

**Supporting Statement
for the
Paperwork Burden Requirement
Notice of Denial of Medicare Prescription Drug Coverage (OMB 0938-0976)**

A. Background

This is a request for approval of nonsubstantive 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.

B. 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(c) – 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(d) – The notice under subsection (c) 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 respondent(s)? **No.**
- If CMS had the capability of accepting electronic signature(s), 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 & 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 issued by plans 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 to enrollees when coverage is denied. The notice informs Part D enrollees of appeal rights.

8. Federal Register/Outside Consultation

A 60-day Federal Register notice will be published on May 23, 2008. Interested parties will have an opportunity to comment.

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 & Wages)

We estimate that 758 Part D plans will issue 290,344 denial notices each year (383.04 notices per plan). We estimate that it will take 30 minutes to issue a denial notice, including completion of the free text field for providing a specific explanation of the reason prescription drug coverage was denied, for a total annual burden of 145,172 hours (191.5 hours per plan).

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 \$26.98. Therefore, the total estimated wage/salary burden associated with providing the notice of denial of Medicare prescription drug coverage is \$3,916,741 or \$5,167 per plan. These estimates are based on relevant data from Part D program experience.

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 plans.

15. Changes to Burden

When approval of this information collection was sought in 2005, the Part D program had not yet been implemented, so there was no Part D program experience or data to rely upon in estimating burden. Thus the annual hour burden in the 2005 PRA submission for this collection (528,000 hours) was based on program experience and appeals volume in the Medicare Advantage/Part C program, which has a higher appeals volume. The current estimate for the burden hours, 145,172 hours, is based on Part D appeals data gathered during the first year of the program. The reduction in the burden hours is due to the adjustment in the agency estimate based on this Part D program data.

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.