**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" (ACA). The ACA 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 ACA 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 ACA 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 ACA 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 rule 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 criteria for medical necessity determinations and the other on providing the reason for denial of claims reimbursement.

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[1] MHPAEA requirements apply to both grandfathered and non-grandfathered health plans. See section 1251 of the ACA 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 ACA, grandfathered health plans are exempted only from certain requirements enacted in Subtitles A and C of Title I of the ACA . 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)

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), HHS, and the Treasury (collectively, the Departments) to solicit feedback from the public on how to improve the process for plans and issuers to disclose the information required under MHPAEA and other laws.

*Medical Necessity Disclosure under MHPAEA*

Section 2726(a)(4) of the PHS Act requires 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. Final Rules at 45 CFR 146.136 implement Section 2726(a)(4) of the PHS Act. CMS oversees non-Federal governmental plans in all States, and health insurance issuers in States where CMS has direct enforcement responsibility for MHPAEA.[4]

Accordingly, any plan or issuer that is subject to MHPAEA that receives a request from a current or potential plan participant, beneficiary, or contracting 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*

Section 2726(a)(4) of the PHS Act requires 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. Final Rules at 45 CFR 146.136 implement Section 2726(a)(4) of the PHS Act. CMS oversees non-Federal governmental plans in all States, and health insurance issuers in States where CMS has direct enforcement responsibility for MHPAEA .

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
[4] Currently, CMS is responsible for enforcement of MHPAEA with regard to issuers in Texas and Wyoming.

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 group health plans and issuers are required under Federal or State law to disclose to participants, beneficiaries, contracting providers or authorized representatives to ensure compliance with existing MHPAEA requirements can be improved while continuing to ensure consumers' rights to access all information required by Federal or State law to be disclosed.[5] The Departments also solicited comments and finalized a model form that participants, enrollees, or their authorized representatives could use to request information from their 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.

The Centers for Medicare & Medicaid Services (CMS) is requesting an extension of OMB approval for the data collections included in this information collection request (ICR).

## B. Justification

1. Need for Legal Basis

Statutory Basis: Section 2726 of the PHS Act

Below is an excerpt of the appropriate statutory language found in MHPAEA (Section 2726 of the PHS Act).

> (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.

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

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 treatments for particular MH/SUD conditions related to medical necessity; 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 in parity 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 as compared to medical/surgical care.

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. 45 CFR 146.136(d)(3) clarifies that section 2719 of the PHS Act 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 in States where CMS has direct enforcement responsibility for MHPAEA, 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 78,163 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. The average cost of compliance for each non-Federal employer group health plan with 50 or fewer participants is estimated to be approximately $23.65 annually over 3 years.

6. Less Frequent Collection

The information collection requirements may 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, 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 and issuers are making decisions about MH/SUD benefits in parity with 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.

45 CFR 146.136(d)(3) clarifies that section 2719 of the PHS Act 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 will be published in the Federal Register, providing the public with a 60-day period to submit written comments on the ICR.

9. Payment/Gifts to Respondents

No payments or gifts are associated with this information collection.

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

This information collection does not involve any sensitive questions.

12. Burden Estimates (Hours & Wages)

The burden estimates below have been updated based on recent data on plans and issuers, labor costs, and mailing costs. We generally used data from the Bureau of Labor Statistics[6] to derive the median labor costs (all wage estimates have been adjusted by 100 percent to include fringe benefits) for estimating the burden associated with the information collection.

Table 12.1 Adjusted Hourly Wages Used in Burden Estimates

| Occupation Title | Occupational Code | Median Hourly Wage ($/hr.) | Fringe Benefits and Overhead ($/hr.) | Adjusted Hourly Wage ($/hr.) |
|---|---|---|---|---|
| Medical Secretaries | 43-6013 | $19.54 | $19.54 | $39.08 |
| Psychiatrist | 29-1223 | $115.00 | $115.00 | $230.00 |

*Medical Necessity Disclosure*

CMS is unable to estimate[7] with certainty the number of requests for medical necessity criteria disclosures that will be received by plan administrators and issuers. As a start, CMS has assumed that there are approximately 25.7 million participants covered by 90,887 State and local government plans that are subject to the MHPAEA disclosure requirements.

