

Supporting Statement - Part A
Hospice Information for Medicare Part D Plans
CMS-10538, OCN 0938-New

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).

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 will encourage use of this form as soon as it is approved 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 being nonprofit organizations. 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.

7. Special Circumstances

Not applicable.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on October 3, 2014 (79 FR 59772). Comments were received are attached to this package along with our response. While changes (see attached Crosswalk) have been made in response to the comments, none of the changes affect our burden estimates.

Subsequent to publication of the 60-day Federal Register notice we are making two revisions to the proposed form. We are removing wording that suggests that Part D plan will be required to use the form prior to a regulatory change. We have also changed the title of package to read, “Hospice Information for Medicare Part D Plans,” to be consistent with the form itself. **These revisions are based on internal CMS review and have no effect on our burden estimates.**

9. Payments/Gifts to Respondents

Not applicable.

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)

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

# of Part D Parent Organizations	424 (respondents)
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Gross covered drug costs under Part D for beneficiaries in hospice, CY 2012	\$417.9 million
# paid Part D claims for beneficiaries in hospice, CY 2012	7.2 million
# beneficiaries in hospice with paid Part D claims during the election period	478,647
# of hospice elections for beneficiaries who were on the any of the four categories of drugs identified above (281,764 analgesics; 72,860 antiemetics; 45,452 laxatives; and 59,934 anti-anxiety drugs)	152,632
Estimate of number of PAs required (initial fills of drugs in four categories)	376,487 (responses)
Hourly rate of a pharmacy technician	\$18.33
# of Medicare-participating hospices, CY 2012	3,897
# of Medicare-billing hospices, CY 2012 claims	3,727
Hourly rate of a registered nurse	\$41

We estimate 478,647 unique prescriptions were paid under the Part D benefit for beneficiaries in hospice elections in CY 2012. **376,487 of these 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 proposed 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 (i.e., 376,487 x 0.666 or 248,481) would be completed by a hospice nurse or a nurse in the prescriber’s office and the remainder (376,487 – 248,481 or 128,006) would be completed by the Part D sponsor’s pharmacy technician.**

We estimate the hospice or prescriber nurse would require 5 minutes per prescription to complete the form. The total time for form completion by hospices and prescribers is estimated to be (376,487 x 5 minutes/ 60) = 31,374 hours.

Salary information is from the Bureau of Labor Statistics (BLS) website at: http://www.bls.gov/oes/current/naics4_621600.htm and includes a fringe benefits package worth 30 percent of the base salary. The hourly rate is based on May 2012 BLS data for registered nurses providing home health care services. At \$41 per hour for a registered nurse,

we estimate an annual cost of $(31,374 \text{ hours} \times \$41) = \$1,286,330.58$ for hospices and prescribers to complete the form.

We estimate 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 also 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 376,487 prescriptions. The total time for form completion by the sponsors' pharmacy technicians is estimated to be $(376,487 \times 5 \text{ minutes} / 60) = \text{for a total of } 31,374 \text{ hours}.$

2012 BLS wage statistics report the median hourly wage for a pharmacy technician of \$14.10; with a fringe benefit package worth 30 percent of the base salary, the pharmacy technician rate would be \$18.33. Thus, the total cost to Part D sponsors for form completion would be \$575,083.89 $(31,374 \text{ hours} \times \$18.33 \text{ per hour}.$

The total cost for all entities to complete the form would be \$ 1,861,414.48 annually.

13. Capital Costs

There are no capital costs associated with the standardized format.

14. Cost to Federal Government

Other than development costs, there are no additional costs to the Federal Government associated with use of the standardized format. CMS will not collect the completed forms.

15. Changes to Burden

Not applicable; this is a new collection.

16. Publication/Tabulation Dates

We hope to have this package approved and the final form posted in early 2015.

17. Expiration Date

This collection does not lend itself to the displaying of an expiration date.

18. Certification Statement

No deviations.

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.