Supporting Statement – Part A
Medical Necessity and Claims Denial Disclosures under MHPAEA
(CMS-10307/OMB control number 0938-1080)

A. Background

Enacted on October 3, 2008, the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), Public Law 110-343, amended the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Service Act (PHS Act), and the Internal Revenue Code of 1986 (Code). MHPAEA expanded existing parity requirements between medical and surgical (med/surg) benefits and mental health benefits and also extended parity requirements to substance use disorder benefits. The law generally requires that group health plans and group health insurance issuers offering both med/surg and mental health or substance use disorder (MH/SUD) benefits do not apply more restrictive financial requirements (e.g., co-pays, deductibles) and/or treatment limitations (e.g., visit limits) to MH/SUD benefits than those requirements and/or limitations applied to substantially all med/surg benefits.

The Patient Protection and Affordable Care Act, Pub. L. 111-148, was enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152, was enacted on March 30, 2010. These statutes are collectively known as the "Affordable Care Act." The Affordable Care Act reorganizes, amends, and adds to the provisions of part A of title XXVII of the PHS Act relating to group health plans and health insurance issuers in the group and individual markets. The Affordable Care Act added section 715(a)(1) to ERISA and section 9815(a)(1) to the Code to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The Affordable Care Act extended MHPAEA to apply to the individual health insurance market and redesignated MHPAEA as section 2726 of the PHS Act.[1] Additionally, section 1311(j) of the Affordable Care Act applies section 2726 of the PHS Act to qualified health plans (QHPs) in the same manner and to the same extent as such section applies to health insurance issuers and groups health plans. Additionally, the Department of Health and Human Services (HHS) final regulation regarding essential health benefits (EHB) requires health insurance issuers offering non-grandfathered health insurance coverage in the individual and small group markets, through an Exchange or outside of an Exchange, to comply with the requirements of the MHPAEA regulations in order to satisfy the requirement to cover EHB.[2]

Under certain circumstances, MHPAEA requires plan administrators and health insurance issuers (plans and issuers) to provide two disclosures regarding MH/SUD benefits--one on providing

[1] MHPAEA requirements apply to both grandfathered and non-grandfathered health plans. See section 1251 of the Affordable Care Act and its implementing regulations at 26 CFR 54.9815-1251T, 29 CFR 2590.715-1251, and 45 CFR 147.140. Under section 1251 of the Affordable Care Act, grandfathered health plans are exempted only from certain Affordable Care Act requirements enacted in Subtitles A and C of Title I of the Affordable Care Act. The provisions extending MHPAEA requirements to the individual market, and requiring that qualified health plans comply with MHPAEA were not part of these sections.
[2] See 45 CFR §§147.150 and 156.115 (78 FR 12834, February 25, 2013).

criteria for medical necessity determinations and the other providing the reason for denial of claims reimbursement.

The 21st Century Cures Act (Cures Act)[3] was enacted on December 13, 2016. Among its requirements, the Cures Act contains provisions that are intended to improve compliance with MHPAEA by requiring the Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury (collectively, the Departments) to solicit feedback from the public on how to improve the process for group health plans and issuers to disclose the information required under MHPAEA and other laws.

Medical Necessity Disclosure under MHPAEA
MHPAEA section 512(b) specifically amends the PHS Act to require plans or issuers 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. The Final Rules under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 implement MHPAEA section 512(b). CMS oversees non-Federal governmental plans and health insurance issuers.

Accordingly, any plan or issuer that is subject to MHPAEA that receives a request from a current or potential plan participant, beneficiary, or contracting health care provider must provide that party with the medical necessity standard information required under MHPAEA. CMS is not directing that plans or issuers use a specific form when providing this information, or that any individual use a specific form to request this information.

Claims Denial Disclosure under MHPAEA
MHPAEA section 512(b) specifically amends the PHS Act to require plans or issuers to provide, upon request, the reason for any denial of reimbursement or payment for MH/SUD services to the participant or beneficiary. The Final Rules under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 implement MHPAEA section 512(b). CMS oversees non-Federal governmental plans and health insurance issuers.

Accordingly, any plan or issuer that is subject to MHPAEA that receives a request from a participant or beneficiary must provide that individual with the required information on the denial of the claim within a reasonable time. CMS is not directing that plans or issuers use a specific form when providing this information, or that any individual use a specific form to request this information.

