

Supporting Statement For Paperwork Reduction Act Submission: Collection of Drug Pricing and Network Pharmacy Data from Medicare Prescription Drug Plans (PDPs and MA-PDs) and Supporting Regulations in 42 CFR 423.48

A. Background

Both stand alone prescription drug plans (PDPs) and Medicare Advantage Prescription Drug (MA-PDs) plans are required to submit drug pricing and pharmacy network data to CMS and these data are made publicly available to people with Medicare through the Medicare Prescription Drug Plan Finder web tool on <http://www.medicare.gov>. Drug prices vary across a plans pharmacy network based on the contracts that each plan negotiates with each pharmacy or pharmacy chain in their networks. The pharmacy networks can change during the course of the year as new pharmacies open, close, change ownership, or plans negotiate new contracts with pharmacies resulting in different dispensing fees for prescriptions. Drug prices also change frequently due to the daily fluctuation of the Average Wholesale Price (AWP), thus plans increase or decrease their drug prices to reflect these changes.

The purpose of the data is to enable prospective and current Medicare beneficiaries to compare, learn, select and enroll in a plan that best meets their needs. The database structure provides the necessary drug pricing and pharmacy network information to accurately communicate plan information in a comparative format.

B. Justification

1. Need and Legal Basis

In the interest of broadly disseminating information that promotes informed decision-making among Part D enrollees and prospective Part D enrollees, as required under Subsection 423.48 of the Prescription Drug Benefit – Title I regulation (Section 1860D-1(c) of the Act), it is required that CMS would extend continue making comparative information about Part D plans' negotiated prices available to beneficiaries through <http://www.medicare.gov>. Section 423.48 of the regulation states:

Each Part D plan must provide, on an annual basis, and in a format and using standard terminology that CMS may specify in guidance, the information necessary to enable CMS to provide to current and potential Part D eligible individuals the information they need to make informed decisions among the available choices for Part D coverage.

We are currently required to provide the following comparative information for qualified prescription drug coverage provided by PDPs and MA-PD plans as part of our dissemination of Part D information and our efforts to promote informed beneficiary decisions:

- Benefits and prescription drug formularies;
- Monthly beneficiary premium;
- Quality and performance;
- Beneficiary cost-sharing; and
- Results of consumer satisfaction surveys.

Secondary to the fluctuating nature of the pricing data and in order to ensure that Medicare beneficiaries have access to the most accurate data possible to make an informed decision regarding their plan selection, CMS requires each plan to submit updated drug pricing and pharmacy network data on a bi-weekly basis. These data are used to populate the Medicare Prescription Drug Plan Finder web tool that is available on the <http://www.medicare.gov> website.

2. Information Users

The data is accessed via the public website, <http://www.medicare.gov>, primarily by Medicare beneficiaries to compare, learn, select and enroll in a plan that best meets their needs. Other individuals accessing the data will be Customer Service Representatives at 1-800-MEDICARE assisting Medicare beneficiaries, caregivers and family members of Medicare beneficiaries, and representatives from community based organizations assisting Medicare beneficiaries with their selection of a Medicare drug plan.

3. Use of Information Technology

All PDPs and MA-PDs are required to submit the drug pricing and pharmacy network data electronically to CMS on a bi-weekly basis. Submission of the data in alternate format is not allowed due to the rapidly fluctuating nature of the data.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

This collection does not impose a significant impact on small businesses and other entities.

6. Less Frequent Collection

Less frequent collection of the drug pricing and pharmacy network data from the PDPs and MA-PDs would result in Medicare beneficiaries not having access to the most current and accurate information necessary to make a plan enrollment decision. The fluctuating nature of the drug pricing data makes it necessary for each plan to submit updated drug pricing and pharmacy network data on a bi-weekly basis to ensure the accuracy of the data represented on the site. Since not all beneficiaries make their selection at the same time, there cannot be an

annual collection of the information. There are always new beneficiaries entering the program, thus bi-weekly submission is needed to convey the correct cost share information.

In an effort to reduce burden to PDPs and MA-PDs, if a plan does not have any pricing adjustments for any given submission, the plan can select a check box indicating that there are no changes on the submission tool. In the case of no updates, the previous bi-weekly submission pricing data will be used.