CMS assumes that each plan affected by the rule will receive one request, which means that plans will need to provide 90,887 medical necessity disclosures. (This 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 5 minutes to respond to each request at a cost of $39.08 per hour.[8] This results in an annual hour burden of 7,574 hours and an associated equivalent cost of approximately $295,989.

Table 12.2 Hour Burden Estimates: Medical Necessity Disclosures provided by Non-Federal Governmental Health Plans

| Notice Type | Estimated Number of Notices | Estimated Burden Hours per Notice | Estimated Number of Labor Hours | Costs per Hour | Estimated Labor Cost per Notice | Estimated Annual Labor Cost |
|---|---|---|---|---|---|---|
| Medical Necessity Disclosure | 90,887 | 0.083 | 7,574 | $39.08 | $3.26 | $295,988.66 |

[6] May 2023 National Occupational Employment and Wage Estimates United States found at https://www.bls.gov/oes/current/oes_nat.htm.
[7] Please note that the numbers throughout are approximations and may not round precisely.
[8] Consistent with estimates included in previous PRA packages that the public had opportunity to provide input on.

In the individual market, there are an estimated 16 million enrollees in plans offered by 385 issuers with 1,194 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 1,194 requests in each year. The annual burden to issuers for sending the medical necessity disclosures is estimated to be 100 hours with an associated equivalent cost of approximately $3,888.

Table 12.3 Hour Burden Estimates: Medical Necessity Disclosures provided by Individual Market Issuers

| Notice Type | Estimated Number of Notices | Estimated Burden Hours per Notice | Estimated Number of Labor Hours | Costs per Hour | Estimated Labor Cost per Notice | Estimated Annual Labor Cost |
|---|---|---|---|---|---|---|
| Medical Necessity Disclosure | 1,194 | 0.083 | 100 | $39.08 | $3.26 | $3,888.46 |

*Claims Denial Disclosure*

CMS estimates that for group health plans, there will be approximately 26.2 million claims for MH/SUD benefits with approximately 18 percent of denials (4.7 million) that could result in a request for an explanation of reason for denial.[9] CMS has no data on the percent of denials that will result in a request for an explanation, but assumes that 10 percent of denials will result in a request for an explanation (471,779 requests). CMS estimates that a medically trained clerical staff member will require 5 minutes to respond to each request at a labor cost of $39.08 per hour.[10] This results in an annual hour burden of nearly 39,315 hours and an associated equivalent cost of approximately $1,536,426.

Table 12.4 Hour Burden Estimates: Claims Denial Disclosure provided by Non-Federal Governmental Health Plans

| Notice Type | Estimated Number of Notices | Estimated Burden Hours per Notice | Estimated Number of Labor Hours | Costs per Hour | Estimated Labor Cost per Notice | Estimated Annual Labor Cost |
|---|---|---|---|---|---|---|
| Claims Denial Disclosure | 471,779 | 0.083 | 39,315 | $39.08 | $3.26 | $1,536,425.51 |

In the individual market, under similar assumptions, CMS estimates that there will be approximately 16.3 million claims for MH/SUD benefits with approximately 2.9 million denials that could result is a request for explanation of denial. CMS has no data on the percent of denials that will result in a request for an explanation, but assumes that 10 percent

[9] Based on the KFF Survey of Consumer Experiences with Health Insurance (2023). Available at: https://www.kff.org/affordable-care-act/issue-brief/consumer-survey-highlights-problems-with-denied-health-insurance-claims/#:~:text=Nearly%201%20in%205%20insured,27%25%20experienced%20a%20denied%20claim.