However, 45 CFR 146.136(d)(2) specifies that non-federal governmental plans (or issuers offering coverage in connection with such plans) will be in compliance with the MHPAEA claims disclosure requirement if they provide the notice in a form and manner consistent with ERISA requirements found in 29 CFR 2560.503-1. The ERISA regulation requires 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

[3] Pub. L. 114-255

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. CMS is not requiring ERISA notice per se but providing a safe harbor: a claims denial disclosure that meets ERISA requirements will comply with MHPAEA claims denial requirements. Other forms of disclosure may meet the requirements of 45 CFR 146.136(d)(2) as well.

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

The Cures Act required the Departments, 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.[4] The Departments also solicited comments and finalized a model form that participants, enrollees, or their authorized representatives could use to request information from their health plan or issuer regarding nonquantitative treatment limitations (NQTLs) that may affect their MH/SUD benefits, or to obtain documentation after an adverse benefit determination involving MH/SUD benefits to support an appeal.

B. Justification

1. Need and Legal Basis

Plans and issuers are required to provide criteria for medical necessity determinations as well as the reason for denying specific claims that involve MH/SUD conditions. One of MHPAEA's central goals is to require parity in the coverage of MH/SUD and med/surg benefits by plans and issuers offering both kinds of benefits. The two disclosures require plans and issuers to provide, respectively: (a) the bases upon which decisions are made regarding whether to cover particular treatments or referrals to certain experts for particular MH/SUD conditions; and (b) the reasons why individuals have had their individual MH/SUD claims denied. These disclosures may make it much easier to determine whether plans are making such decisions regarding MH/SUD benefits on par with med/surg benefits. Furthermore, providing beneficiaries and participants with more knowledge about how plans and issuers operate may enable them to access not only more, but more efficient treatment for their MH/SUD conditions--thus reducing barriers to MH/SUD care.

Statute
Below is an excerpt of the appropriate statutory language found in MHPAEA, which also indicates the changes made to the PHS Act.

[4] Cures Act section 13001(c)(1).

Subtitle B—Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008

* * *

SEC. 512. MENTAL HEALTH PARITY.
(b) AMENDMENTS TO PUBLIC HEALTH SERVICE ACT.—Section 2705 of the Public Health Service Act (42 U.S.C. 300gg–5) is amended—

(1) in subsection (a), by adding at the end the following:

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‘‘(4) AVAILABILITY OF PLAN INFORMATION.—The criteria for medical necessity determinations made under the plan with respect to mental health or substance use disorder benefits (or the health insurance coverage offered in connection with the plan with respect to such benefits) shall be made available by the plan administrator (or the health insurance issuer offering such coverage) in accordance with regulations to any current or potential participant, beneficiary, or contracting provider upon request. The reason for any denial under the plan (or 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 shall, on request or as otherwise required, be made available by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary in accordance with regulations.

2. Information Users

Medical Necessity Disclosure
Upon request, plans and issuers must provide the information on the medical necessity standard. Receiving this information will enable potential and current participants and beneficiaries to make more educated decisions given the choices available to them through their plans and may result in better treatment of their MH/SUD conditions. MHPAEA also requires that plans and issuers provide the information on the medical necessity standard to current and potential contracting health care providers upon request. Because medical necessity criteria generally indicate appropriate treatment of certain illnesses in accordance with generally accepted standards of current medical practice, this information should enable physicians and institutions to structure available resources to provide the most efficient health care for their patients.

Claims Denial Disclosure
Upon request, plans and issuers must explain the reason that a specific claim for MH/SUD benefits is denied. Most practically, participants and beneficiaries need this information to determine whether they agree with the decision and, if not, whether to appeal. As with the

information on the medical necessity standard, the required information on the denial of the claim may also enable patients to better understand how to navigate their insurance benefits to find the best treatment available for their MH/SUD conditions. For instance, a participant may learn what diagnostic tests will or will not be covered for his or her specific condition, or how often he or she may access that test per year. A beneficiary may learn there is a more appropriate provider that could treat his or her MH/SUD condition. Section 146.136(d)(3) of the final rule clarifies that PHS Act section 2719 governing internal claims and appeals and external review as implemented by 45 CFR §147.136, covers MHPAEA claims denials and requires that, when an NQTL is the basis for a claims denial, a non-grandfathered plan or issuer must provide the processes, strategies, evidentiary standards, and other factors used in developing and applying the NQTL to med/surg benefits and MH/SUD benefits.