7. Special Circumstances

Plan drug prices are based on the Average Wholesale Price (AWP), or the price for which payments for drugs are commonly based upon. The AWP fluctuates daily causing frequent changes in the drug pricing for plans. CMS is requiring plans to submit updated drug pricing and pharmacy network data on a bi-weekly basis. This will ensure that the pricing data presented on the <http://www.medicare.gov> website is as accurate as possible for Medicare beneficiaries, but will also provide plans the opportunity to adjust their drug prices according to fluctuations in AWP.

If a plan does not have any pricing adjustments for any given week, they will not have to resubmit their bi-weekly files, instead they will check a box stating that there was no changes to their pricing. In the case of no updates, the previous week's pricing data will be used.

If a plan has had trouble submitting via FTP, they have sent the files to a CMS contractor via secured e-mail system. Once the contractor receives the files, they upload the files using a special log in and password system.

8. Federal Register/Outside Consultation

A 60-day Federal Register was published on July 22, 2008. CMS staff reviewed the draft requirements and answered questions from prospective PDPs and MA-PDs during the weekly User Group call held on Wednesday, May 14, 2008. Final data requirements were posted on <http://www.cms.hhs.gov> on Tuesday, May 6, 2008.

9. Payments/Gifts to Respondents

There are no payments or gifts to respondents for providing information in this collection.

10. Confidentiality

CMS will adhere to all statutes, regulations, and agency policies. Currently plans log in to a secure FTP Internet site using their user ID and password. The system allows submission on, thus plans cannot log on to view their previously submitted data. They can check the results of their submission in the Admin Console. However, ultimately the data gets posted for Public display on <http://www.medicare.gov> on a bi-weekly basis.

11. Sensitive Questions

This information collection request does not contain any questions of a sensitive nature.

12. Burden Estimate (Hours & Wages)

Based on the known information of the process of gathering information, testing data, and submitting the pricing files through the online tool on a bi-weekly basis and factoring in the instances of the plans stating they have no changes, the following information has been determined as an accurate burden estimate.

Estimated Number of Respondents/Plans = 680 PDPs and MA-PDs.

Hourly wage rate for respondents = \$29.75

Frequency of Drug Pricing and Pharmacy Network Data Submission: Bi-weekly (26 weeks / year)

Estimated Per Respondent Burden:

Bi-weekly Hour Burden per Respondent = 4 hrs

Annualized Hour Burden per Respondent = 4 hrs x 26 weeks = 104 hours

Total Annual Responses = 680 respondents x (26 responses/respondent) = 17,680

Estimated Burden Across All Respondents:

Annualized Burden for All Respondents = (680 x 4 hours/bi-week) x 26 weeks = 70,720 hrs

Estimated Annual Cost per Respondent = (4 hours/bi-week x \$29.75) x 26 weeks = \$3,094

13. Capital Costs

There are no capital costs to the respondent. All PDPs and MA-PDs already possess drug pricing and pharmacy network data for the purpose of claim adjudication; therefore, there should be no startup costs for the plans associated with the submission of this data to CMS.

14. Cost to Federal Government

CMS contracts with Destination Rx to collect, maintain and disseminate the Part D pricing data. These costs include Help Desk Operations, Test Submissions, Previews, Processing and disseminating the data, and infrastructure costs.

Data Collection and Support Costs = \$484,000

Data Management and Processing Costs = \$585,000

Bandwidth and Infrastructure Costs = \$100,000

Total Cost to Federal Government = \$1,170,000

Note: In previous the previous submission, this cost estimate was erroneously left out.

15. Changes to Burden

The changes to burden which included both number of respondents, frequency of submission, and hours of burden can be explained as follows:

The number of respondents increased from 350 to 680 due to the growth of the program. The first submission for approval was when the program was just beginning and the registered PDPs and MA-PDs were not at their full potential.

Due to the effort to reduce burden on respondents, the frequency changed from a weekly submission to a bi-weekly submission. This still allows the program to have accurate pricing information for beneficiaries while reducing burden on respondents.

Based on better understanding of the submission process by the plans, the estimated number of hours to collect, verify, and submit data through the online tool changed from 2 hours to 4 hours. There is a chance for respondents to spend a maximum of 5 minutes selecting the “No changes” box to verify that they had no pricing changes compared to the previous bi-weekly submission.

16. Publication/Tabulation Dates

This is a continuous request for information. The collection of the data began July 2005 and will continue bi-weekly indefinitely. The data is updated on the website on a bi-weekly basis to reflect the pricing changes.

17. Expiration Date

CMS would like an exemption from displaying the expiration date on the website as these data feeds are requested on a continuing basis.

18. Certification Statement

There are no exceptions.