

**SUPPORTING STATEMENT FOR PAPERWORK REDUCTION ACT 1995
SUBMISSIONS FOR COBRA CONTINUATION COVERAGE:
PREMIUM ASSISTANCE**

This ICR seeks approval for an emergency clearance 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 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 that have between two and 50 employees. The changes made by MHPAEA are generally effective for plan years beginning after October 3, 2009.

Additionally, the Department of Health and Human Services (HHS) final regulation regarding essential health benefits (EHB) 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.¹ This information collection has been revised to include these added burdens.

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.

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

Medical Necessity Disclosure under MHPAEA

MHPAEA and section 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 these final regulations (29 CFR 2590.712(d)(2)) also 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 from and manner consistent with the Department's ERISA claims procedure regulation (29 CFR 2560.503-1). This 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 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 of Labor (DOL), Health and Human Services (HHS), and the Treasury (collectively, 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

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

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 non-quantitative 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 Appropriations Act 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 benefits classification;
2. The factors used to determine that the NQTLs will apply to MH/SUD benefits and medical or surgical benefits;
3. The evidentiary standards used for the factors identified, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTLs to MH/SUD benefits and medical or surgical benefits;
4. The comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to MH/SUD benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical/surgical benefits in the benefits classification; and
5. The specific findings and conclusions reached by the plan or issuer, including any results of the analyses that indicate that the plan or coverage is or is not in compliance with this section.⁵

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).

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).

The Appropriations Act 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.

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 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/SUD conditions. 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 mental health care for their patients.

Claims Denial Disclosure

MHPAEA and the final regulations require plans and issuers, upon request, 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 Appropriations Act, 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 Appropriations Act, it must contain a detailed, written, and reasoned explanation of the specific plan terms and practices at issue, and include the bases for the plan's or issuer's conclusion that the NQTLs comply with MHPAEA. At a minimum, sufficient analyses must include a robust discussion of all of the following elements:

1. A clear description of the specific NQTL, plan terms, and policies at issue.
2. Identification of the specific MH/SUD and medical/surgical benefits to which the NQTL applies within each benefit classification, and a clear statement as to which benefits identified are treated as MH/SUD and which are treated as medical/surgical.
3. Identification of any factors, evidentiary standards or sources, 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.

Additionally, not later than one year after enactment of the Appropriations Act and annually by October 1 thereafter, the Departments must submit to Congress and make publicly available a report 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
- 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 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. 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. 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. 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 Essential Health Benefits Regulation requires non-grandfathered plans in the small group market (generally plans 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 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. 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.

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 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.**

None.

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

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

None.

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

Not applicable

- 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.**

Not applicable.

- 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.**

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)) contain two 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. Therefore, the final regulations (29 CFR 2590.712(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 (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. The Department estimates that 516,324 ERISA-covered health plans are affected by this rule.⁶ The Department estimates that approximately 93 percent of large plans, which comprise seven percent of total affected plans, will create and distribute the medical necessity disclosures using in-house resources. The remaining large plans and all small plans, will use service providers to create and distribute the disclosures. For PRA purposes, plans using service providers will report the burden as a cost burden (discussed below in Item 13), while plans administering claims in-house will report the burden as an hour burden.

The Department assumes that it will take a medically trained clerical staff member five minutes to respond to each request at a labor cost of \$45.39 per hour.⁷ This results in an annual hour burden of 13,781 hours and an associated equivalent cost of \$625,527 for the 165,374 requests done in-house by plans. The remaining 1,924,757 medical necessity criteria disclosures will be provided through service providers resulting in a cost burden reported in Item 13, below.

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, DOL assumes that 25 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. DOL 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 \$171.07 per hour.⁸

⁶ Grandfathered plans with less than 50 participants are not required to comply with the medical necessity requirement. The Medical Expenditure Survey releases data by number of participants; however, the survey's cross-section does not align with the cross section of affected entities. The Department's estimate considers two-thirds of plans with between 25 and 99 participants, in addition to all plans with 100 or more participants.