Disclosure Request Form
Group health plan participants, beneficiaries, covered individuals in the individual market, or persons acting on their behalf, may use this optional 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. Use of Information Technology

The regulation does not restrict plans or issuers from using electronic technology to provide either disclosure. The disclosure request form may also be submitted electronically.

4. Duplication of Efforts

MHPAEA amended ERISA and the Code in addition to the PHS Act. Accordingly, both the Department of Labor (DOL) and the Department of the Treasury (the Treasury) require plans and issuers to provide, upon request, medical necessity and claims denial disclosures as well. However, because only CMS oversees non-Federal governmental health plans and individual health insurance issuers, there will be no duplication of effort with the DOL and the Treasury.

In some circumstances, states may require substantially similar information to be provided to insured persons. However, no duplication will occur because CMS does not require use of any particular form and the same information disclosure may be used to satisfy duplicative or overlapping requirements.

5. Small Businesses

Group health plans and health insurance coverage offered by non-grandfathered small employers will incur costs to comply with the provisions of this final rule. There are an estimated 59,000 public, non-Federal employer group health plans with 50 or fewer participants sponsored by state and local governments that are required to comply with these requirements.

6. Less Frequent Collection

The information collection requirements (ICRs) arise in connection with the occurrence of individual claims for benefits and consist 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, then the Federal policy goals underlying MHPAEA would be thwarted. Access to information about reasons for denials and medical necessity criteria enables participants, beneficiaries, and health care providers to better utilize health care resources, which in turn may result in better treatment for MH/SUD conditions. At the very least, these disclosures make it easier to determine whether plans are making decisions about MH/SUD benefits in parity to those made regarding med/surg benefits as required under MHPAEA.

7. Special Circumstances

Medical Necessity Disclosure
There are no special circumstances.

Claims Denial Disclosure
45 CFR 146.136(d)(2) provides a safe harbor under which non-Federal governmental plans (and issuers offering coverage in connection with such plans) will be in compliance with this requirement if they provide the reason for claims denial in a form and manner consistent with ERISA requirements found in 29 CFR 2560.503-1. The ERISA regulation imposes special timing requirements for the handling of claims under group health plans. Depending on circumstances indicating the urgency of the need for a claims decision, group health plans may be required to notify claimants about health benefit claim determinations in fewer than 30 days.

First, for claims involving "urgent care," the regulation requires, in general, that claimants be notified of health benefit determinations "as soon as possible, but not later than 72 hours after receipt of the claim by the plan....." (29 CFR 2560.503-1(f)(2)(ii)). In cases involving urgent care where the health claim is a request to extend the time period or number of treatments of ongoing medical care, this period is 24 hours (29 CFR 2560.503- 1(f)(2)(ii)(B)).

Second, for "pre-service" claims, the regulation requires that claimants be notified of health benefit determinations "within a reasonable period of time appropriate to the medical circumstances, but not later than 15 days after receipt of the claim by the plan" (29 CFR 2560.503-1(f)(2)(iii)(A)). Pre-service claims involve plan requirements that a claimant obtain approval from the plan prior to receiving health care services or products in order to maintain eligibility for benefits.

Third, for "post-service" health benefit claims, the regulation requires notification of an adverse benefit determination "within a reasonable period of time, but not later than 30 days

after receipt of the claim." Even though 30 days is the maximum response time for these claims, a plan must provide a determination sooner if it is reasonable to do so. Disability benefit claims are subject to a similar construct, except that the maximum response time is 45 days.

Appeals of denied claims must be decided within similar, short time limits.

These timing requirements are reasonably related to important policy objectives in an area of important public concern. For example, the shortest time frame for "urgent care" claims applies only under circumstances in which delay could seriously jeopardize the life or health of the claimant or the ability of the claimant to regain maximum function, or where delay would subject the claimant to severe pain. The next shortest time frame applies under circumstances in which medical care, while not urgent, has not been provided to a claimant who needs treatment for a medical problem and where the plan itself requires pre-approval of the medical care before providing coverage. Post-service health claims and disability claims also involve important concerns relating to the sick and disabled, but under these circumstances plans may take at least 30 days to respond if it is reasonably necessary to do so.

