

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

Background

This is a request for 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 optional language for Part D plan sponsors to use when explaining their denial rationale. Specifically, CMS has added optional language in the denial rationale section of the notice to allow plans to populate text explaining that a drug denied under Part D may be (or is) covered under a different benefit, such as Part B. The instructions have also been changed to guide plans on when to use this optional text.

CMS would like to solicit feedback on this new addition. We would also like to solicit feedback on other situations where another benefit may cover a drug (i.e. employer group benefits) and what changes to the denial notice may be helpful in addressing those situations.

Finally, CMS would like to solicit comments regarding the potential viability and usefulness of developing a combined notice for Part C and Part D, which would allow MA-PD plans that deny a drug under Part D to simultaneously issue an approval letter under Part B.

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/Regulatory 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.

§ 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

Not applicable. This denial notice is sent by Part D plans when coverage is denied. The notice informs Part D enrollees of appeal rights.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on May 3, 2013 (78 FR 26053). No comments were received.

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

No questions of a sensitive nature will be asked.

12. Burden Estimates (Hours and Wages)

We estimate that 596 Part D plan sponsors will issue a total of 1,497,929 denial notices each year (2,513 notices per plan sponsor). These estimates are based on 2011 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 374,482 hours (1,497,929 notices x .25 hour), or 628 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 is the eighth year of the Medicare prescription drug program and

most plan sponsors now have several years of program experience using this denial notice. 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. We estimate that the written disclosure of unfavorable coverage determinations will be performed by a plan staff person with skills at the GS-12/Step 1 hourly base salary of \$28.88. The total estimated wage/salary burden associated with providing the notice of denial of Medicare prescription drug coverage is \$10,815,040 (374,482 hours x \$28.88 per hour), or \$18,146 per plan sponsor.

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 optional language for Part D plan sponsors to use when explaining their denial rationale. Specifically, CMS has added optional language in the denial rationale section of the notice to allow plans to populate text explaining that a drug denied under Part D may be (or is) covered under a different benefit, such as Part B. The instructions have also been changed to guide plans on when to use this optional text. A Crosswalk of the changes has been added to this package.

There is an increase to the total hourly burden estimate for this collection. When this information collection was approved in November 2010, the estimate for the burden hours was 145,172 hours. The estimated annual hour burden for this package is now 374,482. Since the last collection was approved, there has been an increase in the number of Part D plan sponsors used to estimate the burden, from 456 to 596. The estimate for the total number of denial notices that will be issued across Part D plan sponsors has increased by 1,207,585 (to a total estimate of 1,497,929) and is based on the most recently validated Part D plan sponsor reported data (2011). The increase in the number of Part D plan sponsors, combined with the availability of validated plan reported data on coverage determinations, results in an increase of \$6,684,987 in the total estimated cost burden. We believe the availability and use of validated plan reported data enhances the accuracy of the burden estimates for the Part D denial notice. Based on these estimates (and as noted in section 12 above), the average annual cost per plan sponsor to notify enrollees of their appeal rights through issuance of this standardized denial notice is \$18,146.

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

N/A