⁷ DOL estimates of labor costs by occupation reflect estimates of total compensation and overhead costs. Estimates for total compensation are based on mean hourly wages by occupation from the 2019 Occupational Employment Statistics and estimates of wages and salaries as a percentage of total compensation by occupation from the 2020 National Compensation Survey's Employee Cost for Employee Compensation. Estimates for overhead costs for services are imputed from the 2017 Service Annual Survey. To estimate overhead cost on an occupational basis, OPR allocates total industry overhead cost to unique occupations using a matrix of detailed occupational employment for each NAICS industry. All values are in 2019 dollars.

⁸ DOL estimates of labor costs by occupation reflect estimates of total compensation and overhead costs. Estimates for total compensation are based on mean hourly wages by occupation from the 2019 Occupational Employment Statistics and estimates of wages and salaries as a percentage of total compensation by occupation from the 2020 National Compensation Survey's Employee Cost for Employee Compensation. Estimates for overhead costs for services are imputed from the 2017 Service Annual Survey. To estimate overhead cost on an occupational basis, OPR allocates total industry overhead cost to unique occupations using a matrix of detailed occupational employment for each NAICS industry. All values are in 2019 dollars.

The total burden will be 41,501 hours, with an equivalent cost of approximately \$7,099,619.

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.

Summary of Disclosures

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 27,641 hours with an associated equivalent cost of \$3,862,573. 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.

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

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 516,324 ERISA-covered health plans are affected by this rule.⁹ 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 insurance 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 self-insured group health plans, which are under jurisdiction of the

⁹ This estimate reflects the number of ERISA plans in the group market with 50 or more participants, based on data from the 2019 Medical Expenditure Survey-Insurance Component. The Medical Expenditure Survey releases data by number of participants; however, the survey's cross-section does not align with the cross section of affected entities. The Department's estimate considers two-thirds of plans with between 25 and 99 participants, in addition to all plans with 100 or more participants.

Department. The Department estimates that there are 113,123 self-insured group health plans subject to ERISA.¹⁰

Prior to the passage of the Consolidated Appropriations Act, the MHPAEA Self-Compliance Tool recommends that plans and issuers analyze NQTLs and document those analyses as a best practice. The Consolidated Appropriations Act makes it a requirement for plans and issuers to conduct and document comparative analyses of the design and application of NQTLs, rather than a best practice. Additionally, plans and issuers are required to make available documents that support the analysis and conclusions of their NQTL comparative analyses, including any documents and other information relevant to the factors used to determine the application of an NQTL and the evidentiary standards used to define the factors identified. The Department assumes that most plans and issuers already comply with best practices. To meet the additional requirements of the Consolidated Appropriations Act, the Department estimates it will take a total of 40 hours in the first year, four hours of a general or operations manager and 36 of a business operations specialist. Once the comparative analysis is written, plans would need to update the analysis when making changes to the terms of the plan or coverage. Thus, in subsequent years, it will take an average of 20 hours per plan to make any updates, 16 hours of a business operations specialist and four hours of a general or operations manager. The Department estimates that a general or operations manager will have an hourly labor cost of \$120.73 and a business operations specialist will have an hourly labor cost of \$98.20.¹¹ This results in a total hour burden of 4,524,936 hours with an equivalent cost burden of \$454,543,421 in the first year and total hour burden of 2,262,468 hours with an equivalent cost burden of \$232,369,051 in the subsequent years.

The CAA requires the Department 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. Thus, the Department expects to request 50 each year. To provide the Department with their comparative analyses and associated documentation, the Department assumes that plans and issuers will incur a de minimis cost as the

¹⁰ Based on data from the 2019 Medical Expenditure Survey Insurance Component, the Department estimates the number of self-insured plans by multiplying the number of establishments with plans by the percent of establishments that self-insure at least one plan, then dividing that value by the number of establishments per firm. These requirements only apply ERISA self-insured plans in the group market with 50 or more participants. The Medical Expenditure Survey releases data by number of participants; however, the survey's cross-section does not align with the cross section of affected entities. The Department's estimate considers two-thirds of plans with between 25 and 99 participants, in addition to all plans with 100 or more participants.

