

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

1. CIRCUMSTANCES NECESSITATING COLLECTION OF INFORMATION

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

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

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

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

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

Medical Necessity Disclosure under MHPAEA

MHPAEA and section 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

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 public outreach process, the Departments solicited comments on a draft model form that participants, enrollees, or their authorized representatives could use to request information from their health plan or issuer regarding NQTLs that may affect their MH/SUD benefits, or to obtain documentation after an adverse benefit determination involving MH/SUD benefits to support an appeal. The Departments received 19 comments and used those comments to make changes to the model form.

2. USE OF DATA

Medical Necessity Disclosure

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

Claims Denial Disclosure

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

Disclosure Request Form

Group health plan participants, beneficiaries, covered individuals in the individual market, or persons acting on their behalf, may use the model form to request information from plans regarding NQTLs that may affect patients' MH/SUD benefits or that may have resulted

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).

in their coverage being denied. The form aims to simplify the process of requesting relevant disclosures for patients and their authorized representatives.

3. USE OF IMPROVED INFORMATION TECHNOLOGY TO REDUCE BURDEN

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

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

4. EFFORTS TO IDENTIFY DUPLICATION

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

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

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

deemed to satisfy the MHPAEA claims denial disclosure requirement if they comply with the ERISA claims procedure regulation.

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

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

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

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

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

In response to the *Federal Register* notice dated June 23, 2022 (87 FR 37557), the IRS received comments from Association for Behavioral Health and Wellness (ABHW) and Groom Law Group.

The two commenters are aware that this proposed collection is a revision of a previously approved collection under MHPAEA and is associated with the Information Collection Requests (ICRs) related to the comparative analysis requirement under the Consolidated Appropriations Act, 2021 (CAA), which is a new requirement. Both commenters noted that the Internal Revenue Service (IRS) ICRs are referring to the ICRs released by the Department of Labor (DOL) and the Department of Health and Human Services (HHS) in the fall of 2021. The commenters also stated that the comments summarized below, are the same comments that were submitted to DOL and HHS.

The commenter from the Association for Behavioral Health and Wellness (ABHW), provided comments and recommendations regarding:

1. *Protecting confidential information*

The commenter thanked DOL and HHS for clarifying that the collection will not include Personally Identifiable Information (PII) or Propriety and Confidential Information (PCI). They requested that the agencies validate these parts of their ICRs. If Correct, they suggested instituting appropriate safeguards to protect against the inadvertent collection of PII or PCI.

2. *Clarify the discrepancies between DOL and HHS ICRs*

Commenter stated, When MHPAEA was first enacted in 2008, only two requirements and related disclosure obligations were identified by Congress: (1) Claims Denial Disclosure and (2) Medical Necessity Disclosure. The initial ICR for 1210-0138 promulgated in 2010 reflects this intent and established those information collections. However, these new ICRs by DOL and HHS created confusion. First and foremost, we request clarification regarding the discrepancy between the information collections. DOL modified one ICR and added one new ICR,¹ while HHS added five new ICRs.² The CAA does not appear to support such a wide variance in the total number of information collections between the two agencies. Aligning the information collections between the agencies would help clarify the scope of the anticipated information collections and establish uniformity amongst the agencies.

Second, FAQ 45 published by CMS and attached to each of the five information collections in 0938-1393 includes a disclaimer stating that its contents do not have the force or effect of law.³ However, DOL's FAQ 45 version does not include this disclaimer.⁴ This introduces ambiguity about express or implied requirements derived from the FAQs, the relation to the proposed information collection, and the cost and burden estimates associated with the collection. The commenter request that the ambiguity be clarified, and the disclaimers be aligned between the agencies. To the extent other supporting documents do not impose information collection obligations on third parties, such as the Compliance Assistance Guide, we ask that similar disclaimers be attached.

3. *Proactively promote uniformity between state and federal requirements.*

Given the significant costs and burdens associated with evaluating MHPAEA compliance, our members support efforts to establish consistency and uniformity regarding MHPAEA compliance examinations. Disparate approaches taken to date by different federal and state regulators confuse the regulatory landscape and impact the ability to effectively scale compliance initiatives. The public would be well served by establishing a uniform information collection program amongst federal regulators that, in turn, is adopted at the state level.

Since the enactment of MHPAEA, DOL, HHS, the National Association of Insurance Commissioners (NAIC), and various states have all codified different requirements, proposed different suggestions, or developed different methodologies for performing

analyses imposing significant operational costs on plans and issuers. Our hope is to collaborate with the agencies to develop a uniform MHPAEA examination process to address disparate approaches to collecting information, performing an analysis, and determining compliance. To that end, commenter strongly urged the agencies to promulgate regulations to codify the Consolidated Appropriations Act's (CAA's) requirements, provide clear rules, and promote uniformity for the examination process.