Another reason why these time frames are important is that these notices relate to the payment of money by a plan to or on behalf of claimants to whom fiduciary responsibilities are owed. Without enforcement of reasonable deadlines, payors could be given a financial incentive to delay the payments, and this would likely be inconsistent with appropriate fiduciary standards. Finally, these time frames for health and disability claims are generally consistent with industry standards and with the requirements of other regulators such as state insurance departments.

Section 146.136(d)(3) of the final rule clarifies that PHS Act section 2719 governing internal claims and appeals and external review as implemented by 45 CFR §147.136, covers MHPAEA claims denials and requires that, when a NQTL is the basis for a claims denial, a non-grandfathered plan or issuer must provide the processes, strategies, evidentiary standards, and other factors used in developing and applying the NQTL with respect to med/surg and MH/SUD benefits. This applies to non-grandfathered non-federal governmental plans and to health insurance issuers offering non-grandfathered coverage in both the group and individual market.

8. Federal Register/Outside Consultation

A notice was published in the Federal Register on October 28, 2020 (85FR 68330), providing the public with a 60-day period to submit written comments on the ICRs. No comments were received.

9. Payments/Gifts to Respondents

No payments or gifts are associated with these ICRs.

10. Confidentiality

These disclosures require plans and issuers to provide information to participants, beneficiaries, and in the case of the medical necessity disclosure, potential participants, beneficiaries, and the contracting provider upon request. Issues of confidentiality between third parties do not fall within the scope of this information collection request.

11. Sensitive Questions

These ICRs involve no sensitive questions.

12. Burden Estimates (Hours & Wages)

The burden estimates below have been updated based on recent data on individual market issuers and labor and mailing costs. We generally used data from the Bureau of Labor Statistics[5] to derive average labor costs (including 100 percent fringe benefits) for estimating the burden associated with the ICRs.

TABLE 1: Adjusted Hourly Wages Used in Burden Estimates

Occupation Title	Occupational Code	Mean Hourly Wage ($/hr.)	Fringe Benefits and Overhead ($/hr.)	Adjusted Hourly Wage ($/hr.)
Medical Secretaries	43-6013	$18.31	$18.31	$36.62
Psychiatrist	29-1223	$105.98	$105.98	$211.96

CMS estimates that approximately 93 percent of large employer group health plans administer claims using third party providers. Furthermore, the vast majority of all smaller employers usually are fully insured such that issuers will be administering their claims. It is estimated that approximately 94.9 percent of claims (for an estimated 78,126 plans) are processed by issuers and third party providers. Therefore, a remaining 5.1 percent of claims (for an estimated 4,199 plans) are processed in-house. For group health plans that administer claims in-house and for issuers of plans in the individual market, the burden is reported as an hour burden. For plans that use issuer or third party providers, the costs are reported as capital costs in the next section.

Medical Necessity Disclosure

CMS is unable to estimate[6] with certainty the number of requests for medical necessity criteria disclosures that will be received by plan administrators. As a start, CMS has assumed that there are approximately 30.3 million participants covered by 82,324 state and local government plans that are subject to the MHPAEA disclosure requirements.

[5] May 2019 National Occupational Employment and Wage Estimates United States found at https://www.bls.gov/oes/current/oes_nat.htm.

[6] Please note that the numbers throughout are approximations and may not round precisely.

Estimating that each plan affected by the rule will receive one request means that plans will need to provide 82,324 medical necessity disclosures. (This 82,324 figure only anticipates the number of medical necessity disclosures that will be requested in and of themselves; below we calculate additional medical necessity disclosures that may be asked for in conjunction with requests for claims denial disclosures.) We assume that it will take a medically trained clerical staff member five minutes to respond to each request at a cost of $36.62 per hour. This results in an annual hour burden of 350 hours and an associated equivalent cost of $12,813 for the 4,199 requests handled by plans in-house.

