

# **Supporting Statement Part-A**

## **Notice of Denial of Medicare Part D Drug Coverage**

### **(CMS-10146, OMB 0938-0976)**

#### **Background**

The Centers for Medicare and Medicaid Services (CMS) requests a Revision type approval to the currently approved collection under section 1860D-4(g)(1) of the Social Security Act which requires Part D plan sponsors that deny prescription drug coverage to provide a written notice of the denial to the enrollee. The notice is due to expire 12/31/2024.

Part D plan sponsors are required to issue the Notice of Denial of Medicare Drug Coverage notice when a request for a prescription drug or payment is denied, in whole or in part. The written notice must include a statement, in understandable language, the reasons for the denial and a description of the appeals process.

This renewal contains the existing notices for renewal and an updated notice with the following changes effective 01/01/2025:

- Updated language and formatting to utilize more research-based “plain language” and formatting consistent with current CMS guideline.
- The timeframe to file an appeal with the plan has been amended in CMS-4205F to allow 65 days rather than 60 days. This change was made to account for the timeframe it takes for an enrollee or other appropriate party to receive the notice.

This notice underwent consumer testing to make sure the notice is clear and easy to understand. Based on feedback from this 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 denied
- Why did we deny your request
- What If I don’t Agree with This Decision
- Who May Request an Appeal
- There are Two Kinds of appeal You Can Request
- What Do I Include with My Appeal
- How Do I Request and Appeal What Happens Next
- Get Help & More Information

## **A. Justification**

### 1. Need and Legal Basis

The purpose of this notice is to provide information to enrollees when prescription drug coverage has been denied, in whole or in part, by their Part D plans. The notice must be readable, understandable, and state the specific reasons for the denial. The notice must also remind enrollees about their rights and protections related to requests for prescription drug coverage and include an explanation of both the standard and expedited redetermination processes and the rest of the appeal process.

#### *Statutory citations*

§ 1860D-4(g)(1) – Entities offering a Part D plan shall meet the requirements of paragraphs (1) through (3) of section 1852(g) of the Social Security Act with respect to covered benefits under the prescription drug plan it offers in the same manner as such requirements apply to an MA organization offering benefits under an MA plan.

§1852(g)(1)(B) – Organization determinations that deny coverage shall be in writing and shall include a statement in understandable language of the reasons for the denial and a description of the reconsideration and appeals processes.

#### *Regulatory citations*

§ 423.568(f) – If a Part D plan decides to deny a drug benefit, in whole or in part, it must give the enrollee written notice of the determination.

§423.568(g) – The notice under subsection (f) must use approved language in a readable and understandable form and must state the specific reasons for the denial. The notice must inform the enrollee of the right to a redetermination, including a description of both the standard and expedited redetermination processes, and must also describe the rest of the appeals process.

§422.136(a) – MA-PD plans have the option to implement step therapy prevent the overutilization and to control the costs of Part B covered drugs.

## 2. Information Users

Medicare beneficiaries who are enrolled in a Part D plan will be informed of adverse decisions related to their prescription drug coverage and their right to appeal these decisions.

## 3. Use of Information Technology

Part D plans are free to take advantage of any information technology they find appropriate for their business operations in order to meet this requirement. This denial notice is primarily issued to Part D plan enrollees (Medicare beneficiaries) and is most commonly sent to enrollees by mail. Plans are required by regulation to maintain a website by which beneficiaries can request an appeal. In this version of the notice, website information is more prominently displayed.

## 4. Duplication of Efforts

This information collection is not duplicative of another collection.

## 5. Small Businesses

There is no significant impact on small businesses. The notice informs Part D plan enrollees of the right to request an appeal if a request for prescription drug coverage is denied.

## 6. Less Frequent Collection

The statute requires written notice by the Part D plan to the enrollee whenever a request for prescription drug coverage is denied. There are no opportunities for less frequent collection. Failure to issue the notice when coverage is denied would result in denying beneficiaries important due process rights.

## 7. Special Circumstances

There are no special circumstances (see below). More specifically, this information collection does not do any of the following:

-Require respondents to report information to the agency more often than quarterly;

-Require respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;

-Require respondents to submit more than an original and two copies of any document;

-Require respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;

-Is connected with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study;

-Require the use of a statistical data classification that has not been reviewed and approved by OMB;

-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

-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/Outside Consultation

The 60-day Federal Register notice published on 6/10/2024 (89 FR 48901).

We received the following comment during the 60-day comment period: We understand the proposed change to the timeframe to file an appeal within 65 days from the 60 days to match the updated requirement in the 2024 Final Rule. We ask, if this change is made, it be made in both the Part C and the Part D documents to ensure consistency in the beneficiary messages. Based on our response there are no changes. We have responded to this comment in the CMS Response to Comment Document.

