

SUPPORTING STATEMENT FOR PAPERWORK REDUCTION ACT OF 1995
SUBMISSIONS

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 who have between two and 50 employees. The changes made by MHPAEA are generally effective for plan years beginning after October 3, 2009.

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

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

EHB.¹ This information collection has been revised to include these added burdens.

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

Medical Necessity Disclosure under MHPAEA

MHPAEA and section 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 2510.712(d)(2)) also provide that the reason for any denial under a group health plan (or health insurance coverage) of reimbursement or payment for services with respect to MH/SUD benefits in the case of any participant or beneficiary must be made available upon request or as otherwise required by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary. The Department of Labor's ERISA claims procedure regulation (29 CFR 2560.503-1) requires, among other things, plans to provide a claimant who is denied a claim with a written or electronic notice that contains the specific reasons for denial, a reference to the relevant plan provisions on which the denial is based, a description of any additional information necessary to perfect the claim, and a description of steps to be taken if the participant or beneficiary wishes to appeal the denial. The regulation also requires that any adverse decision upon review be in writing (including electronic means) and include specific reasons for the decision, as well as references to relevant plan provisions. Therefore, the final regulations provide that ERISA-covered plans (and health insurance coverage offered in connection with such plans) will be deemed to satisfy the MHPAEA claims denial disclosure requirement if they comply with the ERISA claims procedure regulation.

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

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

Among its provisions, the Cures Act requires 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 public outreach process, the Departments are soliciting comments on a draft model form that participants, enrollees, or their authorized representatives could use to request information from their health plan or issuer regarding NQTLs that may affect their MH/SUD benefits, or to obtain documentation after an adverse benefit determination involving MH/SUD benefits to support an appeal.

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

Claims Denial Disclosure

² Cures Act section 13001(c)(1).

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

Upon request, 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 draft 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.

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 affect plans with less than 50 participants, the ACA Essential Health Benefits Regulation requires non-grandfathered plans with less than 50 participants to comply with MHPAEA. To help minimize burden, the final regulations provide that ERISA-covered plans (and health insurance coverage offered in connection with such plans) will be deemed to satisfy the MHPAEA claims denial disclosure requirement if they comply with the ERISA claims procedure regulation.

6. *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 mental health/substance use disorder conditions in parity to those made regarding med/surg conditions.

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 provided the public with 60-days to comment on the ICR at the interim final rule stage and in a proposed notice of extension of the ICR that was published in the Federal Register on May 26, 2016 (81 FR 33550) as required by 5 CFR 1320.8(d). No comments were received.

On October 27, 2016, the Departments issued Affordable Care Act Implementation FAQs Part 34, which, among other things, solicited feedback regarding disclosures with respect to MH/SUD benefits under MHPAEA and other laws.⁴ In the FAQs, the Departments indicated that they had received questions and suggestions regarding disclosures with respect to NQTLs. The feedback included requests from various stakeholders for model forms that group health plan participants, beneficiaries, covered individuals in the individual market, or persons acting on their behalf could use to request relevant disclosures. Stakeholders also requested guidance on other ways in which disclosures, or the process for requesting disclosures, could be more uniform, streamlined, or otherwise simplified.

As discussed above, the Departments currently are soliciting comments on a draft model form that participants, enrollees, or their authorized representatives could use to request information from their health plan or issuer regarding NQTLs that may affect their MH/SUD benefits, or to obtain documentation after an adverse benefit determination involving MH/SUD benefits to support an appeal. The Department published a notice in the Federal Register on Tuesday, June 20, 2017, providing the public until September 1, 2017 to submit written comments on the draft model notice. In response, the Department received XX comment letters, which are discussed below [update after the close of the comment period].

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.*

⁴ See Affordable Care Act Implementation FAQs, Part 34, Q&A-1, available at <https://edit.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xxix.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQ-part-34-10-26-16_FINAL.PDF.

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 and aggregate the hour burdens in Item 13.*
 - *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.*

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 upon request or as otherwise required by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary.