In the individual market, there are an estimated 13.4 million enrollees in plans offered by 387 issuers with 1,293 issuer/state combinations offering coverage in multiple states. Assuming that, on average, each issuer will receive 1 request in each state in which it offers coverage, there will be a total of 1,293 requests in each year. The annual burden to issuers for sending the medical necessity disclosures is estimated to be 108 hours with an associated equivalent cost of approximately $3,946.

Claims Denial Disclosure
CMS estimates that for group health plans, there will be approximately 30.9 million claims for MH/SUD benefits with approximately 4.6 million denials that could result in a request for an explanation of reason for denial. CMS has no data on the percent of denials that will result in a request for an explanation, but assumed that ten percent of denials will result in a request for an explanation (463,533 requests). CMS estimates that a medically trained clerical staff member will require five minutes to respond to each request at a labor cost of $36.62 per hour. This results in an annual hour burden of nearly 1,970 hours and an associated equivalent cost of nearly $72,142 for the approximately 23,640 requests completed by plans in-house.

In the individual market, under similar assumptions, the Department estimates that there will be approximately 13.7 million claims for MH/SUD benefits with approximately 2 million denials that could result is a request for explanation of denial. Assuming that 10 percent of denials result in such a request, it is estimated that there will be about 206,168 requests for an explanation of reason for denial, which will be completed with a burden of approximately 17,181 hours and equivalent cost of approximately $629,155.

Medical Necessity Disclosures requested along with Claims Denial Disclosures
When requesting an explanation as to why their specific claims have been denied, participants may request copies of the relevant medical necessity criteria. While the Department does not know how many notices of denial will result in a request for the criteria of medical necessity determinations, the Department assumes that, for group health plans, ten percent of those 463,533 requesting an explanation of the reason for denial will also request the criteria of medical necessity. CMS estimates that a medically trained clerical staff member may require five minutes to respond to each request at a labor rate of $36.62 per hour. About 2,364 of those disclosures will be completed in-house with an hour burden of 197 hours and equivalent cost of approximately $7,214.

In the individual market, under similar assumptions, the Department estimates that there will be about 20,617 requests for medical necessity criteria, which will be completed with a burden of about 1,718 hours and equivalent cost of approximately $62,916.

Delivery Costs
To estimate delivery costs, we assume that 75 percent of the explanation of denials disclosures and 38 percent of non-denial related requests for the medical necessity criteria will be delivered electronically. Many insurers or plans may already have the information prepared in electronic format, and CMS assumes that requests will be delivered electronically resulting in a de minimis cost.

Reversing the above percentages of documents estimated to be sent electronically, we assume that 25 percent of claims denial disclosures and 62 percent of medical necessity disclosures will be delivered in a paper format. Additionally, we are anticipating that the 25 percent of the medical necessity disclosures requested by individuals who have also requested a claims denial disclosure will be sent to those participants and beneficiaries in the same manner as the claims denial disclosure--in other words, 25 percent will be sent in a paper format. CMS assumes that it will cost $0.75 to send out each disclosure. This estimate is based on an average document size of four pages, $0.05 per page material and printing costs, and $0.55 postage costs.

Cost per Response: Electronic
We noted above that it would take about five minutes for a medically trained clerical staff member to respond to each response at a labor rate of $36.62 per hour. This figure would be the same regardless of whether the notices are processed in-house or by issuers or third party providers. Therefore, the labor cost per response is $3.05.

Cost per Response: Paper
As noted above CMS assumes that it will cost $0.75 to send out each paper disclosure. We also estimated the administration cost, for both in-house and third party or issuer processing, to equal $3.05 per response. Therefore, the total is $3.80 per paper response. For group health plans processing notices in-house, the total cost of delivery of about 9,104 notices is estimated to be approximately $6,828. In the individual market, the total cost of delivering about 57,498 notices is estimated to be approximately $43,123.

Table 2 below details calculations related to notices processed in-house and Table 3 details calculations related to notices processed by issuers in the individual market.

