

Supporting Statement – Part A
Notice of Denial of Medical Coverage (or Payment) - NDMCP
(CMS-10003, OMB 0938-0829)

Background

Medicare health plans, including Medicare Advantage plans, cost plans, and Health Care Prepayment Plans (HCPPs), are required to issue the Notice of Denial of Medical Coverage (or Payment) (NDMCP) when a request for either a medical service or payment is denied, in whole or in part. Additionally, the notices inform Medicare enrollees of their right to file an appeal, outlining the steps and timeframes for filing. All Medicare health plans are required to use these standardized notices. In 2013, Medicaid appeal rights were integrated into form CMS-10003 for beneficiaries who are eligible for Medicare and full Medicaid benefits under a State Medicaid plan. These appeal rights are provided in instances where a Medicare health plan enrollee receives full benefits under a State Medical Assistance (Medicaid) program being managed by the plan and the plan denies a service or item that is also subject to Medicaid appeal rights. As a result of integrating Medicare Advantage and Medicaid appeal rights for the 2013 package, this notice is commonly referred to as the Integrated Denial Notice (IDN).

The Centers for Medicare & Medicaid Services (CMS) requests an extension of this collections (CMS-10003), which is due to expire on 12/31/2024. OMB has previously approved these notices (OMB approval #0938-0829).

A. Justification

1. Need and Legal Basis

Section 1852(g)(1)(B) of the Social Security Act (the Act) requires Medicare health plans to provide enrollees with a written notice in understandable language of the reasons for the denial and a description of the applicable appeals processes. Regulatory authority for this notice is set forth in Subpart M of Part 422 at 42 CFR 422.568, 422.572, 417.600(b), and 417.840.

Section 1932 of the Act sets forth requirements for Medicaid managed care plans, including beneficiary protections related to appealing a denial of coverage or payment. Section 1902(a)(3) of the SSA requires State plans to provide for a fair hearing before the State agency to any individual whose claim for medical assistance under the plan is denied or not acted upon promptly. The Medicaid managed care appeals regulations are set forth in Subpart F of Part 438, Title 42 of the Code of Federal Regulations (CFR). Rules on the content of the written denial notice can be found at 42 CFR 438.404. Related requirements on the information a Medicaid managed care plan must provide to enrollees related to grievances, appeals and fair hearing procedures can be found at 42 CFR 438.10(g)(1). A State may provide for greater appeal protections under its Medicaid State plan.

2. Information Users

Medicare health plans, including Medicare Advantage plans, cost plans, and Health Care Prepayment Plans (HCPPs), are required to issue form CMS-10003 to Medicare Advantage plan enrollees when a request for either a medical service or payment is denied in whole or in part. The notice explains to the enrollee why the plan denied the service or payment and informs Medicare enrollees of their appeal rights.

In addition this notice is also used, as appropriate, to explain Medicaid appeal rights to full dual eligible individuals enrolled in a Medicare health plan that is also managing the individual's Medicaid benefits. To that end, the revised notice contains bracketed text the plan will insert if the denial notice is being delivered to an enrollee who is a full dual eligible. The text in square brackets "[]" reflects the Federal protections for Medicaid managed care enrollees. Since a State may offer additional protections, there is also free-text space for inclusion of any State-specific protections that exceed the Federal protections.

CMS will not use these notices to collect and analyze data on Medicare health plan appeals.

3. Use of Information Technology

The notice is available for completion electronically, however, the notice must be delivered in writing unless an enrollee opts in to receive this notification via electronic means. Currently, there is no data available to determine how many Medicare Advantage enrollees have chosen to receive notifications electronically and CMS has no current plans to rely on electronic delivery of this notice. The notice does not require a signature from respondents, so the question of CMS accepting electronic signatures is not applicable.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

There is no significant impact on small businesses. The notices inform enrollees of the right to file an appeal if a request for service or payment is denied in whole or in part.

6. Less Frequent Collection

The statute requires plans to issue written notice to enrollees whenever requests for items/services or payment are denied by Medicare. Thus, there are no opportunities for less frequent collection.