The Department of Labor's ERISA claims procedure regulation (29 CFR 2560.503-1) requires, among other things, provides a claimant who is denied a claim with a written or electronic notice that contains the specific reasons for denial, a reference to the relevant plan provisions on which the denial is based, a description of any additional information necessary to perfect the claim, and a description of steps to be taken if the participant or beneficiary wishes to appeal the denial. The regulation also requires that any adverse decision upon review be in writing (including electronic means) and include specific reasons for the decision, as well as references to relevant plan provisions. Therefore, the final regulations (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).

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 1,910,415 ERISA-covered health plans are affected by this rule. 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, which comprise 93 percent of total affected plans will use service providers to create and distribute the disclosures. For PRA purposes, plans using service providers will report the costs as a cost burden (discussed below in Item 13), while plans administering claims in-house will report the burden as an hour burden. Based on the assumption that each plan will receive one request, seven percent of notices will be produced in-house and 93 percent will be produced using service providers.

The Department assumes that it will take a medically trained clerical staff member five minutes to respond to each request at a wage rate of \$42.08 per hour.⁵ This results in an annual hour burden of 11,089 hours and an associated equivalent cost of \$466,619 for the 133,066 requests done in-house by plans. The remaining 1,777,349 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

⁵ For a description of the Department's methodology for calculating wage rates, see <http://www.dol.gov/sites/default/files/ebsa/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-august-2016.pdf>.

response will be 5 minutes with an equivalent cost of \$13.15 (at a labor rate of \$157.80 per hour). The total burden will be 41,501 hours, with an equivalent cost of approximately \$6,548,897.

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 the 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..

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 26,295 hours with an associated equivalent cost of \$3,507,758. These burden hours, along with the cost burden discussed in question 13, are assessed on half of the total respondents or 1,204,215 respondents, and half of the total responses or 1,204,215 responses.

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.)*

As reported above in Item 12, above, plans using service providers will report the costs associated with the medical necessity disclosure as a cost burden. The Department estimates that 93 percent of claims are done using a service provider resulting in 1,777,349 medical necessity criteria disclosures being provided through service providers.⁶ The Department assumes that it will take a medically trained clerical staff member five minutes to respond to each of the 1,777,349 requests at a labor rate of \$42.08 per hour. This results in a cost burden of \$6,232,569.

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 51.8 percent of requests will be

⁶ This number is calculated as 93% of the total number of affected plans.

delivered electronically resulting in a de minimis cost.⁷ The Departments estimate that the cost burden associated with distributing the 936,103⁸ medical necessity criteria disclosures sent by paper will be \$616,949. This estimate is based on an average document size of four pages, five cents per page material and printing costs, and 47 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 \$6,849,519.⁹ Because the Department of Labor and the Department of the Treasury share enforcement jurisdiction against 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 \$3,424,759.

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.*

Not applicable.

15. *Explain the reasons for any program changes or adjustments reporting in Items 13 or 14*

The increase in hour burden is associated with the ICRs related to the new draft model disclosure request form the Department is issuing in order to meet the MHPAEA-related requirements in the 21st Century Cures Act.

16. *For collections of information whose results will be published, outline plans for tabulation, and publication. Address any complex analytical techniques that will be*

⁷ According to data from the National Telecommunications and Information Agency (NTIA), 33.4 percent of individuals age 25 and over have access to the internet at work. According to a Greenwald & Associates survey, 84 percent of plan participants find it acceptable to make electronic delivery the default option, which is used as the proxy for the number of participants who will not opt out that are automatically enrolled (for a total of 28.1 percent receiving electronic disclosure at work). Additionally, the NTIA reports that 38.9 percent of individuals age 25 and over have access to the internet outside of work. According to a Pew Research Center survey, 61 percent of internet users use online banking, which is used as the proxy for the number of internet users who will opt in for electronic disclosure (for a total of 23.7 percent receiving electronic disclosure outside of work). Combining the 28.1 percent who receive electronic disclosure at work with the 23.7 percent who receive electronic disclosure outside of work produces a total of 51.8 percent who will receive electronic disclosure overall.

⁸ This number is calculated as 48.2% of the total number of affected plans.

⁹ The number is calculated as the sum of the mailing costs and the cost of the labor hours.

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.*

The OMB expiration date will be published in the Federal Register following OMB approval.

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

None.

B. Collections of Information Employing Statistical Methods

Not applicable.