

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

Note: We have revised the title of this collection because Medicare style has dropped “prescription” as an adjective in most cases and now uses “Medicare drug coverage”, per the CMS Office of Communications (OC).

Background

CMS is requesting an Extension OMB approval due to minor non-substantive language/formatting changes and revising burden estimates based on CMS Program Statistics for Medicare Part D for CY 2021.

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 Drug Coverage and Your Rights” (hereafter, “notice”) if an enrollee’s prescription cannot be filled.

This package contains the following changes:

- Updated language and formatting to utilize more research-based ‘plain language’ and formatting consistent with current CMS guidelines.

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. For example, electronic communication via a portal to communicate updates related to this notice and applicable requirements to network pharmacies.

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 8/9/2024 (89 FR 65359).
No comments were received during the 60-day comment period.

The 30-day notice published in the Federal Register 10/21/2024 (89 FR 84154).

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

CMS pledges to maintain privacy to the extent provided by law.

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 2023 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	Median Hourly Wage (\$/hr)	Fringe Benefit (\$/hr)	Adjusted Hourly Wage (\$/hr)
Pharmacy Technician	29-2052	\$19.37	\$19.37	\$38.74

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 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 \$38.74/hr to calculate costs.

Previously, CMS utilized the number of rejected pharmacy transactions available in the Public Reporting File (PUF) data to calculate the burden for this package. However, in 2017 based on an agency wide effort to reduce burden for Part D sponsors, the Rejected Pharmacy Transactions data elements were removed from the CY 2019 Part D Reporting Requirements. As a result, in this PRA submission, we have extrapolated the data to determine the number of rejected pharmacy transactions. Based on the most recent CMS Program Statistics for Medicare Part D for CY 2021, the number of filled prescriptions in 2021 was 2,703,396,907. This was an 11.1% increase from 2018. After applying the 11.1% growth rate to the rejected pharmacy transactions

in 2018 (82,802,153), the number of extrapolated rejected pharmacy transactions in 2021 was 92,026,567. However, we estimate that 40% of rejected pharmacy transactions are resolved at point of sale. These resolutions could be attributed to a phone call to the prescriber to obtain a system override, or could be due to data entry error. Based on this 40% resolution assumption, we are estimating that 55,215,940 notices will be issued annually.

Assuming an average time per response of 1 minute (0.01666 hour) we estimate a total annual burden of 919,898 hours (0.01666 hours x 55,215,940 notices) at a cost of \$35,636,849 (919,898 hrs x \$38.74/hr).

For each respondent/pharmacy we estimate an annual burden of 13 hours per pharmacy per year (919,898 hrs / 72,900 pharmacies) at a cost of \$ 488.85 per pharmacy per year (\$35,636,849 / 72,900 pharmacies).

Occupation Title	Median Hourly Wage*	# Respondents	# Responses	Hours per response	Total hours	Total Cost
Pharmacy Technician	38.74	72,900	55,215,940	13	919,898	55,215,940

Information Collection/Reporting Instruments and Instruction/Guidance Documents

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

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

The cost to the Federal government is on a triennial basis and is associated with the preparation and release of the updated notice and supplemental documents (e.g., form instructions and alternate versions). This includes the time it takes the employee to complete the PRA process, draft an HPMS memo announcing the release of the updated form, and posting the documents to CMS.gov. Because the notices will be printed and distributed by Part D plan sponsor’s network pharmacies, this alleviates additional cost to the Federal government.

The analysis and preparation of the PRA package and the subsequent release of documents is performed by a CMS employee. The average salary of the employee who would be completing this task, which includes the locality pay adjustment for the area of Washington-Baltimore/Arlington, is listed in the table below. See OPM 2024 General Schedule (GS) Locality Pay Tables, <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2024/generalschedule>. We estimate that on average it takes a CMS employee 20 hours to perform these activities and the triennial cost to the Federal government to be \$1,281.20.

Employee	Hourly Wage	Number of Hours	Triennial Cost to Government
GS-13, step 5	\$64.06	20	\$1,281.20
			TOTAL: \$1,281.20

15. Changes to Burden

The changes made to this form were completed by OC to utilize plain language in order to increase accessibility and reduce health disparities. The OC supplied the following information on how their design and language decisions used in this form are research based.

OC recommendations are soundly based on research-based best practices in plain language and information design. Along with decades of research in cognitive science and behavioral economics, we draw from a wealth of research data specific to CMS programs. We've been conducting consumer research with the patients, caregivers, providers and partners who interact with CMS programs for more than 20 years, and we use feedback from this research to make sure our information and products are clear and easy to use. Consumer testing is ongoing, and we iteratively refine language and design standards as our audiences and their information needs evolve. We work to apply the same research-based standards across all products and channels to make sure our language, messaging and branding are consistent.

We also updated the non-discrimination language to include the enrollees right to file a complaint with Medicare if they feel they have been discriminated against.

The annual hourly burden associated with this collection is estimated to be 919,898 hours. The annual hourly burden in the 2020 PRA submission for this collection was 827,690 hours. The 159,624 hour increase in burden is an adjustment that is based on the increased number of applicable pharmacies (+2,900 pharmacies) and the increased number of standardized pharmacy notices (+5,534,648 notices) that are likely to be distributed.

16. Publication/Tabulation Dates

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

17. Expiration Date

The expiration date is displayed in the bottom right-hand corner of the notice.

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.