Table 2. Hour Burden Estimates: Disclosures Processed In-House

2.a. Hour Burden Estimates: Medical Necessity Disclosures Processed In-House					
Notice Type and Method of Distribution	**Number of Notices**	**Labor Hours**	**Cost per Hour (including 100% fringe benefits rate)**	**Estimated Labor Costs**	**Paper, Printing & Postage Costs**
Medical Necessity Disclosure	4,199	350	$36.62	$12,813	
38% sent electronically	1,595	133	$36.62		
62% sent by paper at $0.75 per notice	2,603	217	$36.62		$1,952
Medical Necessity Disclosure (provided with Claims Denial Disclosure)	2,364	197	$36.62	$7,214	
75% sent electronically	1,773	148	$36.62		
25% sent by paper at $0.75 per notice	591	49	$36.62		$443
Approximate Total: In-House Medical Necessity Disclosures	6,563	547		$20,027	$2,396
2.b. Hour Burden Estimates: Claims Denial Disclosures Processed In-House					
Notice Type and Method of Distribution	**Number of Notices**	**Labor Hours**	**Cost per Hour (including 100% fringe benefits rate)**	**Estimated Labor Costs**	**Paper, Printing & Postage Costs**
Claims Denial Disclosure	23,640	1,970	$36.62	$ 72,142	
75% sent electronically	17,730	1,478	$36.62		
25% sent by paper at $0.75 per notice	5,910	493	$36.62		$4,433
2.c. Total Burden: In-House Medical Necessity and Claims Denial Disclosures					
	Number of Notices	**Labor Hours**			
Approximate Total In-House Notices	30,203				
Approximate Total Annual Burden Hours		2,517			

Table 3. Hour Burden Estimates: Disclosures Processed By Issuers In The Individual Market

3.a. Hour Burden Estimates: Medical Necessity Disclosures In The Individual Market					
Notice Type and Method of Distribution	**Number of Notices**	**Labor Hours**	**Cost per Hour (including 100% fringe benefits rate)**	**Estimated Labor Costs**	**Paper, Printing & Postage Costs**
Medical Necessity Disclosure	1,293	108	$36.62	$3,946	
38% sent electronically	491	41	$36.62		

62% sent by paper at $0.75 per notice	802	67	$36.62		$601
Medical Necessity Disclosure (provided with Claims Denial Disclosure)	20,617	1,718	$36.62	$62,916	
75% sent electronically	15,463	1,289	$36.62		
25% sent by paper at $0.69 per notice	5,154	430	$36.62		$3,866
Approximate Total: Medical Necessity Disclosures	21,910	1,826		$66,861	$4,467
3.b. Hour Burden Estimates: Claims Denial Disclosures In The Individual Market					
Notice Type and Method of Distribution	**Number of Notices**	**Labor Hours**	**Cost per Hour (including 100% fringe benefits rate)**	**Estimated Labor Costs**	**Paper, Printing & Postage Costs**
Claims Denial Disclosure	206,168	17,181	$36.62	$629,155	
75% sent electronically	154,626	12,885	$36.62		
25% sent by paper at $0.75 per notice	51,542	4,295	$36.62		$38,656
3.c. Total Burden: Medical Necessity and Claims Denial Disclosures In The Individual Market					
	Number of Notices	**Labor Hours**			
Approximate Total Notices	228,078				
Approximate Total Annual Burden Hours		19,006			

Disclosure Request Form

Group health plan participants, beneficiaries, covered individuals in the individual market, or their authorized representatives may use this form to request disclosures from plans. Use of this form to request disclosures is optional. For this analysis, CMS 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. CMS estimates that it will take a provider approximately 5 minutes (at a labor rate of $211.96 per hour) to review clinical records and complete this form. Therefore, approximately 167,425 requests will be made using the model form. The burden per response will be 5 minutes with an equivalent cost of $17.66. The total burden will be approximately 13,952 hours, with an equivalent cost of approximately $2,957,289.

Table 4. Hour Burden Estimates: Disclosure Request Form

Notice Type	Number of Notices	Total Labor Hours	Cost per Hour (including 100% fringe benefits rate)	Estimated Labor Costs
Disclosure Request Form	167,425	13,952	$211.96	$2,957,289

13. Capital Costs

For group health plans that use issuer or third party providers, the costs incurred to prepare and send disclosures are reported as capital costs in this section.

Medical Necessity Disclosures
As in section 12, CMS is unable to estimate with certainty the number of requests for medical necessity criteria disclosures that will be received by plans and issuers; but CMS has assumed that, on average, each plan affected by the rule will receive one request, meaning plans will need to provide about 82,324 medical necessity disclosures.