4. *Rules for MHPAEA examinations should be established using the normal notice and comment process.*

To the extent that the ICRs attempt to create procedural rules for examinations established pursuant to the CAA, we question the appropriateness of using the ICR process for that purpose. Since the CAA clearly requires a new examination process, agencies should follow the normal notice and comment process for codifying rules of procedure under the code of federal regulations.

Ultimately, issuers and plans are responsible for achieving compliance with mental health parity and proving the same by documenting the analyses that demonstrate compliance. In attempting to meet these requirements, issuers and plans continue to strive to understand expectations with respect to parity compliance, most of which are centered around nonquantitative treatment limitations (NQTLs). Accordingly, we appreciate that the CAA affords parity stakeholders an opportunity for further clarifications by requiring that the DOL, HHS, and Department of Treasury (collectively "the tri-Departments") promulgate regulations on NQTL analyses and compliance. Under such rulemaking efforts, we urge the tri-Departments to consider the following actions to comply with the CAA mandate and help issuers and plans better understand the regulators' expectations with respect to NQTLs:

- **Define a set of standard or "core" NQTLs that issuers and plans must analyze and document and provide a best-practice example analysis for each.**

It is not possible for plans and issuers to develop 5-step analyses for "all" NQTLs proactively (i.e., in advance of a specific request and available on demand) without guidance to establish which NQTLs must be analyzed and documented. The current definition of an NQTL can conceivably involve almost any aspect of plan design and operations. The final rules define "Treatment limitations" to be "limits on the scope or duration of treatment" and define NQTLs somewhat circularly to be treatment limits that "otherwise limit the scope or duration of benefits for treatment under a plan or coverage."⁵ However, no guidance has been provided to define or provide any boundaries to what can constitute a "limit on the scope or duration of treatment," and the NQTL types that regulators have focused on for enforcement have varied over time.

ABHW members appreciate the clarity and specificity of FAQ 45, Q8, in which the tri-Departments identify the four specific NQTLs they intend to focus on for the near future. In the long term, ABHW reiterates its request for regulators to define a set of

NQTLs on which issuers and plans are expected to have documented analyses prepared for submission within a very short timeframe upon request.⁶ Defining such a list will facilitate plans' responsiveness to regulator requests for information relating to the core NQTLs, particularly upon short notice, and would in no way prevent regulators from requesting documentation on other non-core NQTLs should a complaint or specific compliance concern arise.

- **Provide a clear, comprehensive example of an NQTL analysis for each NQTL on the core list.**

The CAA requirement to document the plan's compliance analysis is new. Moreover, the 5-step framework mandated by the CAA differs materially from existing guidance in the DOL Self Compliance Guide,⁸ and guidance in FAQ 45 on the documentation requirements of the CAA expands substantially on the substantive compliance considerations set forth in previous guidance. No example of a complete NQTL analysis is available that the tri-Departments would consider complying with the CAA requirements. When ABHW met with the tri-Departments, the regulators informed us that, to date, they had not seen what they would consider a model NQTL analysis. Significant ambiguity remains about the breadth and depth of details and supporting documentation required for each component of the CAA's five-step analyses. Model NQTL analyses would help clarify expectations, promote uniformity, and ultimately improve parity compliance. Accordingly, for each NQTL on the core list, we believe the tri-Departments should provide at least one complete example of a compliant analysis. This would help clarify expectations, promote uniformity, and improve parity compliance.

- **Define a standard by which NQTL analyses are evaluated and a process by which examinations are pursued.**

In FAQ 45, Q2 and Q4, the tri-Departments address the information plans and issuers must make available to regulators and the types of documents issuers and plans should be prepared to submit in support of a given NQTL analysis. In practice, however, ABHW's members have found that the back and forth with the regulators during examinations can be confusing due to the lack of a defined process for NQTL documentation requests. As such, we hope to work with regulators to outline a process to better MHPAEA compliance.

5. *The Cost burden estimate proposed in the ICRs is not Comprehensive.*

In terms of cost and burden estimates, the ICRs include many unrealistic assumptions that flow from the conclusion that plans and issuers have operationalized what the agencies call "best practices." "Best practices" appear to correlate with the DOL's suggested approach under its Compliance Assistance Guide, which, for the first time, is now attached as a supporting document to ICR 1210-0138. This document is not attached to ICR 0938-1393. This disconnect introduces yet another ambiguity.

Until the enactment of the CAA, plans and issuers were able to perform an analysis in any reasonable manner so long as it was consistent with MHPAEA's final regulation. HHS, the NAIC, and state regulators, likewise, were free to propose and, in fact, actively used varying means for performing a MHPAEA compliance analysis. As a result, many regulators, plans, and issuers will have to revamp their compliance initiatives to align with the CAA's prescriptive approach.

