SUPPORTING STATEMENT
TD 9640 (Notice of Medical Necessity Criteria under the Mental Health Parity and Addiction Equity Act of 2008)
OMB # 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.

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)

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

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

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 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.

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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).

3. USE OF IMPROVED INFORMATION TECHNOLOGY TO REDUCE BURDEN

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

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

4. EFFORTS TO IDENTIFY DUPLICATON

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

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

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

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

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

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 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

4 See Affordable Care Act Implementation FAQs, Part 34, Q&A-1, available at https://www.dol.gov/ebsa/faqs/faq-aca19.html and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQ-part-34_10-26-16_FINAL.PDF.

involving MH/SUD benefits to support an appeal. The Department published a notice in the Federal Register (82 FR 117, page 28095) on 20 June, 2017, providing the public until September 1, 2017 to submit written comments on the draft model notice. In response, the Department received 19 comment letters.[5] The comment letters did not address the burden estimates. Below is a summary of the comments received.

1. Some commenters emphasized that the model form should be optional, not duplicative, not part of the appeals process, simplified and consumer friendly.

Commenters were generally unified on having the model be optional, but also voiced concern that the Department should ensure the model was not duplicative of other forms that already existed. Commenters also raised the concern that plan participants using the form could confuse the submission of the request for documents as the request for an appeal.

The Departments specifically asked if there should be one general form or different forms for specific NQTLs. While there where comments supporting both positions, more commenters urged a single form in order to provide simplicity and avoid consumer confusion. Some commenters also thought the model was too extensive, while others supported the inclusion of additional information.

Commenters also emphasized that the model needed to be simple for plan participants to understand. Some commenters urged the use of plain English, adding additional examples of NQTLs, simplifying the form, and adding definitions. One commenter expressed the view that a model disclosure could make the disclosure process more understandable for the average consumer.

Response: A single model notice continues to be provided. Clarifying edits were included in the model notice (see Appendix II). Text was added to the model notice telling the participants that they still needed to initiate the appeals process.

2. Some commenters also suggested specific edits to the model form.

Response: The model form was revised to include these edits. Appendix II includes a crosswalk of changes.

3. Some commenters suggested that if the form is submitted by an authorized representative, there should be documentation supporting the authorization.

Response: The model form was revised to address this comment.

4. Some commenters had suggestions regarding State regulators' examinations of plan documents and State compliance review.

5 Comments can be viewed at https://www.dol.gov/agencies/ebsa/laws-and-regulations/rules-and-regulations/public-comments/faq-38

Response: The Departments will take these suggestions into consideration for future work in this area.

5. Some commenters suggested additional forms and guidance on MHPAEA implementation, compliance and education.

Response: The Departments will take these suggestions into consideration for future work in this area.

In response to the Federal Register notice dated March 4, 2019 (84 FR 7417), we received comments during the comment period regarding TD 9640 (1545-2165).

IRS received a comment from Advance Health Care Policy for Mental Health and Addiction. Advance Health Care Policy for Mental Health and Addiction thinks the IRS can achieve a greater efficiency if these recommendations are considered:

• Eliminate the "general information request" from the model form because it exceeds disclosure requirements in current law. Also eliminate the checkbox list of potential bases for the claim denial on the model form. The checkbox list could create confusion among enrollees and is extraneous to the disclosure request as the plan or issuer already knows why an individual's claim was denied. Instead provide two checkbox options for each of the two specific disclosures required under MHPAEA.

• The IRS should estimate the burden on plans and issuers. The estimated burden only considers the authorized representatives who would initially complete and submit the form but does not contemplate the burden imposed on plans and issuers.

• Eliminate the request for plans or issuers to "[i]dentify the factors used in the development of the limitation" and "the evidentiary standards used to evaluate the factors" from the model form. These requests could cause confusion among enrollees.

• Instead of requiring plans to identify all medical/surgical and mental health/substance use disorder (MH/SUD) benefits to which the limitation at issue applies, limit the request to identifying categories of services used in the plan's classification approach. This will help prevent confusion and is the information an enrollee would need to assess parity.

• Add a statement to the model form that the completion and submission of the form does not represent a request to appeal a denial and the disclosure process does not substitute for filing an appeal.

• Make the language regarding the 30-day timeline for plans or issuers to respond consistent, preferably using the language in the background section of the model form which allows plans to return the form within 30 calendar days of receipt of a request.

IRS has received similar comments and recommendations are under current consideration.

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 http://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 2,327,339 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 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 $42.55 per hour.[7] This results in an annual hour burden of 12,911 hours and an associated equivalent cost of $549,371 for the 154,934 requests done in-house by plans. The remaining 1,782,801 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 with an equivalent cost of $13.55 (at a labor rate of $162.63 per hour). The total burden will be 41,501 hours, with an equivalent cost of approximately $6,749,348.

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

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

7 For a description of the Department's methodology for calculating wage rates, see https://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-july-2017.pdf

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.

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 **27,206** hours with an associated equivalent cost of $**3,649,360.** These burden hours, along with the cost burden discussed in question 13, are assessed on half of the total respondents or **1,217,875** respondents, and half of the total responses or **1,217,875** 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	1,217,875	1	1,217,875	.02233891	27,206	3,649,360

13. ESTIMATED TOTAL ANNUAL COST BURDEN TO RESPONDENTS

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 most claims are done using a service provider with 1,771,139 medical necessity criteria disclosures being provided through service providers.[8] The Department assumes that it will take a medically trained clerical staff member five minutes to respond to each of the 1,782,801 requests at a labor rate of $42.55 per hour. This results in a cost burden of $6,321,514.

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 56.4 percent of requests will be delivered electronically resulting in a de minimis cost.[9] The Departments estimate that the cost burden associated with distributing the 844,852[10] medical necessity criteria disclosures sent by

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

9 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.

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

paper will be $633,639. 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 $6,955,154.[11] 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 $3,649,360.

14. ESTIMATED ANNUALIZED COST TO THE FEDERAL GOVERNMENT

There are no annualized costs to the Federal government.

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 **27,206** hours with an associated equivalent cost of $**3,649,360.** These burden hours, along with the cost burden discussed in question 13, are assessed on half of the total respondents or **1,217,875** respondents, and half of the total responses or **1,217,875** responses.

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 is issuing 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	1217875	0	0	1103875	0	114000
Annual IC Time Burden (Hours)	27206	0	0	21218	0	5988
Annual IC Cost Burden (Dollars)	3649360	0	0	3393360	0	256000

16. PLANS FOR TABULATION, STATISTICAL ANALYSIS AND PUBLICATION

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

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