CMS estimates that approximately 93 percent of large employer plans administer claims using third party providers. Furthermore the vast majority of smaller employers usually are fully insured such that issuers will be administering their claims. For plans whose claims are administered by issuers or third party providers, the costs are reported as cost burden. It is estimated that approximately 94.9 percent of claims (for an estimated 78,126 plans) are processed by issuers and third party providers. For purposes of the estimate, we assume that it will take a medically trained clerical staff member five minutes to respond to each request at a labor cost of $36.62 per hour. Therefore, we estimate about 78,126 disclosures will be processed through a third-party service provider or issuer and result in a cost burden of approximately $238,413. Assuming that 62 percent of the disclosures will be sent in paper format, there will be additional cost of nearly $36,328 in materials and postage costs.

Claims Denial Disclosures
Using assumptions similar to those used for the ERISA claims procedure regulation, CMS estimates that there will be approximately 30.9 million claims for MH/SUD benefits with approximately 4.6 million denials that could result in a request for an explanation of reason for denial. CMS has no data on the percent of denials that will result in a request for an explanation, but assumed that ten percent of denials will result in a request for an explanation (463,533 requests).

For purposes of the estimate, we assume that it will take a medically trained clerical staff member five minutes to respond to each request at a labor cost of $36.62 per hour. We estimate that nearly 439,893 claims will be processed through an issuer or a third-party provider, which results in a cost burden of approximately $1,342,408. Assuming that 25

percent of the disclosures will be sent in paper format, there will be additional cost of nearly $82,480 in materials and postage costs.

Medical Necessity Disclosures requested along with Claims Denial Disclosures
We estimate that when requesting an explanation as to why their specific claims have been denied, 10 percent of participants will request copies of the relevant medical necessity criteria. Therefore, approximately 43,989 disclosures will be processed by an issuer or a third-party provider and will result in a labor cost burden of $134,241. Assuming that 25 percent of the disclosures will be sent in paper format, there will be additional cost of nearly $8,248 in materials and postage costs.

Table 5 below details calculations related to notices. (Please see section 12 above of this Supporting Statement for many assumptions made in calculations.)

Table 5. Cost Burden Estimates: Disclosures Processed By Issuers Or Third Party Providers

5.a. Medical Necessity Disclosures Processed By Issuers or Third Party Providers					
Notice Type and Method of Distribution	**Number of Notices**	**Estimated Labor Costs**	**Paper, Printing & Postage Costs**	**Total Cost (Number of Notices x $3.05)**	**Total Cost (Number of Notices x $3.80)**
Medical Necessity Disclosure	78,126	$238,414			
38% sent electronically	29,688			$90,597	
62% sent by paper at $0.69 per notice	48,438		$36,328		$184,145
Total Costs	$ 274,742				
Medical Necessity Disclosure (provided with Claims Denial Disclosure)	43,989	$134,241			
75% sent electronically	32,992			$100,681	
25% sent by paper at $0.66 per notice	10,997		$8,248		$41,808
Total Costs	$142,489				
5.b. Claims Denial Disclosures Processed By Issuers or Third Party Providers					
Notice Type and Method of Distribution	**Number of Notices**	**Estimated Labor Costs**	**Paper, Printing & Postage Costs**	**Total Cost (Number of Notices x $3.05)**	**Total Cost (Number of Notices x $3.80)**
Claims Denial Disclosure	439,893	$1,342,408			

75% sent electronically	329,920			$1,006,806	
25% sent by paper at $0.66 per notice	109,973		$82,480		$418,082
Total Costs	$1,424,888				

14. Cost to Federal Government

There are no costs to the Federal government.

15. Changes to Burden

The total burden related to medical necessity disclosures and claims denial disclosures decreased by approximately -7,851 hours (from 43,327 to 35,476 hours) because of a reduction in the estimated number of issuer/state combinations in the individual market (from 2,045 to 1,293) which reduced the number of medical necessity disclosures and related burden hours. Additionally, burden related to the optional disclosure request form decreased by approximately 1,442 hours (from 15,394 to 13,952) because of a reduction in the estimated number of issuer/state combinations in the individual market (from 184,733 to 167,425 requests).

16. Publication/Tabulation Dates

There are no plans to publish the outcome of the data collection.

17. Expiration Date

The expiration date will be displayed on each instrument (top, right-hand corner).