

Supporting Statement - Part A
Hospice Information for Medicare Part D Plans
CMS-10538, OMB 0938-1269

Background

The Social Security Act in section 1861(dd) and Federal regulations in 42 CFR §418.106 and § 418.202(f) require hospice programs to provide individuals under hospice care with drugs and biologicals related to the palliation and management of the terminal illness as defined in the hospice plan of care. Medicare payment is made to the hospice for each day an eligible beneficiary is under the hospice's care, regardless of the amount of services provided on any given day. Because hospice care is a Medicare Part A benefit, drugs provided by the hospice and covered under the Medicare payment to the hospice program are not covered under Part D.

For prescription drugs to be covered under Part D when the enrollee has elected hospice, the drug must be for treatment of a condition that is completely unrelated to the terminal illness and/or related conditions. The DHHS Office of the Inspector General (OIG) released a report in June 2012 identifying situations in which Medicare may be paying twice for prescription drugs for hospice beneficiaries, who in turn could also be paying unnecessary co-payments for prescription drugs. CMS has issued numerous guidance documents to the industry expressing concern that Part D sponsors may be paying for drugs that should be the responsibility of the Medicare hospice provider. In the latest guidance released on July 18, 2014, CMS encouraged sponsors to place beneficiary-level prior authorization (PA) requirements on the following four categories of prescription drugs identified by the OIG as typically used to treat the common symptoms generally experienced during the end of life: analgesics, antinauseants (antiemetics), laxatives, and antianxiety drugs (anxiolytics).

CMS is requesting a Reinstatement without change approval type from OMB. We are making no changes to the previously approved existing form.

A. Justification

1. Need and Legal Basis

In response to the CMS request for comment on the guidance issued December 6, 2013, many industry commenters recommended that we require the use of a standard PA form to facilitate coordination between Part D sponsors, hospices and prescribers. The industry in conjunction with the National Council for Prescription Drug Programs, (NCPDP) has developed a standard form that with minor modifications will meet the program needs. CMS encourages use of this form and will likely propose requiring its use in future rulemaking.

2. Information Users

The form would be completed by the prescriber or the beneficiary's hospice, or if the prescriber or hospice provides the information verbally to the Part D sponsor, the form would be completed by the sponsor. Information provided on the form would be used by the Part D sponsor to establish coverage of the drug under Medicare Part D. Per statute, drugs that are necessary for the palliation and management of the terminal illness and related conditions are not eligible for payment under Part D. The standard form provides a vehicle for the hospice provider, prescriber or sponsor to document that the drug prescribed is "unrelated" to the terminal illness and related conditions. It also gives a hospice organization the option to communicate a beneficiary's change in hospice status and/care plan to Part D sponsors.

3. Use of Information Technology

This collection is not currently available for completion electronically. However, Part D sponsors are encouraged to incorporate these data into electronic health records, bi-directional digital communications with providers, and other aspects of national health information technology.

4. Duplication of Efforts

This is not a duplication of effort and the information cannot be obtained from any other source.

5. Small Businesses

The Small Business Administration (SBA) defines a small business in the service sector as having revenues of less than \$7.0 million to \$34.5 million in any 1 year, or if they are a nonprofit organization. While the SBA does not define a size threshold in terms of annual revenues for hospices, it does define one for home health agencies (\$14 million; see <http://www.sba.gov/content/small-business-size-standards>). For the purposes of this PRA, because the hospice benefit is a home-based benefit, we are applying the SBA definition of "small" for home health agencies to hospices and use this definition of "small" in determining if this information collection tool (IC) has a significant impact on a substantial number of small entities (for example, hospices). We estimate that 95 percent of hospices have Medicare revenues below \$14 million or are nonprofit organizations and therefore are considered small entities.

HHS's practice is to consider effects economically "significant" only if they reach a threshold of 3 to 5 percent or more of total revenue or total costs. The estimated impact of this IC is below that threshold; therefore, we estimate that it will generally not impose a significant impact on small businesses and other small organizational entities.

Part D sponsors must possess an insurance license and be able to accept risk. Generally, State statutory licensure requirements effectively prevent small organizations from accepting the level of risk needed to provide the pharmacy benefits required in the Medicare Prescription Drug Benefit Program. Thus, Part D prescription benefit plan sponsors are not small businesses.

6. Less Frequent Collection

The form would not affect the timing of information collected rather it would provide a standard instrument for collection of the data required. Without collection, data would be lost and miscommunications would cost time and money for CMS, hospice providers, and Part D sponsors. We must collect this information otherwise this could lead to FWA (fraud/waste/abuse) in the Medicare program. Having a standardized form means that everyone gets and sends the same kind of data and knows immediately if they need to request anything else in particular.

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 the Office of Management and Budget (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 TBD (FR).

9. Payments/Gifts to Respondents

No gifts or payments are being made to respondents..... Beneficial outcomes are not in a form of payment but instead use of information helps inform Part D drug coverage decisions.

10. Confidentiality

Part D sponsors, healthcare providers, and hospice providers are subject to Health Insurance Portability and Accountability Act (HIPAA) privacy and security requirements.