7. Special Circumstances

The Notice of Denial of Medical Coverage (or Payment) is issued by plans when an enrollee's request for either an item/service or payment is denied in whole or in part. There are no special circumstances to report, and no statistical methods will be employed. More specifically this notice:

- Does not require respondents to report information to the agency more often than quarterly;
- Does not require respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Does not require respondents to submit more than an original and two copies of any document;
- Does not require respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Is not connected with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Does not require the use of a statistical data classification that has not been reviewed and approved by OMB;
- Does not includes a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Does not require respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register Notice/Outside Consultation

The 60-day notice published in the Federal Register (88 FR 19956) 4/4/2023.

We received one comment during the 60-day comment period related to bracketed language in the "Fast Appeal" section specific to Part B drug timeframes that was removed in the current iteration of the notice. It was identified that this bracketed language was erroneously removed from the current version of the notice and therefore, we are reinserting the bracketed content related to Part B drug timeframes. We have responded to this comment in the CMS Response to Comments document.

The 30-day notice published in the Federal Register (88 FR) TBD.

9. Payments/Gifts to Respondents

This collection provides zero payments or gifts to respondents, but it does provide information on why the plan denied the service or payment and informs Medicare enrollees of their appeal rights.

10. Confidentiality

Personally identifiable information contained in the notice is protected by the Privacy Act and Health Insurance Portability and Accountability Act (HIPAA) standards for plans and their providers. CMS will not collect data from the notices. Thus, CMS assurance of confidentiality is not applicable to this collection.

11. Sensitive Questions

No questions of a sensitive nature will be asked.

12. Burden Estimate (Total Hours and Wages)

Background

The number of respondents for this collection is based on May 2022 CMS Medicare Advantage/Part D Contract and Enrollment Data which indicate that there are 937 Medicare health plans (excluding stand-alone prescription drug plans). Source: May 2022 Monthly Contract Summary Report:

<https://www.cms.gov/files/zip/monthlycontract-summary-report-may-2022.zip>

The most current CMS validated plan reported data is for 2020 and indicated a 10% denial rate (16,191,812 denials issued out of a total of 162,898,815 organization determinations), which is slightly higher than the 8.4% and 9.0% denial rate contained in the 2015 and 2016 data, respectively. While higher, we believe these three data sets are still consistent with respect to the rate at which plans are denying organization determination requests.

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2021 National Occupation Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted salary wage.

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefit (\$/hr)	Adjusted Hourly Wage (\$/hr)
Healthcare Support Workers	31-9099	19.56	19.56	39.12

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Burden Estimates

We estimate it will take plans an average of 10 minutes (0.1666 hours) to complete the notice for Medicare services that have been denied. This estimate takes into consideration that completion of the notice will take slightly longer in instances where the plan has to populate information on the enrollee's Medicaid benefits and rights. As previously noted, the estimates below are based on 937 Medicare health plans.

Based on data reported to CMS by Medicare health plans, there were 16,191,812 adverse and partially favorable decisions issued in 2020. As explained more fully below, since the previous submission of this data collection the plan reported data requirements have been revised to exclude contract provider claims where there is no enrollee liability. Because the total universe of adverse decisions (16,191,812) no longer includes contract provider claims where there is no enrollee liability (and the IDN is not issued), where we previously estimated that 21% of the universe was reflective of instances when the IDN would be issued, the burden estimate for this PRA package utilizes the total universe of adverse decisions to estimate the number of IDNs that will be issued.

Prior to 2018, plans were instructed to report all determinations for both contract and non-contract providers (in addition to decisions issued directly to enrollees). Beginning in 2018, plans were instructed to exclude contract provider claims where there is no enrollee liability from their reporting. This change to the reporting requirements resulted in a substantial decrease in the total number of adverse and partially favorable organization determinations. However, for the purposes of this PRA package, the total universe of partially or fully adverse decisions is now a more accurate representation of the IDN usage.

The total annual hourly burden for this collection is 2,697,556 hours (0.1666 hours x 16,191,812 notices) or 2,879 hours per plan.