Both ICR estimates assume two individuals, an operations manager, and a business operations specialist can complete these analyses in less than 80 hours. In the case of HHS, it presumes this timeframe is reasonable to conduct an analysis for all products, keep records, and prepare documentation for HHS or state authorities.⁹ While DOL's analysis is more practical in that it attributes its estimate to the plan level ("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."), our members do not believe these estimates to be realistic.¹⁰ Furthermore, plans and issuers are already assuming significant costs attempting to implement CAA's requirements without the benefit of proposed or final regulations, given the CAA provided only 45 days to come into compliance.

Both commenters disagreed on the accuracy of burden estimates in the ICRs, but supported the opportunity to provide feedback and consideration of these comments. As stated by the commenter, this information collection exercise helps "assess the impact of its information collection requirements and minimize the reporting burden on the public and helps the public understand the Department's information collection requirements and provide the requested data in the desired format.

HHS, DOL and the Department of the Treasury (the Departments) are considering commenters' suggestions, as well as the potential benefits and costs of such changes, as the Departments consider what, if any, additional guidance and regulation is needed to ensure compliance with MHPAEA, including in light of the amendments of the Consolidated Appropriations Act, 2021.

Regarding the comment on the burden estimates, we expect that plans and issuers are already conducting NQTL analyses as best practice when creating benefit packages to ensure that the NQTLs are imposed in a manner that is compliant with MHPAEA. Therefore, we are only estimating the burden to comply with the additional requirements of the Appropriations Act. The burden estimated is an average burden for issuers and non-federal governmental plans to "document the analyses for all products, keep records, and prepare the documentation for submission to HHS or state authorities upon request." Based on our experience, the burden imposed by NQTL audits are likely to be lower than that imposed by market conduct examinations. Therefore, we do not agree that we have underestimated the burden.

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

RESPONDENTS

No payment or gift will be provided to any respondents.

10. ASSURANCE OF CONFIDENTIALITY OF RESPONSES

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

11. JUSTIFICATION OF SENSITIVE QUESTIONS

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

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

12. ESTIMATED BURDEN OF INFORMATION COLLECTION

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 2,102,579 ERISA-covered health plans are affected by this rule.⁴ 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 costs 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 wage rate of \$45.39 per hour. This results in an annual hour burden of 175,215 hours and an associated equivalent cost of \$7,953,004 for the 2,102,579 requests.

Model Disclosure Request Form

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

⁴ Grandfathered plans with less than 50 participants are not required to comply with the medical necessity requirement.

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.

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

Authority	Description	# of Respondents	# Responses per Respondent	Annual Responses	Hours per Response	Total Burden	Equivalent Cost
TD 9640	Technical Amendment to External Review for Multi-State Plan Program	1,413,420	1	1,413,420	.02233891	31,574	\$4,235,310
		1,413,420		1,413,420		31,574	\$4,235,310

13. ESTIMATED TOTAL ANNUAL COST BURDEN TO RESPONDENTS

The Department calculated the cost to deliver the requested medical necessity criteria disclosures (regardless of whether the disclosure is prepared in-house or by service providers). Many insurers and plans already may have the information prepared in electronic form, and the Departments assume that 58.2 percent of requests will be delivered electronically resulting in a de minimis cost.⁵ The Departments estimate that the cost burden associated with distributing the \$878,878 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.

⁵ According to data from the National Telecommunications and Information Agency (NTIA), 40.0 percent of individuals age 25 and over have access to the Internet at work. According to a Greenwald & Associates survey, 84 percent of plan participants find it acceptable to make electronic delivery the default option, which is used as the proxy for the number of participants who will not opt-out of electronic disclosure that are automatically enrolled (for a total of 33.6 percent receiving electronic disclosure at work). Additionally, the NTIA reports that 40.4 percent of individuals age 25 and over have access to the internet outside of work. According to a Pew Research Center survey, 61.0 percent of internet users use online banking, which is used as the proxy for the number of internet users who will affirmatively consent to receiving electronic disclosures (for a total of 24.7 percent receiving electronic disclosure outside of work). Combining the 33.6 percent who receive electronic disclosure at work with the 24.7 percent who receive electronic disclosure outside of work produces a total of 58.2 percent who will receive electronic disclosure overall.

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

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

14. ESTIMATED ANNUALIZED COST TO THE FEDERAL GOVERNMENT

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

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

	Requested	Program Change Due to New Statute	Program Change Due to Agency Discretion	Change Due to Adjustment in Agency Estimate	Change Due to Potential Violation of the PRA	Previously Approved
Annual Number of Responses for this IC	1413420	0	0	195545	0	1217875
Annual IC Time Burden (Hours)	31574	0	0	4368	0	27206
Annual IC Cost Burden (Dollars)	4235310	0	0	585950	0	3649360

16. PLANS FOR TABULATION, STATISTICAL ANALYSIS AND PUBLICATION

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

17. REASONS WHY DISPLAYING THE OMB EXPIRATION DATE IS INAPPROPRIATE

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

18. EXCEPTIONS TO THE CERTIFICATION STATEMENT

There are no exceptions to the certification statement.

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

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103