11. Sensitive Questions

The discussion of sensitive issues is inherent in the delivery of health care and interactions between patients and their healthcare providers. For example, this form may include certain medications and conditions that are considered “sensitive,” such as mental health disease or HIV/AIDS. These interactions and the use of the standardized format are subject to HIPAA privacy and security requirements.

12. Burden Estimates (Hours & Wages)

Wage Estimates

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 median 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	Fringe Benefit (at 100%)	Adjusted Hourly Wage
Pharmacy Technicians	29-2052	\$19.37/hr	\$19.37/hr	\$38.74/hr
Registered Nurses	29-1141	\$41.38/hr	\$41.38/hr	\$82.76/hr

Burden Estimates

The following assumptions are used to project the burden associated with this standardized form:

# of Part D Parent Organizations	319 (respondents)
Gross covered drug costs under Part D for beneficiaries in hospice, CY 2024	\$430.1 million
# paid Part D claims for beneficiaries in hospice, CY 2024	6.3 million
# beneficiaries in hospice with paid Part D claims during the election period	285,134
# of hospice elections for beneficiaries who were on the any of the four categories of drugs identified above (5,653 analgesics; 1,473 antiemetics; 504 laxatives; and 4,140 anti-anxiety drugs)	11,770
Estimate of number of PAs required (initial fills of drugs in four categories)	57,027 (responses)
Hourly rate of a pharmacy technician	\$38.74/hr

# of Medicare-participating hospices, CY 2024	6,040
# of Medicare-billing hospices, with CY 2024 claims	5,640
Hourly rate of a registered nurse	\$82.76/hr

We estimate 399,188 unique prescriptions were paid under the Part D benefit for beneficiaries in hospice elections in CY 2024. Of those prescriptions, 27,943 would require prior authorization because they would be for initial fills for drugs in the four categories for which prior authorization is suggested. To identify unique prescriptions, we used the first 9 digits of the 11-digit NDC code on each Part D record (the first 5 digits is the FDA “labeler” code of the drug’s manufacturer, and the next 4 digits are the “product” code for the drug, the last 2 digits are the “package” code giving the package form or the size of the package).

The form would be used only after a beneficiary has elected hospice and when a drug as prescribed is unrelated to the beneficiary’s terminal illness and related conditions. The form may be completed by a hospice nurse or the prescriber when providing written information to the Part D sponsor prior to a claim being submitted, after a claim has rejected due to a hospice PA reject, but prior to the submission of a coverage determination request, or in response to a coverage determination request. When this information is provided verbally, the Part D sponsor would complete the form to document the basis for the coverage of the drug under Part D.

We estimate that two-thirds of the forms (18,610 **forms** = 27,943 x 0.666) would be completed by a hospice nurse or a nurse in the prescriber’s office and the remaining **9,333 forms** (27,943–18,610) would be completed by the Part D sponsor’s pharmacy technician.

We further estimate that the hospice or prescriber nurse would require 5 minutes per prescription to complete the form. For hospices and prescribers we estimate a total burden of **1,551 hours** (18,610 forms x 5 min/60) at a cost of **\$128,360.76** (1,551 hr x \$82.76/hr).

We also estimate that the pharmacy technicians who staff each Part D sponsor’s pharmacy help desk to coordinate with hospice providers in satisfying the sponsor’s PA requirements would require 5 minutes per prescription to complete the remaining third of the forms. This means that the pharmacy technician would receive the information verbally from the hospice or prescriber for 9,333 forms. The total time for form completion by the sponsors’ pharmacy technicians is estimated to be **778 hours** (9,333 forms x 5 min/60) at a cost of **\$30,139.72** (778 hr x \$38.74/hr).

In aggregate we estimate an annual burden of **2,329 hours** (1,551 + 778 hr) at a cost of **\$162,874.20** (\$132,765.60 + \$30,108.60).

13. Capital Costs

There are no capital costs associated with the standardized format.

14. Cost to Federal Government

There are no additional costs to the Federal Government associated with use of the standardized format. CMS will not collect the completed forms. In terms of the cost to prepare this PRA package, it involved 3 hours at the GS 12 level and 1 hour at the GS 12 step 5 level. Adjusted with locality pay that is \$196.46.

15. Changes to Burden

There is a reduction in burden for this iteration, from 20,707 hours to 2,329 hours. This is due to a smaller number of Part D Parent organizations, as well as built-in efficiencies for facilitation of this information collection. The only changes in cost are answered in the previous Cost to Federal Government section. There were two respondents involved in preparing this PRA package, one at the GS 12 level for 3 hours and one at the GS 12 step 5 level for 1 hour. The costs for this are determined by the opm.gov federal and locality pay scales. Previously this was not required to be calculated for this section.

16. Publication/Tabulation Dates

No publication or tabulation of data expected.

17. Expiration Date

The expiration date is displayed within the Hospice Information for Part D Plans form.

18. Certification Statement

There are no exceptions to the certification statement to be explained.

B. Collections of Information Employing Statistical Methods

This form is neither a survey nor questionnaire for statistical analysis. Rather, the form can be used by Part D sponsors to collect beneficiary-specific drug information so that a determination can be made as to whether the drugs are eligible for coverage under Part D.