 467,711 |
| Total Equivalent Cost of Hour Burden (Subsequent Years) | $143,260,339 | $51,512,472 |
| **Total Hour Burden (Three-Year Average)** | **1,415,902** | **707,951** |
| **Total Equivalent Cost of Hour Burden (Three-Year Average)** | **$183,495,735** | **$91,747,867** |

**Table 6. Estimated Annualized Respondent Cost and Hour Burden**

| **Activity** | **Number of Respondents** | **Number of Responses per Respondent** | **Total Responses** | **Average Burden (Hours)** | **Total Burden (Hours)** | **Hourly Wage Rate** | **Equivalent Cost of Hour Burden** |
|---|---|---|---|---|---|---|---|
| **Notices under the Mental Health Parity and Addiction Equity Act of 2008** | | | | | | | |
| Medical secretaries prepare Medical Necessity Criteria Disclosures | 2,129,516 | 1 | 2,129,516 | 0.08 | 177,460 | $57.10 | $10,132,946 |
| Medical providers review and complete | 498,015 | 1 | 498,015 | 0.08 | 41,501 | $216.39 | $8,980,455 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Model Disclosure Request Forms | | | | | | | |
| **Requirements under the Consolidated Appropriations Act of 2021 and the MHPAEA FAQ 45** | | | | | | | |
| Managers provide correction incorrect for comparative analyses | 10 | 1 | 10 | 1 | 10 | $137.67 | $1,377 |
| Business Operation Specialists provide correction for incorrect comparative analyses | 10 | 1 | 10 | 4 | 40 | $114.36 | $4,574 |
| Managers submit additional comparative analyses that demonstrate compliance | 8 | 1 | 8 | 8 | 64 | $137.67 | $8,811 |
| Business Operation Specialists submit additional comparative analyses that demonstrate compliance | 8 | 1 | 8 | 120 | 960 | $114.36 | $109,786 |
| Lawyers draft notice that the coverage is determined to be noncompliant with MHPAEA | 5 | 1 | 5 | 1 | 5 | $165.71 | $829 |
| **2024 Final Rules** | | | | | | | |
| TPAs (first year) | 103 | 1 | 103 | 60 | 61,800 | $167.48 | $10,350,264 |
| Self-funded plans with more than 500 participants that will conduct the comparative analysis themselves (first year) | 709 | 1 | 709 | 60 | 425,400 | $167.48 | $71,245,992 |
| Self-funded plans with more than | 4,076 | 1 | 4,076 | 60 | 2,445,600 | $167.48 | $409,589,088 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 500 participants that will initially receive generic comparative analyses from the TPA, and will then customize it (first year) | | | | | | | |
| Plan MEWAs that are not fully insured (first year) | 132 | 1 | 132 | 60 | 79,200 | $167.48 | $13,264,416 |
| Non-Plan MEWAs that are not fully insured (first year) | 21 | 1 | 21 | 60 | 12,600 | $167.48 | $2,110,248 |
| TPAs (subsequent years) | 103 | 1 | 103 | 12 | 12,360 | $167.48 | $2,070,053 |
| Self-funded plans with more than 500 participants that will conduct the comparative analysis themselves (subsequent years) | 709 | 1 | 709 | 12 | 85,080 | $167.48 | $14,249,198 |
| Self-funded plans with more than 500 participants that will initially receive generic comparative analyses from the TPA, and will then customize it (subsequent years) | 4,076 | 1 | 4,076 | 12 | 244,560 | $167.48 | $40,958,909 |
| Plan MEWAs that are not fully insured (subsequent years) | 132 | 1 | 132 | 12 | 15,840 | $167.48 | $2,652,883 |
| Non-Plan MEWAs that are not fully insured (subsequent years) | 21 | 1 | 21 | 12 | 2,520 | $167.48 | $422,050 |
| Business | 20 | 1 | 20 | 1 | 20 | $137.67 | $2,753 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| operations specialists prepare comparative analysis for audits | | | | | | | |
| General operation managers prepare comparative analysis for audits | 20 | 1 | 20 | 4 | 80 | $114.36 | $9,149 |
| Clerical workers prepare and distribute comparative analyses upon participant request | 2,129,516 | 1 | 2,129,516 | 0.083 | 177,460 | $65.99 | $11,710,585 |
| Clerical workers maintain recordkeeping | 2,129,516 | 1 | 2,129,516 | 0.083 | 177,460 | $65.99 | $11,710,585 |
| **Total (3-year average)*** | **2,873,882** | **1** | **2,873,882** | | **1,415,902** | | **$183,495,735** |
| **DOL Total (3-year average)*** | **1,436,941** | **1** | **1,436,941** | | **707,951** | | **$91,747,867** |

Note:
*The total estimates reflect the three-year average burden.
**The total number of responses and respondents is calculated in the following manner: 498,016 (Model Disclosure Request Form) + 2,129,516 (Medical Necessity Notices) + 246,350 (CAA, 2021) = 2,873,882.
*** Because the Department of Labor and the Department of the Treasury 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.