¹¹ DOL estimates of labor costs by occupation reflect estimates of total compensation and overhead costs. Estimates for total compensation are based on mean hourly wages by occupation from the 2019 Occupational Employment Statistics and estimates of wages and salaries as a percentage of total compensation by occupation from the 2020 National Compensation Survey's Employee Cost for Employee Compensation. Estimates for overhead costs for services are imputed from the 2017 Service Annual Survey. To estimate overhead cost on an occupational basis, OPR allocates total industry overhead cost to unique occupations using a matrix of detailed occupational employment for each NAICS industry. All values are in 2019 dollars.

comparative analysis can be provided electronically, or as part of an investigation. 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 25 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 \$120.73 and a business operations specialist will have an hourly labor cost of \$98.20.¹² This results in a total hour burden of 125 hours with an equivalent cost burden of \$12,838.

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 requires the plan or issuer to specify to the Department the actions the plan or issuer will take to come into compliance. 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 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 \$120.73 and a business operations specialist will have an hourly labor cost of \$98.20. This results in a total hour burden of 2,560 hours with an equivalent cost burden of \$254,997.

The CAA 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 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 \$1,380 (10*\$138.05).¹³

¹² DOL estimates of labor costs by occupation reflect estimates of total compensation and overhead costs. Estimates for total compensation are based on mean hourly wages by occupation from the 2019 Occupational Employment Statistics and estimates of wages and salaries as a percentage of total compensation by occupation from the 2020 National Compensation Survey's Employee Cost for Employee Compensation. Estimates for overhead costs for services are imputed from the 2017 Service Annual Survey. To estimate overhead cost on an occupational basis, OPR allocates total industry overhead cost to unique occupations using a matrix of detailed occupational employment for each NAICS industry. All values are in 2019 dollars.

¹³ DOL estimates of labor costs by occupation reflect estimates of total compensation and overhead costs. Estimates for total compensation are based on mean hourly wages by occupation from the 2019 Occupational Employment Statistics and estimates of wages and salaries as a percentage of total compensation by occupation from the 2020 National Compensation Survey's Employee Cost for Employee Compensation. Estimates for overhead costs for services are imputed from the 2017 Service Annual Survey. To estimate overhead cost on an occupational basis,

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 use 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.

In the first year, the total hour burden for this requirement is 4,527,631 hours and an equivalent cost of \$454,812,637. In subsequent years, the total hour burden is 2,265,163 hours and equivalent cost of \$232,638,267. Thus, the three-year average hour burden is 3,019,319 hours and equivalent cost of \$306,696,390.

Summary

In summary, the total hour burden in the first year associated with this information collection is 4,555,272 hours and an equivalent cost of \$458,675,210. In subsequent years, the total hour burden is 2,292,804 hours and equivalent cost of \$236,500,840. Thus, the three-year average hour burden is 3,046,961 hours and equivalent cost of \$310,558,963.

Estimated Annualized Respondent Cost and Hour Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Responses	Average Burden (Hours)	Total Burden (Hours)	Hourly Wage Rate	Total Burden Cost
Notices under the Mental Health Parity and Addiction Equity Act of 2008							
Medically Trained Clerical Staff Member responds to each request	1,051,289	0.07865297	82,687	0.08333	6,891	\$45.39	\$312,764
Providers review and complete Model Disclosure Request Form	249,008	1	249,008	0.08333	20,751	\$171.07	\$3,549,809
Requirements under the Consolidated Appropriations Act of 2021 and the MHPAEA FAQ 45							
ERISA Plans-Managers document comparative analyses and recordkeeping (first year)	113,123	1	113,123	4	452,494	\$120.73	\$54,629,555
ERISA Plans-Business Operation Specialists document comparative analysis and recordkeeping (first year)	113,123	1	113,123	36	4,072,443	\$98.20	\$399,913,866
ERISA Plans-Managers document comparative analyses and recordkeeping (subsequent years)	113,123	1	113,123	4	452,494	\$120.73	\$54,629,555
ERISA Plans-Business Operation Specialists document comparative analysis and recordkeeping (subsequent years)	113,123	1	113,123	16	1,809,975	\$98.20	\$177,739,469
Managers provide	25	1	25	1	25	\$120.73	\$3,018

