Supporting Statement Part-A
Notice of Denial of Medicare Prescription Drug Coverage
(CMS-10146, OMB 0938-0976)

Background

Part D plan sponsors are required to issue the Notice of Denial of Medicare Prescription 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.

The Centers for Medicare and Medicaid Services (CMS) requests approval of an extension to a 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 on June 30, 2023. The nondiscrimination language that is included in the notice has been revised, but this revision does not impact the burden or the collection requirements.

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 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

-Require respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect die information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on 09/23/2022 (87 FR 58096).
No comments were received.

The 30-day Federal Register notice published on 12/15/2022 (87 FR 76624)

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 2021 National Occupational 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 hourly wage.

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr.)	Fringe Benefit ($/hr.)	Adjusted Hourly Wage

				($/hr.)
Healthcare Support, All Other	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 that 683 Part D plan sponsors will issue a total of 2,627,898 denial notices each year. These estimates are based on 2020 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 656,975 hours (2,627,898 notices x .25 hour), or 962 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 13 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 $25,700,862 (656,975 hr. x $39.12/hr.). Per response, we estimate a cost of $9.78($25,700,862/ 2,627,898).

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	683	3,848	2,627,898	0.25 hr (15 min)	656,975	39.12	$25,700,862

Information Collection Instruments/Instructions

- Notice of Denial of Medicare Part D Prescription Drug Coverage (English)
- Form Instructions for the "Notice of Denial of Medicare Prescription Drug Coverage"
- Notice of Denial of Medicare Part D Prescription 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 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 20 hours to perform these activities and the triennial cost to the Federal government to be $1260.00.

Employee	Hourly Wage	Number of Hours	Triennial Cost to Government
GS-13, step 8	$63.00	20	$1,262.00
			TOTAL: $1,260.00

15. Changes to Burden

There is a change to the non-discrimination language that is included in this notice, however, this change does not impact the burden or the collection requirements. This is the standardized nondiscrimination language required on CMS forms and notices. There are no other changes to the Part D denial notice.

There is no increase in the total hourly burden estimate for this collection. When this information collection was approved in 2020, the estimate for the burden hours was 721,967. Based on current validated 2020 data, the estimated annual hour burden for this package is 656,975 which represents a decrease of 64,992 hours. From the time that this collection was approved in 2020, there has been an increase of Part D plan sponsors, from 525 sponsors with previous data to a current count of 683 plan sponsors based on 2020 validated data. This change represents an overall increase of 158 plan sponsors. The total number of denial notices issued has decreased since the 2020 approval of this collection.
At the last approval of this package, 2,887,866 denial notices were issued by plans. Using 2020 validated data, 2,627,898 denial notices were issued, representing a decrease of 259,968 denial notices. 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 Denial of Medicare Prescription Drug Coverage notice.

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.