[10] Consistent with estimates included in previous PRA packages that the public had opportunity to provide input on.

of denials will result in a request for an explanation (293,760 requests). CMS estimates that a medically trained clerical staff member will require 5 minutes to respond to each request at a labor cost of $39.08 per hour.[11] This results in an annual hour burden of nearly 24,480 hours and equivalent cost of approximately $956,678.

Table 12.5 Hour Burden Estimates: Claims Denial Disclosure provided by Individual Market Issuers

| Notice Type | Estimated Number of Notices | Estimated Burden Hours per Notice | Estimated Number of Labor Hours | Costs per Hour | Estimated Labor Cost per Notice | Estimated Annual Labor Cost |
|---|---|---|---|---|---|---|
| Claims Denial Disclosure | 293,760 | 0.083 | 24,480 | $39.08 | $3.26 | $956,678.40 |

*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 CMS does not know how many notices of denial will result in a request for the criteria of medical necessity determinations, CMS assumes that, for group health plans, 10 percent of those 471,779 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 5 minutes to respond to each request at a labor rate of $39.08 per hour. About 47,178 disclosures will be provided, with an hour burden of 3,931 hours and equivalent cost of approximately $153,643.

Table 12.6 Hour Burden Estimates: Medical Necessity Disclosures Requested with Claims Denial Disclosure provided by Non-Federal Governmental Health Plans

| Notice Type | Estimated Number of Notices | Estimated Burden Hours per Notice | Estimated Number of Labor Hours | Costs per Hour | Estimated Labor Cost per Notice | Estimated Annual Labor Cost |
|---|---|---|---|---|---|---|
| Medical Necessity Disclosures Requested Along with Claims Denial Disclosure | 47,178 | 0.083 | 3,931 | $39.08 | $3.26 | $153,642.55 |

In the individual market, under similar assumptions, CMS estimates that there will be about 29,376 requests for medical necessity criteria, which will be completed with a burden of about 2,448 hours and equivalent cost of approximately $95,668.

[11] Consistent with estimates included in previous PRA packages that the public had opportunity to provide input on.

Table 12.7 Hour Burden Estimates: Medical Necessity Disclosures Requested with Claims Denial Disclosure provided by Individual Market Issuers

| Notice Type | Estimated Number of Notices | Estimated Burden Hours per Notice | Estimated Number of Labor Hours | Costs per Hour | Estimated Labor Cost per Notice | Estimated Annual Labor Cost |
|---|---|---|---|---|---|---|
| Medical Necessity Disclosures Requested Along with Claims Denial Disclosure | 29,376 | 0.083 | 2,448 | $39.08 | $3.26 | $95,667.84 |

*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 $230.00 per hour) to review clinical records and complete this form.[12] Therefore, approximately 191,385 requests will be made using the model form. The burden per response will be 5 minutes with an equivalent cost of $19.17. The total burden will be approximately 15,949 hours, with an equivalent cost of approximately $3,668,206.

Table 12.8 Hour Burden Estimates: Disclosure Request Form

| Notice Type | Estimated Number of Notices | Estimated Burden Hours per Notice | Estimated Number of Labor Hours | Costs per Hour | Estimated Labor Cost per Notice | Estimated Annual Labor Cost |
|---|---|---|---|---|---|---|
| Medical Necessity Disclosures Requested Along with Claims Denial Disclosure | 191,385 | 0.083 | 15,949 | $230.00 | $19.17 | $3,668,205.60 |

*Total Annual Burden Summary*

A summary of the total annual burden is presented in Table 12.9.

[12] Consistent with estimates included in previous PRA packages that the public had opportunity to provide input on.

