

Supporting Statement Part A
Medicare Prescription Drug Coverage and Your Rights
CMS-10147, OMB 0938-0975

Background

Section 423.562(a)(3) and an associated regulatory provision at § 423.128(b)(7)(iii) require that Part D plan sponsors' network pharmacies provide Part D enrollees with a printed copy of our standardized pharmacy notice "Medicare Prescription Drug Coverage and Your Rights" (hereafter, "notice") if an enrollee's prescription cannot be filled.

In this 2017 iteration we propose to revise the notice and accompanying instructions to enhance the clarity and accuracy of the notice and instructions, including when the notice must be delivered. The revisions also add language that informs beneficiaries of their rights under Section 504 of the Rehabilitation Act of 1973 (Section 504), by alerting the beneficiary to CMS's nondiscrimination practices and the availability of alternate forms of this notice, if needed.

We are also revising our burden estimates based on calendar year (CY) 2016 prescription drug event data.

A. 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. Through delivery of this standardized notice, a Part D plan sponsor's network pharmacies are in the best position to inform enrollees at point of sale about how to contact their Part D plan if the prescription cannot be filled.

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 contact the plan and request a coverage determination.

2. Information Users

Through the notice, 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 notice.

6. Less Frequent Collection

There are no opportunities for less frequent collection. Each time an enrollee's prescription cannot be filled under the Part D benefit and the issue cannot be resolved at the point of sale, the network pharmacy is responsible for providing the enrollee this notice. Failure to provide the enrollee with a copy of the notice at the pharmacy if the prescription can't be filled may result in enrollees being uninformed of important due process rights. The pharmacist can't issue a coverage determination on behalf of the plan.

7. Special Circumstances

There are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

The 60-day notice published in the Federal Register on April 6, 2017 (82 FR 16843). Comments were received and have been added to this package along with our response. From the comments we have revised the language in the form instructions to specify that the OMB control number must be displayed in the lower right corner of the notice.

The 30-day notice published in the Federal Register on August 10, 2017 (82 FR 37453). We did not receive any comments.

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

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Burden Estimates (Hours & Wages)

Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2016 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

| Occupation Title | Occupation Code | Mean Hourly Wage (\$/hr) | Fringe Benefit (\$/hr) | Adjusted Hourly Wage (\$/hr) |
|---------------------|-----------------|--------------------------|------------------------|------------------------------|
| Pharmacy Technician | 29-2052 | 15.47 | 15.47 | 30.94 |

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Burden Estimates

We estimate that the burden associated with the requirement to distribute the standardized pharmacy notice, entitled **Medicare Prescription Drug Coverage and Your Rights**, is 1 minute (0.01666 hour) per enrollee. We believe that because such delivery is an administrative function, a pharmacy technician would generally be the person distributing the notice, not the pharmacist. Assuming that the staff person distributing the notice will most likely be a pharmacy technician, we are using an adjusted wage of \$30.94/hr to calculate costs.

Based on the most recent data from CY 2016 prescription drug event (PDE) data, we estimate the annual number of transactions (filled prescriptions) to be 1,203,000,000. We estimate that approximately 10% (or 120,300,000) 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. The 10% is a proxy to estimate the number of notices we expect to be issued. 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 of a systems edit. We estimate that these types of issues can be resolved at the point of sale for about two-thirds of the 120,300,000 rejected claims and that for one-third (or 40,100,000) of the rejected claims, the pharmacy will not be able to fill the prescription under the Part D benefit and will be required to provide the enrollee with the standardized pharmacy notice.

Assuming an average time per response of 1 minute (0.01666 hour) we estimate a total annual burden of 668,066 hours (0.01666 min x 40,100,000 notices) at a cost of \$20,669,962.04 (668,066 hr x \$30.94/hr).

For each respondent/pharmacy we estimate an annual burden of 11 hours (668,066 hr / 62,000 pharmacies) at a cost of \$333.39 (\$20,669,962.04 / 62,000 pharmacies).

Information Collection/Reporting Instruments and Instruction/Guidance Documents

- Instructions for the standardized pharmacy notice “Medicare Prescription Drug Coverage and Your Rights”
- Medicare Prescription Drug Coverage and Your Rights (English)
- Medicare Prescription Drug Coverage and Your Rights (Spanish)

We are keeping the 2014-approved version in this submission. We are excluding the revised Spanish version from this 2017 iteration due to our belief that the best use of the agency’s limited translation resources is to wait until after OMB approves a notice (in English) before translating that notice into another language. At that time the Spanish version will be provided to OMB as a nonsubstantive change.

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

We propose to revise the notice and accompanying instructions to enhance the clarity and accuracy of the notice and instructions. We also propose to add language that informs beneficiaries of their rights under Section 504 of the Rehabilitation Act of 1973 (Section 504), by alerting the beneficiary to CMS’s nondiscrimination practices and the availability of alternate forms of this notice, if needed.

The annual hourly burden associated with this collection is estimated to be 668,066 hours. The annual hourly burden in the 2014 PRA submission for this collection was 626,749 hours. The 41,317 hour increase in burden is an adjustment that is based on the increased number of applicable pharmacies (+6,000 pharmacies) and the increased number of standardized pharmacy notices (+2,479,760 notices) that are likely to be distributed based on CY 2016 prescription drug event data.

Reconciling the burden increase: $41,313 \text{ hr} = 2,479,760 \times 0.01666$. We attribute the 4 hour difference ($41,317 \text{ hr} - 41,313 \text{ hr}$) to 1 min/response rounding differences (when converted to hours) between this 2017 iteration and the currently approved 2014 iteration.

We are also adjusting our cost estimates based on current BLS wage data for pharmacy technicians. In this iteration we are doubling that wage to account for burden and overhead.

16. Publication/Tabulation Dates

CMS does not intend to publish data related to the notices.

17. Expiration Date

The expiration date is displayed.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collection of Information Employing Statistical Methods

This collection does not employ statistical methods.