

**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.

Part D denial notice has been revised for clarity. The notice now describes within one section every way the beneficiary can file an appeal and describes the circumstances in which plans must or may accept different methods of appeal requests (verbal or written). The Part D instructions have also been revised to explain the process to providers that in the case that a request for a coverage determination is denied under Part B due to step therapy requirements, a different notice should be given.

### **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 11/18/2019 (84 FR 63655).

Three comments were received during the 60-day comment period.

The 30-day notice published in the Federal Register on 03/02/2020 (85 FR 12303).  
One comment was received during the 30-day comment period.

## 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 2018 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, All Other	31-9099	18.80	18.80	37.60

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 525 Part D plan sponsors will issue a total of 2,887,866 denial notices each year. These estimates are based on 2017 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 721,967 hours (2,887,866 notices x .25 hour), or 1375 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 \$27,145,959 (721,967 hr x \$37.60/hr). Per response, we estimate a cost of \$9.40(\$27,145,959/ 2,887,866).

#### *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	525	5,501	2,887,866	0.25 hr (15 min)	721,967	37.60	\$27,145 ,940

#### *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 and instructions have been revised for clarity. The notice has consolidated information regarding ways beneficiaries may request an appeal and the instructions contain new language informing providers that if a request is processed as a coverage determination and a requested drug is covered under the Part B benefit but has step therapy requirements, the provider should not send this notice and instead send the notice CMS-10003. Neither of these changes impact current burden estimates.

There is an increase in the total hourly burden estimate for this collection. When this information collection was approved in 2017, the estimate for the burden hours was 475,514. Based on current validated 2017 data, the estimated annual hour burden for this package is 721,967 which represents an increase of 264,453 hours. From the time that this collection was approved in 2017, there has been a decrease of Part D plan sponsors, from 546 sponsors with previous data to a current count of 525 plan sponsors based on 2017 validated data. This change represents an overall decrease of 55 plan sponsors. The total number of denial notices issued has increased since the 2017 approval of this collection. At the last approval of this package, 1,902,055 denial notices were issued by plans. Using 2017 validated data, 2,887,866 denial notices were issued, representing an increase of 985,811 denial notices.

After the 60-day publication in the Federal Register, the following changes were made: the section describing language requirements was condensed and streamlined; the sentence in the beginning of the paragraph changed from “last page” to “third page”; the sentence regarding payment appeals was added back in; and the direction for filing an appeal were revised. There were no changes to burden with this revision.

After the 30-day publication, one change was made: the sentence in the beginning of the paragraph changed from “If you need help, you can call one of the numbers listed on the third page under ‘Get help & more information’” to “If you need help, you can call one of the numbers listed under the section titled ‘Get help & more information’”. There were no changes to burden with this revision.

**16. Publication/Tabulation Dates**

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

**17. Expiration Date**

CMS will display the expiration date.

**18. Certification Statement**

Not applicable.

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

Not applicable.