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 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.

§423.580 - Pursuant to CMS-4131-FC, effective March 13, 2009, 423.582(a) has been revised to permit an enrollee's prescribing physician or other prescriber (acting on behalf of the enrollee) to request a standard redetermination on behalf of the enrollee. The revisions made to the denial notice reflect this regulatory change related to the standard redetermination process.

§423.582(a) – Pursuant to CMS-4131-FC, effective March 13, 2009, 423.582(a) has been revised to permit an enrollee's prescribing physician or other prescriber (acting on behalf of the enrollee) to request a standard redetermination on behalf of the enrollee. The revisions made to the denial notice reflect this regulatory change related to the standard redetermination 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

A 60-day Federal Register notice will be published on March 12, 2010. One comment was 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 456 Part D plans will issue a total of 290,344 denial notices each year. 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. There is no change to the total hourly burden from the previous collection approved October 2008. 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 $28.45. Therefore, the total estimated

wage/salary burden associated with providing the notice of denial of Medicare prescription drug coverage is $4,130,143. These estimates are based on relevant data from the Part D program.

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

    There are no changes to the total hourly burden estimate for this collection. When this information collection was approved in October 2008, the estimate for the burden hours was 145,172 hours. Since the last collection was approved, there has been a reduction in the number of Part D plan sponsors used to estimate the burden, from 758 to 456. However, the estimates for the expected number of denial notices that will be issued (290,344) across Part D plans remains the same and is based on the most recent Part D program data available related to appeals volume. There is a $213,402 increase in the total cost burden, due to a small increase in the GS-12/Step 1 hourly base salary (from $26.98 in 2008 to $28.45 in 2009) that is used to calculate cost burden for providing the written notice of denial of prescription drug coverage.

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.