Table 12.9 Total Annual Burden Summary

| Notice Type | Estimated Number of Respondents | Estimated Total Notices | Estimated Burden Hours per Notice | Estimated Number of Labor Hours | Estimated Annual Labor Cost |
|---|---|---|---|---|---|
| Medical Necessity Disclosure | 91,272 | 92,081 | 0.083 | 7,673 | $299,877.12 |
| Claims Denial Disclosure | 91,272 | 765,539 | 0.083 | 63,795 | $2,493,103.91 |
| Medical Necessity Disclosures Requested Along with Claims Denial Disclosure | 91,272 | 76,554 | 0.083 | 6,379 | $249,310.39 |
| Disclosure Request Form | 191,385 | 191,385 | 0.083 | 15,949 | $3,668,205.60 |
| **Total** | **282,657** | **1,125,558** | | **93,797** | **$6,710,497.02** |

13. Capital Costs

To estimate delivery costs, we assume that 75 percent of the explanation of denial disclosures and 38 percent of non-denial related requests for the medical necessity criteria will be delivered electronically. Many issuers 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.[13] Therefore, 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 anticipate that 25 percent of the medical necessity disclosures requested by individuals who have also requested a claims denial disclosure will also be sent to those participants and beneficiaries in a paper format. CMS assumes that it will cost $0.88 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 $0.68 postage costs.

Non-Federal governmental health plans will send approximately 186,089 disclosures annually in paper format. The total paper, printing and postage costs is estimated to be approximately $163,758 annually.

[13] Consistent with estimates included in previous PRA packages that the public had opportunity to provide input on.

Table 13.1 Capital Cost Estimates: Mailed Notices provided by Non-Federal Governmental Health Plans

| Notice Type | Estimated Number of Notices | % of Notices Delivered by Mail | Estimated Number of Notices Delivered by Mail | Paper, Printing, & Postage Costs per Notice | Estimated Total Capital Costs |
|---|---|---|---|---|---|
| Medical Necessity Disclosure | 90,887 | 62% | 56,350 | $0.88 | $49,587.95 |
| Claims Denial Disclosure | 471,779 | 25% | 117,945 | $0.88 | $103,791.28 |
| Medical Necessity Disclosures Requested Along with Claims Denial Disclosure | 47,178 | 25% | 11,794 | $0.88 | $10,379.13 |
| **Total** | **609,843** | | **186,089** | | **$163,758.36** |

Issuers in the individual market will send approximately 81,524 disclosures annually in paper format. The total paper, printing and postage costs is estimated to be approximately $71,741 annually.

Table 13.2 Capital Cost Estimates: Mailed Notices provided by Individual Market Issuers

| Notice Type | Estimated Number of Notices | % of Notices Delivered by Mail | Estimated Number of Notices Delivered by Mail | Paper, Printing, & Postage Costs per Notice | Estimated Total Capital Costs |
|---|---|---|---|---|---|
| Medical Necessity Disclosure | 1,194 | 62% | 740 | $0.88 | $651.45 |
| Claims Denial Disclosure | 293,760 | 25% | 73,440 | $0.88 | $64,627.20 |
| Medical Necessity Disclosures Requested Along with Claims Denial Disclosure | 29,376 | 25% | 7,344 | $0.88 | $6,462.72 |
| **Total** | **324,330** | | **81,524** | | **$71,741.37** |

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 increased by approximately 11,488 hours (from 82,309 to 93,797) largely due to an increase in the number of estimated denials (from 15% to 18%), which was not offset by the reduction in the estimated number of participants covered by State and local government plans (from 30.3 million to 25.7 million) or the reduction in the number of issuer/State combinations in the individual market (from 1,293 to 1,194). This change also resulted in the increase of burden related to the optional disclosure request form by approximately 1,997 hours (from 13,952 to 15,949). Capital costs have increased by approximately $58,492 (from $177,008 to $235,500) as a result of changes in postage costs and an increase in the number of disclosures delivered by mail (from 236,011 to 267,613).

16. Publication/Tabulation Dates

There are no plans to publish the outcome of the information collection. This is because the information collection consists of third-party disclosures. Upon request, plans and issuers must provide the information on the medical necessity standard, and explain the reason that a specific claim for MH/SUD benefits is denied. Participants, beneficiaries and enrollees may use the disclosure request form to request such information. No data is reported to the Federal government.

17. Expiration Date

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