**13. Provide an estimate of the total annual cost burden to respondents or record-keepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12.)**

- **The cost estimate should be split into two components: (a) a total capital and start up cost component (annualized over its expected useful life); and (b) a total operation and maintenance and purchase of service component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring,**

**sampling, drilling and testing equipment; and record storage facilities.**

- **If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collection services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.**
- **Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.**

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

The Department calculated the cost to deliver the requested medical necessity criteria disclosures. Many insurers and plans already may have the information prepared in electronic form, and the Department assumes that 58.3 percent of requests will be delivered electronically, resulting in a de minimis cost.[22] The Department assumes that each medical necessity criteria is approximately four pages, and an average document size of four pages. The Department estimates that the cost of postage is $0.73 and the material costs per page is $0.05, resulting in a mailing cost of $0.93.[23] Please see Table 7 for calculations and burden totals.

***Requirements under the Consolidated Appropriations Act, 2021***

Plans and issuers are likely to store Comparative Analyses in electronic form and, likewise, to deliver Comparative Analyses and documentation electronically to requesting parties and the Departments. Accordingly, the Department estimates that these requirements have a de minimis cost burden.

22 According to data from NTIA, 37.4 percent of individuals aged 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 31.4 percent receiving electronic disclosure at work). Additionally, the NTIA reports that 44.1 percent of individuals aged 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 26.9 percent receiving electronic disclosure outside of work). Combining the 31.4 percent who will receive electronic disclosure at work with the 26.9 percent who will receive electronic disclosure outside of work produces a total of 58.3 percent who will receive electronic disclosure overall.

23 The mailing cost is calculated in the following manner: $0.73 + ($0.05 × 4 pages) = $0.93.

***2024 Final Rules***

These final rules also require plans and issuers to make the comparative analyses and other applicable information required by the CAA, 2021 available upon request to participants, beneficiaries, and enrollees in all non-grandfathered group health plans and non-grandfathered group or individual health insurance coverage (including a provider or other person acting as a participant's, beneficiary's, or enrollee's authorized representative) in connection with an adverse benefit determination, as well as to participants and beneficiaries in plans subject to ERISA. The Departments estimate that each plan will receive one request per covered health plan annually. The Department also assumes that 58.3 percent of requests will be delivered electronically, resulting in a de minimis cost. The remaining 41.7 percent of requests will be mailed, at a cost of $2.79.[24] Please see Table 7 for calculations and burden totals.

***Overall Summary of Cost Burden***

Because the Department of Labor and the Department of the Treasury 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. Please see Table 7 for burden totals.

**Table 7. Total Cost Burden**

| | **Number of Responses** | **Mailing Cost per Response** | **Cost Burden** |
|---|---|---|---|
| | **(A)** | **(B)** | **(A x B x 41.7 percent)** |
| Clerical worker distributes Medical Necessity Criteria disclosures | 2,129,516 | $0.93 | 825,848 |
| Clerical workers distribute comparative analyses upon participant request | 2,129,516 | $2.79 | $2,477,543 |
| **Total** | **2,129,516** | **-** | **$3,303,390** |
| **DOL Total** | **1,064,758** | **-** | **$1,651,695** |

24 The postage for a first-class mail large envelope letter is $2.04 and the material cost is $0.05 per page. Thus, $2.04 + ($0.05 × 15 pages) = $2.79.

**14. Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies also may aggregate cost estimates from Items 12, 13, and 14 in a single table.**

The statute requires the Department to request and review comparative analyses for plans that involve a potential NQTL violation or complaint and any other instances in which the Secretary deems appropriate. The statutory floor for the number of such analyses is 20 per year, and the Department anticipates the number to be 20 based on prior experience and current funding levels. It is estimated that the DOL will require 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 per year). These costs include 648 FTEs (average 162 FTEs/year) and $9,260,000 in additional expenses (average of $2,315,000/year), which include contracts with subject matter experts and costs to amend EBSA electronic case 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.

**15. Explain the reasons for any program changes or adjustments.**

These final rules amend the regulations implementing MHPAEA and add new regulations implementing the NQTL comparative analyses requirements under MHPAEA, as amended by the Consolidated Appropriations Act, 2021 (CAA, 2021). Specifically, these final rules amend the existing NQTL standard to prohibit plans and issuers from using NQTLs to place greater restrictions on access to mental health and substance use disorder benefits as compared to medical/surgical benefits.

In addition, the data inputs, mailing costs, and wage rates have been updated. As a result, the number of responses has decreased by 23,521, the hour burden has decreased by 2,419,726 hours, and the cost burden has increased by $1,223,236.

**16. For collections of information whose results will be published, outline plans for tabulation, and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.**

The CAA, 2021, required the Departments to annually submit to Congress and make publicly available a report. This information collection is used in preparing that 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.

**17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.**

This information collection will display the expiration date for OMB approval.

**18. Explain each exception to the certification statement identified in Item 19.**

There are no exceptions to the certification statement identified in Item 19.

## B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

There are no statistical methods used in this information collection.