

**Supporting Statement
for the
Paperwork Burden Requirement
Medicare Prescription Drug Coverage and Your Rights (OMB 0938-0975)**

A. Background

This is a request for approval of nonsubstantive changes to a currently approved collection under 42 CFR § 423.562(a)(3), which requires each Part D plan sponsor to arrange with its network pharmacies to post or distribute the *Medicare Prescription Drug Coverage and Your Rights* notice to Part D plan enrollees at each pharmacy visit during which the enrollee disagrees with the information provided by the pharmacist.

B. Justification

1. Need and Legal Basis

The purpose of this notice is to provide enrollees with information about how to contact their Part D plans to request a coverage determination, including a request for an exception to the Part D plan's formulary. The notice reminds enrollees about certain rights and protections related to their Medicare prescription drug benefits, including the right to receive a written explanation from the drug plan about why a prescription drug is not covered. A Part D plan sponsor's network pharmacies are in the best position to notify enrollees about how to contact their Part D plan if the enrollee disagrees with the information provided by the pharmacist at the point of service (for example, if the prescription cannot be filled as written).

Statutory/Regulatory Basis

§ 1860D-4(g)(1) – A Part D plan sponsor 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 must be in writing and include a statement in understandable language of the reasons for the denial and a description of the reconsideration and appeals processes.

§ 423.562(a)(3) –A Part D plan sponsor must arrange with its network pharmacies to post or distribute notices instructing enrollees to contact their plans to obtain a coverage determination or request an exception if they disagree with the information provided by the pharmacist.

2. Information Users

Medicare beneficiaries who are enrolled in a Part D plan will be informed of their right to request a coverage determination (including an exception) and will be better able to access their Medicare prescription drug benefits.

3. Use of Information Technology

Part D plans and their network pharmacies 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 notice is posted at the pharmacy or is distributed to Part D plan enrollees (Medicare beneficiaries). Use of an electronic version 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 requirement may be fulfilled by the pharmacy electing to display the notice in a prominent place or by distributing a copy of the notice to the enrollee.

6. Less Frequent Collection

There are no opportunities for less frequent collection. Failure to issue the notice at the pharmacy would result in denying beneficiaries important due process rights. The pharmacist cannot issue a coverage determination on behalf of the plan. As a result, the enrollee may not be aware of the right to contact the plan for a written coverage determination or to request an exception.

7. Special Circumstances

Not applicable. This notice is posted at the pharmacy or distributed to a Part D enrollee if the enrollee disagrees with information provided by the pharmacist (e.g., the prescription cannot be filled as written).

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 pharmacies will receive any payment or gifts related to issuance of this notice.

10. Confidentiality

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 the paperwork burden associated with the requirement to distribute the *Medicare Prescription Drug Coverage and Your Rights* notice to a Part D plan enrollee who disagrees with information provided by the pharmacist is approximately one minute per enrollee. This assumes that a preprinted notice will be given to an enrollee during the visit to the pharmacy or that the enrollee will be directed to a posted notice. Assuming that the staff person distributing the notice will most likely be a pharmacy technician, we estimate the relevant salary to be \$13.00 per hour, based on the Bureau of Labor Statistics/2006 National Occupational Employment & Wage Estimates. In addition, per the 2002 U.S. Census Bureau's Economic Census, there were about 40,000 retail pharmacies and drug store establishments continuously through 2002.

We assume that, on average, a Part D enrollee will visit a pharmacy once each month (12 times per year). According to recent Part D enrollment data, about 25 million Medicare beneficiaries are enrolled in a Part D plan. This means that there will be an estimated 300 million pharmacy visits per year. The notice is only required in cases where an enrollee disagrees with information provided by the pharmacist (e.g., the prescription cannot be filled

as written). We assume that enrollees will disagree with the information provided by the pharmacist in approximately ten percent of pharmacy visits, resulting in approximately 30 million instances where the enrollee will be provided with or directed to the notice. We further estimate that it will take an average of one minute for a pharmacy technician to give an enrollee the notice or to direct an enrollee to a posted notice, for a total burden of 500,000 hours or \$6,500,000 (500,000 hours x \$13.00 per hour). For each of the 40,000 retail pharmacies, this equates to 12.5 hours of burden at \$13.00 per hour, for a total of approximately \$162.50 per year.

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

There are no direct costs to the Federal government for the posting or distribution of the notice by Part D plans' network pharmacies.

15. Changes to Burden

The annual hour burden associated with this collection is estimated to be 500,000 hours. The annual hour burden in the 2005 PRA submission for this collection was 583,333 hours. The reduction in the burden hours from the previous PRA submission is due to an adjustment in the agency estimate based on current Part D enrollment 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.