

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

**Background**

CMS requests approval of changes 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 written notice must include a statement, in understandable language, of the reasons for the denial and a description of the appeals process.

The Part D denial notice has been revised for clarity and includes new language in the denial rationale section of the notice explaining to enrollees that they should discuss the denial notice with their prescriber, as well as language explaining the need for a prescriber's supporting statement in some circumstances. Additional resource numbers have also been added.

**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.

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.

To comply with the Government Paperwork Elimination Act (GPEA), you must also include the following information in this section:

- Is this collection currently available for completion electronically? **No.**
- Does this collection require a signature from the respondents? **No.**
- If CMS had the capability of accepting electronic signatures, could this collection be made available electronically? **N/A. No signature required.**
- If this collection isn't currently electronic but will be made electronic in the future, please give a date (month and year) as to when this will be available electronically and explain why it can't be done sooner. **N/A.**
- If this collection cannot be made electronic or if it isn't cost beneficial to make it electronic, please explain. **This denial notice is primarily issued to Part D plan enrollees (Medicare beneficiaries) and is most commonly sent to enrollees by mail. Relying on electronic transmission of this notice to beneficiaries is impractical.**

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 March 11, 2016 (81 FR 12904). Public comments were received. They are attached to this package along with our response.

The 30-day notice published in the Federal Register on September 12, 2016 (81 FR 62741). One comment was received. The comment and our response are attached to this package.

#### 9. Payments/Gifts to Respondents

Neither Part D plans nor enrollees will receive any payment or gifts related to issuance of this notice.

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 2015 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 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, Other	31-9099	17.75	17.75	35.50

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 580 Part D plan sponsors will issue a total of 1,902,055 denial notices each year. These estimates are based on 2014 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 475,514 hours (1,902,055 notices x .25 hour), or 820 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 ten 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 \$16,880,747 (475,514 hr x \$35.50/hr). Per response, we estimate a cost of \$8.875 (\$16,880,747 / 1,902,055).

*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	580	3,279	1,902,055	0.25 hr (15 min)	475,514	35.50	16,880,747

*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)

To make the most of CMS’ limited translation resources, the revised Spanish version will be submitted to OMB as a nonsubstantive change subsequent to their approval of the attached English version. Until, that time, the currently approved Spanish version is unchanged.

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

There are no additional costs to the Federal government for the distribution of the notice. The notice will be printed and distributed by Part D plan sponsors.

15. Changes to Burden

The Part D denial notice has been revised for clarity and includes new language explaining to the enrollee that the notice should be shared with his/her doctor. A Crosswalk of the changes

to the notice and the instructions is included with this package. None of the changes impact our currently approved burden estimates.

There is an increase to the total hourly burden estimate for this collection. When this information collection was approved in February 2014, the estimate for the burden hours was 374,482 hours. The estimated annual hour burden for this package is now 475,514 (+101,032). Since the last collection was approved, there has been a slight decrease in the number of Part D plan sponsors used to estimate the burden, from 596 to 580 (-16), but the estimate for the total number of denial notices that will be issued across Part D plan sponsors has increased by 404,126 (to a total estimate of 1,902,055) and is based on the most recently validated Part D plan sponsor reported data (2014).

We believe the availability and use of validated plan reported data enhances the accuracy of the burden estimates for the Part D denial notice.

16. Publication/Tabulation Dates

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

17. Expiration Date

Display of the notice expiration date is acceptable.

18. Certification Statement

Not applicable.

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

Not applicable.