

**Supporting Statement for the
Paperwork Burden Requirement
Medicare Prescription Drug Coverage and Your Rights
Standardized Pharmacy Notice (CMS-10147/OMB 0938-0975)**

A. Background

This is a request for approval of changes to a currently approved collection under 42 CFR § 423.562(a)(3). This regulatory provision has recently been modified to eliminate the previously available option of posting the standardized notice at the pharmacy. Revised 423.562(a)(3) and an associated regulatory provision at § 423.128(b)(7)(iii) require the pharmacy to provide the Part D enrollee with a printed copy of this standardized notice if the prescription cannot be filled.

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 prescription cannot be filled.

As noted in a final rule published April 15, 2011 (CMS-4144-F), the option of posting this notice at the pharmacy has been eliminated. If a prescription cannot be filled, the pharmacy must provide the enrollee with this written notice.

Statutory/Regulatory Basis

§ 1860D-4(g)(1) – A Part D plan sponsor shall provide coverage determination and redetermination procedures with respect to covered prescription drug benefits offered by the plan.

§ 423.562(a)(3) –A Part D plan sponsor must arrange with its network pharmacies to 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.

§ 423.128(b)(7)(iii)–Network pharmacies must provide a printed notice at the point-of-sale to an enrollee explaining how the enrollee can request a coverage determination by contacting the plan sponsor's toll free customer service line or by accessing the plan sponsor's internet Web site.

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? **Not applicable. 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. **Not applicable.**
- If this collection cannot be made electronic or if it isn't cost beneficial to make it electronic, please explain. This written notice must be given to a Part D plan enrollee if the enrollee's prescription cannot be filled under the Medicare Part D benefit and the rejection cannot be resolved at point of sale. Electronic distribution of the written notice via e-mail is not prohibited if the pharmacy has the capability to transmit the written notice electronically and the enrollee has indicated a preference for receiving it electronically.

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 is fulfilled by the pharmacy providing the enrollee with the written notice.

6. Less Frequent Collection

There are no opportunities for less frequent collection. Failure to issue the notice at the pharmacy may 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. A written copy of this notice is provided to a Part D enrollee if the prescription cannot be filled under the Medicare Part D benefit.

8. Federal Register/Outside Consultation

A 30-day Federal Register notice will be published. 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 written standardized pharmacy notice entitled **Medicare Prescription Drug Coverage and Your Rights** is one minute per enrollee. Assuming that the staff person distributing the notice will most likely be a pharmacy technician, we estimate the relevant salary to be \$13.50 per hour, based on the Bureau of Labor Statistics/2009 National Occupational Employment & Wage Estimates.

Based on current prescription drug event data, the projected number of transactions (filled prescriptions) for 2010 is 1,123,860,661. Further, based on anecdotal information provided by pharmacy benefits managers (PBMs), approximately 10% (or 112,386,066) of these transactions do not get automatically processed and require some type of action at point of sale in an attempt to remedy the rejection. For example, a keying or data entry error may need to be corrected in order to process the transaction or the pharmacy may need to contact the plan to obtain an override on a systems edit. We estimate that these types of issues can be resolved at the point of sale for about two-thirds of the 112,386,066 rejected claims. In other words, for one-third (or 37,087,402) of the rejected claims, the pharmacy will not be able to process the transaction (fill the prescription under the Part D benefit) and will be required to

provide the enrollee with the written standardized pharmacy notice. Again, assuming an average time per response of one minute (0.01666 hour), we estimate the total annual hour burden to be 617,876 hours (0.01666 multiplied by 37,087,402 notices). Applying the aforementioned hourly rate of \$13.50 per hour, this results in an estimated annual cost burden of \$8,341,326 (617,876 hours multiplied by \$13.50).

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

There are no direct costs to the Federal government for the 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 617,876 hours. The annual hour burden in the 2008 PRA submission for this collection was 500,000 hours. The increase in the burden hours from the previous PRA submission is due to an adjustment in the agency's estimate of the number of standardized pharmacy notices that are likely to be distributed based on current prescription drug event data, and increased enrollment in the Part D program.

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.