The 30-day Federal Register notice published on 9/17/2024 (89 FR 76113).

#### 9. Payments/Gifts to Respondents

Neither Part D plans nor enrollees will receive any payment or gifts related to issuance of this notice. The written notice serves as information to inform Part D plan enrollees, prescribers and representatives of their rights to request an appeal.

10. Confidentiality

All enrollee specific information contained in the notice is protected by the Privacy Act and HIPAA standards for Part D plans. No assurances for confidentiality are necessary as data are not being collected.

11. Sensitive Questions

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Burden Estimates (Hours and Wages)

*Wage Estimates*

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2023 National Occupational Employment and Wage Estimates for all salary estimates ([http://www.bls.gov/oes/current/oes\\_nat.htm](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 hourly wage.

Occupation Title	Occupation Code	Median Hourly Wage (\$/hr.)	Fringe Benefit (\$/hr.)	Adjusted Hourly Wage (\$/hr.)
Healthcare Support, All Other	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 that 772 Part D plan sponsors will issue a total of 2,962,857 denial notices each year. These estimates are based on 2022 validated Part D plan reported data. We estimate that it will take 15 minutes to issue a denial notice, including completion of the free text field for providing a specific explanation of the reason Medicare Part D prescription drug coverage was denied, for a total annual burden of 740,714.25 hours (2,962,857 notices x .25 hour), or 886 hours per plan sponsor per year. We believe 15 minutes is an accurate estimate of the time it will take for a Part D plan sponsor to complete the notice given that this notice has been in use in the Part D program for more than 15 years. In addition, most of the information contained is standardized language that cannot be modified; in other words, the information the plan sponsor is required to populate is limited and much of that information can be automated.

In aggregate we estimate a cost of \$31,687,756 (740,714.25 hr. x \$42.78/hr.). Per response, we estimate a cost of \$10.70 (31,687,756/2,962,857).

*Burden Summary*

**Annual Recordkeeping and Reporting Requirements**

Issuance of Denial Notice	Potential Respondents	Responses per Respondent	Total Responses	Burden per Response	Total Annual Burden (hours)	Hourly Labor Cost of Reporting (\$/hr.)	Total Cost (\$)
TOTAL	772	3,837	2,962,857	0.25 hr (15 min)	740,714.25	42.78	31,687,756

*Information Collection Instruments/Instructions*

- Notice of Denial of Medicare Part D Drug Coverage (English)

- Form Instructions for the “Notice of Denial of Medicare Part D Drug Coverage”
- Notice of Denial of Medicare Part D Drug Coverage (Spanish)

13. Capital Costs

There are no capital costs.

14. Cost to 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 2023 General Schedule (GS) Locality Pay Tables, <https://www.opm.gov/policy-dataoversight/pay-leave/salaries-wages/salary-tables/pdf/2023/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 \$1324.00.

<b>Employee</b>	<b>Hourly Wage</b>	<b>Number of Hours</b>	<b>Triennial Cost to Government</b>
GS-13, step 5	\$66.20	20	\$1324.00
			<b>TOTAL: \$1324.00</b>

15. Changes to Burden

An increased number of denial notices being issued is responsible for increase in our estimated burden for the Part D denial notice. When this information collection was approved in 2021, the estimate for the burden hours was 657,932. Based on current validated 2022 data, the estimated annual hour burden for this package is 740,714.25 which represents an increase of 82,782.25 hours. From the time that this collection was approved in 2022, there has been an increase of Part D plan sponsors, from 743 sponsors with previous data to a current count of 772 plan sponsors based on 2022 validated data. This change represents an overall increase of 29 plan sponsors.

At the last approval of this package, 2,962,857 denial notices were issued by plans. Using 202 validated data, 2,962,857 denial notices were issued, representing an increase of 331,129 denial notices. CMS believes these adjusted burden estimates, drawn from the most current and reliable data available (2022 plan reported data) are appropriate for the purpose of developing the burden estimates for the Denial of Medicare Prescription Drug Coverage notice.

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's recommendations in plain language and information design are research-based best practices. 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 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, easy to use and understand. 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 researchbased 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.<sup>1</sup> This change was made to account for the time it takes for an enrollee or other appropriate party to receive the notice.

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16. Publication/Tabulation Dates

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

17. Expiration Date

CMS will display the OMB # and expiration date in the lower right corner of the notice.

18. Certification Statement

Not applicable.

**B. Collections of Information Employing Statistical Methods**

Not applicable.

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<sup>1</sup> 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