The total estimated annual cost for this collection is \$105,528,391 (2,697,556 hours x \$39.12/hr) or \$112,624 per plan.

CMS does not have Medicaid data on the rate at which services are denied for only dual eligible enrollees in the managed care setting. However, since the integrated version of this notice will be provided to individuals who are eligible for Medicare and full Medicaid benefits (full duals), we believe these burden estimates adequately account for this population and inclusion of Medicaid appeals information materially does not affect the burden estimate with respect to the total number of denial notices that will be issued by health plans.

13. Capital Costs

There are no capital costs.

14. Cost to the Federal Government

The cost to the Federal government is on a triennial basis and is associated with the preparation and release of the updated notice and supplemental documents (e.g., form instructions and alternate versions). This includes the time it takes the employee to complete the PRA process, draft an HPMS memo announcing the release of the updated form, and posting the documents to CMS.gov. Because the notices will be printed and distributed by individual Medicare health plans, this alleviates additional cost to the Federal government.

The analysis and preparation of the PRA package and the subsequent release of documents is performed by a CMS employee. The average salary of the employee who would be completing this task, which includes the locality pay adjustment for the area of Washington-Baltimore-Arlington, is listed in the table below. See OPM 2022 General Schedule (GS) Locality Pay Tables, <https://www.opm.gov/policydata-oversight/pay-leave/salaries-wages/salary-tables/pdf/2022/DCB.pdf>. We estimate that on average it takes a CMS employee 15 hours to perform these activities and the triennial cost to the Federal government to be \$870.00.

Employee	Hourly Wage	Number of Hours	Triennial Cost to Government
GS-13, step 5	\$58.00	15	\$870.00
			TOTAL: \$870.00

15. Changes to Burden

In the course of this PRA process, CMS has identified language that was in the previously approved notice that has been erroneously removed or changed in the current version. Specifically, we reinserted the following changes:

- All terms that stated, “Part B or Medicaid drug” have been changed to “Part B drug or Medicaid drug”.
- Bracketed text in the “Fast Appeal” section related to Part B drug timeframes
- Specified that if an enrollee is asking for an appeal and has missed the deadline, they may request an extension.
- Restored curly brackets around “Phone” under standard appeals. Plans are not required to accept verbal requests for appeals and curly brackets provide plans the option to add a phone number.
- Removed language regarding enrollees receiving a decision letter because plans are not required to send notification to an enrollee if a denial is upheld and their case is forwarded to the IRE.

In addition to these revisions, this notice also includes new nondiscriminatory language. This is the updated standardized nondiscrimination language required on CMS forms and notices. The change does not affect the burden of this PRA collection.

The increase in burden is largely due to the significant increase in the number of Medicare health plan enrollees, which results in a greater number of organization determinations made by a Medicare health plan. Since 2016, the number of enrollees has risen from 18.3 million to 29.8 million. As a result, in 2016, we estimated that the IDN would be issued 9,373,200 times compared to the current submission, where we estimate the IDN will be issued 16,191,812 times.

Additionally, the increase in burden is, in part, due to the change in reporting requirements since the previous submission of this collection. In 2016, we were using an estimate of 21% of the total universe of partially or fully adverse decisions to calculate the burden associated with the use of the IDN. However, we are now able to more accurately calculate the burden since the total universe of adverse decisions is fully reflective of when the IDN would be issued.

The annual hourly burden associated with this collection is estimated to be 2,697,556 hours. The annual hourly burden in the previous submission for this collection was 1,561,575 hours, resulting in an increase in the burden. CMS believes these adjusted burden estimates, drawn from the most current and reliable data available (2020 plan reported data) are appropriate for the purpose of developing the burden estimates for the IDN (CMS-10003).

16. Publication / Tabulation Dates

CMS does not intend to publish data related to the notices.

17. Expiration Date

CMS will display the expiration date in the footer of the notice and form instructions.

18. Certification Statement

No exception to any section of the 83i is requested.

B. Collection of Information Employing Statistical Methods

N/A