

Supporting Statement – Part A
Data Request and Attestation for PDP Sponsors
CMS-10691, OMB 0938-TBD (New)

Background

Section 50354 of the Bipartisan Budget Act of 2018 (BBA) amends section 1860D-4(c) of the Social Security Act by adding a new paragraph (6) entitled “Providing Prescription Drug Plans with Parts A and B Claims Data to Promote the Appropriate Use of Medication and Improve Health Outcome”. Specifically, it provides that the Secretary shall establish a process under which the sponsor of a Prescription Drug Plan (PDP) that provide prescription drug benefits under Medicare Part D may request, beginning in plan year 2020, that the Secretary provide on a periodic basis and in an electronic format standardized extracts of Medicare claims about its plan enrollees.

Section 1860D-4(c)(6)(B), as added by section 50354 of the BBA, further specifies that PDP sponsors receiving such Medicare claims data for their corresponding PDP plan enrollees may use the data for (1) optimizing therapeutic outcomes through improved medication use, (2) improving care coordination so as to prevent adverse healthcare outcomes, such as preventable emergency department visits and hospital readmissions, and (3) for any other purposes determined appropriate by the Secretary.

Finally, section 1860D-4(c)(6)(C) states that the PDP sponsor may not use the data: (1) to inform coverage determinations under Part D, (2) to conduct retroactive review of medically accepted conditions, (3) to facilitate enrollment changes to a different PDP or a MA-PD plan offered by the same parent organization, (4) to inform marketing benefits; and (5) for any other purpose the Secretary determines is necessary to include in order to protect the identity of individuals entitled to or enrolled in Medicare, and to protect the security of personal health information.

This information collection request allows a PDP sponsor to submit a request to CMS for claims data for its enrollees and to attest that it will adhere to the permitted uses and limitations on the use of the Medicare claims data that are listed in 42 CFR 423.153(g)(3) and (4).

A. Justification

1. Need and Legal Basis

As discussed above in the background section, Section 50354 of the BBA requires that the Secretary establish a process for PDP sponsors to submit a request for standardized extracts of claims data for their enrollees. In addition, Section 50354 of the BBA provides for a number of purposes and limitation for the use of the claims data and also permits the Secretary to establish other limitations necessary to protect the identity of individuals entitled to or enrolled in Medicare, and to protect the security of personal health information.

42 CFR 423.153 implements Section 50354 of the BBA.

Specifically, 42 CFR 423.513(g)(1)(i) states that beginning in plan year 2020, a PDP sponsor may submit a request to CMS for the data described in paragraph (g)(2) of this section about enrollees in its prescription drug plans. In addition, 42 CFR 423.513(g)(5) provides that as a condition of receiving the requested data, the PDP sponsor must attest that it will adhere to the permitted uses and limitations on the use of the Medicare claims data listed in paragraphs (g)(3) and (4) of this section.

2. Information Users

The PDP sponsors use this to submit a request for claims data on their enrollees and attest that they understand the requirements around the use of the data, as well as submit a request to stop receiving claims data on their enrollees.

CMS will use this to determine which PDP sponsors requested claims data on their enrollees.

3. Use of Information Technology

We anticipate that the submission of the request, as well as the attestation, will be fully automated (100%). We also anticipate utilizing the Health Plan Management System (HPMS) to submit a request since PDP sponsors already access this system for other actions.

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

We anticipate the request will be fully electronic utilizing HPMS, a system that PDP sponsors already access.

6. Less Frequent Collection

This is an optional collection meaning the PDP sponsor can choose whether to submit a request for claims data on its enrollees. If the collection is not conducted then we will not have a process for PDP sponsors to request data and will therefore have failed to implement Section 50354 of the BBA.

7. Special Circumstances

There are no special circumstances. More specifically, this information collection does not do any of the following:

-Require respondents to report information to the agency more often than quarterly;

- Require respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Require respondents to submit more than an original and two copies of any document;
- Require respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Is connected with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Require the use of 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
- Require respondents to 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

At the time of our proposed rule's (RIN 0938-AT59) publication date (November 1, 2018; 83 FR 54982), we did not finalize the operational aspects of the provisions proposed under §423.153(g). Therefore, we did not set out such burden or request comment in the Collection of Information section of that rule. However, since that time, we have finalized the operational aspects and published a stand-alone 60-day Federal Register notice that set out the requirements and burden associated with the request and attestation (November 30, 2018; 83 FR 61638).

While the stand alone package received a few comments, none of them were related to the PRA or any of our collection of information requirements or burden estimates.

We have realigned the proposed (November 1, 2018) and the stand-alone (November 30, 2018) provisions with the April 16, 2019 (84 FR 15680) final rulemaking by setting out such requirements and burden in that rule.

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents.

10. Confidentiality

There are no assurances of confidentiality provided to respondents.

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimates (Hours & Wages)

Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2018 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 Titles and Wage Rates*

Occupation Title	Occupation Code	Mean Hourly Wage(\$/hr)	Fringe Benefit (\$/hr)	Adjusted Hourly Wage(\$/hr)
Business Operations Specialist	13-1199	37.00	37.00	74.00

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. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Requirements and Associated Burden Estimates

Section 423.153(g)(1)(i) states that beginning in plan year 2020, a PDP sponsor may submit a request to CMS for claims data on enrollees in its prescription drug plans. In addition, §423.153(g)(5) provides that as a condition of receiving the requested data, the PDP sponsor must attest that it will adhere to the permitted uses and limitations on the use of the Medicare claims data. We anticipate that the data request and attestation will be combined into a single submission. We estimate it will take a business operations specialist 1 minute at \$74.00/hr to complete the request for data and the attestation. Currently, there are 63 PDP sponsors and we are including an estimate that would account for all PDP sponsors submitting a request and attestation.

We also estimate that each year –at most 5 PDP sponsors will start requesting CMS claims data for its enrollees. We estimate it will take a business operations specialist 1 minute to complete the request for data and the attestation. We also estimate that each year at most 5 PDP sponsors will request that CMS stop sending claims data for its enrollees. We estimate it will take a business operations specialist 1 minute to submit a request to CMS to stop sending claims data for its enrollees.

Burden Summary

Regulation Section(s)	Summary	No. Respondents	Responses (per Respondent)	Total Responses	Time (per response) (hours)	Total time (hours)	Labor Rate (\$/hr)	Total Cost (\$)
§423.153(g)(1)(i) and 423.153(g)(5)	Initial one-time combined data request and attestation.	63	1	63	1 min (1/60)	1.05	74.00	78
§423.153(g)(1)(i) and 423.153(g)(5)	New one-time combined data request and attestation	5	1	5	1 min (1/60)	0.08	74.00	6
§423.153(g)(1)(i)	Data discontinuation request	5	1	5	1 min (1/60)	0.08	74.00	6
TOTAL		68	--	73	Varies	1.21	74.00	90

Information Collection Instruments and Associated Instructions

Request for Standardized Extracts of Medicare Claims Data for Our Enrollees
 Certify Request for Standardized Extracts of Medicare Claims Data for Our Enrollees

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

We estimate that there will be a one-time cost of approximately \$385,000 for CMS contractors to update the HPMS system.

15. Changes to Burden

This is a new collection. Consequently, there are no changes.

16. Publication/Tabulation Dates

There are no publication/tabulation dates associated with this collection.

17. Expiration Date

This expiration date will be displayed once it becomes available.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collection of Information Employing Statistical Methods

There are no statistical methods.