

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 notice informs Medicare enrollees of their right to file an appeal, outlining the steps and timeframes for filing. All Medicare health plans are required to use this standardized notice. Medicaid appeal rights are also 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. Because this notice integrates Medicare Advantage and Medicaid appeal rights, it is commonly referred to as the Integrated Denial Notice (IDN).

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

This package contains the existing notice for renewal and an updated notice with the following changes effective 1/1/2025:

- Updated language and formatting for both notices to utilize more research-based ‘plain language’ and formatting consistent with current CMS guidelines.
- The timeframe to file an appeal with the plan was amended in CMS-4205-F to allow 65 days rather than 60 days. This change was made to account for the time it takes for an enrollee or other appropriate party to receive the notice.
- Language was added to comport with the requirements at 422.562(a)(5) which requires D-SNPs to offer Medicaid assistance.

This notice underwent consumer testing to ensure the notice is clear and easy to understand. Based on feedback from testing, several revisions were made to the notice, including language and formatting changes to improve clarity and readability for enrollees who receive this notice. Corresponding changes have been made to the form instructions. Revisions were made to the following section titles and/or related content:

- Your request was {Insert appropriate term: partially approved, denied}
- Why did we deny your request
- You have the right to appeal our decision
- If you want someone else to act for you

- Important Information About Your Appeal Rights
- How to ask for an appeal
- What happens next?
- Get help & more information

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 statue 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 Federal Register notice published on 6/10/2024 (89 FR 48901).

We received comments on this collection and have revised the notice accordingly. We have responded to these comments in the CMS Response to Comments document where we have noted the changes that were made as a result. These changes are also displayed in the Crosswalk.

The 30-day Federal Register notice published on TBD (89 FR).

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 April 2024 CMS Medicare

Advantage/Part D Contract and Enrollment Data which indicate that there are 970 Medicare health plans (excluding stand-alone prescription drug plans). Source: April 2024 Monthly Contract Summary Report: <https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-advantagepart-d-contract-and-enrollment-data/monthly-contract-and-enrollment-summary-report>

The most current CMS validated plan reported data is for 2022 and indicated a 10% denial rate (18,232,560 denials issued out of a total of 181,292,669 organization determinations), which is exactly the same denial rate as reported in 2020. We believe these 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 2023 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 median hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted salary wage.

Occupation Title	Occupation Code	Median Hourly Wage (\$/hr)	Fringe Benefit (\$/hr)	Adjusted Hourly Wage (\$/hr)
Healthcare Support Workers	31-9099	21.39	21.39	42.78

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 970 Medicare health plans.

Based on data reported to CMS by Medicare health plans, which excludes contract provider claims where there is no enrollee liability, there were 18,232,560 adverse and partially favorable decisions issued in 2022. For purposes of this PRA package, the total universe of partially or fully adverse decisions is an accurate representation of

IDN usage because it is used when a medical service or payment is denied, in whole or in part.

The total annual hourly burden for this collection is 3,037,544 hours (0.1666 hours x 18,232,560 notices) or 3,131 hours per plan.

The total estimated annual cost for this collection is \$129,946,132 (3,037,544 hours x \$42.78/hr) or \$133,965 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.

Time to complete each notice	Number of decisions that would require notification	Total Hourly Burden (0.1666 hours x 18,232,560 notices)	Total Annual Cost (3,037,544 hours x \$42.78/hr)
10 minutes (0.1666 hours)	18,232,560 notices	3,037,544 hours	\$129,946,132

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 2024 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 20 hours to perform these activities and the triennial cost to the Federal government to be \$1,281.20.

Employee	Hourly Wage	Number of Hours	Triennial Cost to Government
GS-13, step 5	\$64.06	20	\$1,281.20
			TOTAL: \$1,281.20

15. Changes to Burden

The changes made to this form were completed by the CMS Office of Communications (OC) to utilize plain language in order to increase accessibility and reduce health disparities. The OC supplied the following information on how their design and language decisions used in this form are research-based.

OC recommendations are soundly based on research-based best practices in plain language and information design. Along with decades of research in cognitive science and behavioral economics, we draw from a wealth of research data specific to CMS programs. We've been conducting consumer research with the patients, caregivers, providers and partners who interact with CMS programs for more than 20 years, and we use feedback from this research to make sure our information and products are clear and easy to use. Consumer testing is ongoing, and we iteratively refine language and design standards as our audiences and their information needs evolve. We work to apply the same research-based standards across all products and channels to make sure our language, messaging and branding are consistent.

Post 1/1/2025

In addition, a change was made where the notice discusses the right to a plan appeal. Where previously the enrollee or other appropriate party had 60 days to file an appeal with the plan, based on recent regulatory changes, effective 1/1/2025, the timeframe to file an appeal is now 65 days.¹ This change was made to account for the time it takes for an enrollee or other appropriate party to receive the notice.

The updated language in the existing notice does not affect the burden of this PRA collection.

The increase in burden is largely due to the 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 the previous submission, the number of enrollees has risen from 29.8 million to 33.8 million. As a result, in 2022, we estimated that the IDN would be issued 16,191,812 times compared to the current submission, where we estimate the IDN will be issued 18,232,560 times.

The annual hourly burden associated with this collection is estimated to be 3,037,544 hours. The annual hourly burden in the previous submission for this collection was 2,697,556 hours, resulting in an increase in the burden. CMS believes these adjusted burden estimates, drawn from the most current and reliable data available 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

¹ Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications (CMS-4205-F). Effective 1/1/2025