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correction incorrect for comparative analyses							
Business Operation Specialists provide correction for incorrect comparative analyses	25	1	25	4	100	\$98.20	\$9,820
Managers submit additional comparative analyses that demonstrate compliance	20	1	20	8	160	\$120.73	\$19,317
Business Operation Specialists submit additional comparative analyses that demonstrate compliance	20	1	20	120	2,400	\$98.20	\$235,680
Lawyers draft notice that the coverage is determined to be noncompliant with MHPAEA	10	1	10	1	10	\$138.05	\$1,380
Total (3-year average)*	1,413,420	1	1,413,420	2.155735644	3,046,961	-	\$310,558,963

Note:

*The total estimates reflect the three-year average burden.

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

As reported above in Item 12, plans using service providers will report the costs associated with the medical necessity disclosure as a cost burden. The Department estimates that most claims are processed using a service provider with 1,937,205 medical necessity criteria disclosures being provided through service providers.¹⁴ The Department assumes that it will take a medically trained clerical staff member five minutes to respond to each of the 1,937,205 requests at a labor rate of \$45.39 per hour.¹⁵ This results in a cost burden of \$7,327,477.

The Department also 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.¹⁶ The Departments estimate that the cost burden associated with

1412,448 large plans+ 338,503 plans with between 50 to 100 participants + 1,586,254 non-Grandfathered plans with less than 50 participants.

¹⁵ DOL estimates of labor costs by occupation reflect estimates of total compensation and overhead costs. Estimates for total compensation are based on mean hourly wages by occupation from the 2019 Occupational Employment Statistics and estimates of wages and salaries as a percentage of total compensation by occupation from the 2020 National Compensation Survey's Employee Cost for Employee Compensation. Estimates for overhead costs for services are imputed from the 2017 Service Annual Survey. To estimate overhead cost on an occupational basis, OPR allocates total industry overhead cost to unique occupations using a matrix of detailed occupational employment for each NAICS industry. All values are in 2019 dollars.

¹⁶ 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

distributing the 878,878¹⁷ medical necessity criteria disclosures sent by paper will be \$659,158. This estimate is based on an average document size of four pages, five cents per page material and printing costs, and 55 cents postage costs.

Based on the foregoing, the preparation and delivery of the medical necessity disclosures is estimated to have a total cost burden of \$7,986,635.¹⁸ 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. Therefore, the portion of the cost burden allocated to the Department of Labor is \$3,993,317.

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

Insurers and plans are likely to store Comparative Analyses in electronic form and, likewise, to deliver Comparative Analyses and documentation electronically to requesting parties. Accordingly, the Department estimates that this requirement has a de minimis cost burden.

The CAA 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 costs to deliver the notices would vary by plan size. The Department does not have an estimate for the number of plans that will still be out of compliance; to account for the burden the Department uses the number of 10 plans that will need to send the notices. If all notices were sent by mail for 10 plans, with the average number of participant in self-insured plans, the cost to distribute the notice would be \$1,200 (10*200*\$0.60).

Summary

In summary, the total cost burden associated with this information collection is \$3,994,517.

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.

¹⁷ (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]

¹⁸ The number is calculated as the sum of the mailing costs and the cost of the labor hours that are outsourced.

- 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 in instances where there is 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, but the Department anticipates the number to be much higher (more than 50) based on the potential violations and complaints alone. It is estimated that the DOL will require a total of \$104,531,172 spread across four years for an average annual cost of \$26,132,793 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.**

The increase in hour burden that is associated with the ICRs is related to the comparative analysis that is required to meet the MHPAEA-related requirements in The Consolidated Appropriations Act of 2021.

- 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.**

There are no plans to publish the results of this collection of information.

- 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.**

N/A

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

None.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable.