

Supporting Statement – Part A
Data Request and Attestation for PDP Sponsors
(CMS-10691, OMB 0938-1371)

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).

After requesting claims data for its enrollees and attesting to the permitted uses and limitations of Medicare claims data, PDP sponsors are required to complete basic on-boarding activities before gaining access to Medicare claims data using the Part A and B Claims Data to Part D Sponsors (AB2D) API. This includes:

- Providing basic organizational contact information
- Providing CMS with the Job ID of a practice job run using the AB2D API sandbox/demo environment in order to ensure a basic understanding of and competence with the tool.

- Providing static IP addresses that the PDP sponsor will use to run production AB2D API jobs in order to receive Medicare claims data. This information will be used in a comprehensive CMS security approach in order to protect sensitive beneficiary claims data.

The burden for this package is increasing from 1.21 hours to 36.83 hours due to additional forms and changes in the labor rates.

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. PDP sponsors are also required to complete basic onboarding activities before gaining access to Medicare claims data using the AB2D API.

CMS will use this to determine which PDP sponsors requested claims data on their enrollees and to onboard them to the API.

3. Use of Information Technology

This collection is 100% automated. It takes place within the Health Plan Management System (HPMS). PDP sponsors already have access to HPMS for other actions. For the purposes of this collection, the PDP sponsor representative logs into HPMS and selects “Claims Data Attestation,” a function under Contract Management. The PDP sponsor representative selects the applicable contracts within the “Contracts without Attestation” window. The PDP sponsor representative then clicks the “Attest” button. After the PDP sponsor representative review the Claims Data Usage Protocols, they select the checkbox acknowledging receipt and understanding of the attestation. The PDP Sponsor representative then clicks confirm and exits the application.

After using HPMS to attest to the permitted uses and limitations of Medicare claims data, CMS sends emails to PDP sponsors requesting information for basic on-boarding activities before gaining access to Medicare claims data using the AB2D API. This information is collected through two google forms. The first form collects contact information from the Attestor for a primary technical point of contact or AB2D Data Operations Specialist (ADOS). The second form collects information for on-boarding pre-requisites from the ADOS.

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 have minimized the impact on small businesses by utilizing HPMS, a system that PDP sponsors already access. In addition, the process is 100% automated.

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

The 60-day Federal Register notice published in the Federal Register on 06/29/2022 (87 FR 38760).

No comment were received during the comment period.

The 30-day Federal Register notice published in the Federal Register on 09/29/2022 (87 FR 59098).

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 2021

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)
Chief Executives	11-1011	102.41	102.41	204.82
Database Architect	15-1243	58.58	58.58	117.16

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. The data request and attestation is combined into a single submission. We estimate it will take a Chief Executive 15 minutes at \$204.82/hr to complete the request for data and the attestation. Currently, there are approximately 70 PDP sponsors. While the initial estimate for the PRA package included a request for each of the 63 PDP sponsors to submit a data request and attestation, on an annual basis there are approximately 5 new PDP sponsors that complete a new data request and attestation. PDPs must have an active Attestor to receive data from AB2D API so they are encouraged to submit multiple data request and attestations by Chief Executives to ensure that they do not lose access to the claims data if one Chief Executive leaves the organization. Therefore, we estimate, that each PDP sponsor will at most complete 3 data requests and attestations per organization. In addition to new PDP sponsors, we estimate that existing PDP sponsors may need to update their data request and attestation. For instance, if there are new contracts or if a new PDP sponsor representative joins the organization. We estimate that each

year at most 10 PDP sponsors will need to make updates to their request and attestation and that each PDP sponsor will complete 3 data request and attestation per organization. We estimate it will take a Chief Executive 15 minutes to update 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 Chief Executive 1 minute to submit a request to CMS to stop sending claims data for its enrollees.

After using HPMS to attest to the permitted uses and limitations of Medicare claims data, CMS sends emails to PDP sponsors requesting information for basic on-boarding activities before gaining access to Medicare claims data using the AB2D API. This information is collected through a Google Form. One Google Form is filled out by the Chief Executive and provides contact information for an AB2D Data Operations Specialist (ADOS) who will be their organizations primary technical point of contact for the AB2D API. We estimate it will take the Chief Executive 10 minutes to fill out the information in the form. There will be one response per PDP sponsor. We estimate that there will be an initial submission of 70 forms and then approximately 5 new submissions each year as new PDP Sponsors request access to the API. The second Google Form is completed by the ADOS. We estimate that it will take the ADOS 10 minutes to fill out the information in the form. There will be one response per ADOS. We estimate that there will be an initial submission of approximately 70 new submissions and 5 new submissions each year as new PDP sponsor join.

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)	New one-time combined data request and attestation	15	1	15	15 min	3.75	204.82	768.08
§423.153(g)(1)(i) and 423.153(g)(5)	Update to data request and attestation	30	1	30	15 min	7.5	204.82	1,536.15
§423.153(g)(1)(i)	Data discontinuation request	5	1	5	1 min	0.08	204.82	16.38

Not applicable	Initial one-time ADOS contact form	70	1	70	10 min	11.9	204.8 2	2,437. 36
Not applicable	New ADOS contact information	5	1	5	10 min	.85	204.8 2	174.10
Not applicable	Initial one-time On-boarding pre-requisite form	70	1	70	10 min	11.9	117.1 6	1,394. 20

Not applicable	New On-boarding prerequisite form	5	1	5	10 min	.85	117.16	99.59
TOTAL		200	--	200	Varies	36.83	varies	6,425.86

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 an annual cost of \$75,000 for operations and maintenance costs for the HPMS system.

15. Changes to Burden

The burden to respondents increased from 1.21 hours in the original package to 36.83 in this collection with a cost increase from \$90 to \$6,425.86. This was a total increase of 35.62 hours and a total cost increase of \$6,335.86. The increase in burden hours and cost to respondents are due to various factors. First, while the number of data requests and attestations decreased, the labor rate increased as a Chief Executive must submit a data request and attestation in HPMS. Second, the time to complete a new data request and attestation increased from 1 minute to 15 minutes. The original PRA package estimated the burden since this was a new collection. Now that the collection has been in place, the PRA package is being updated to reflect more accurate estimates of the burden for the collection of information. This increased the hourly burden by 10.09 hours. Third, the PRA package now accounts for updates to existing data request and attestations. The original collection did not account to updates to the data request and attestations. These updates are needed when a contact may leave the PDP sponsor and a new contact must take over the data request and attestation. Finally, there are also two new forms that need to be completed for onboarding activities so the PDP sponsor may gain access to the AB2D API. We also accounted for new requests for onboarding activities in the burden totals. The addition of the two new forms added 25.5 burden hours.

There is also an annual cost to the federal government of \$75,000 for operations and maintenance costs for the HPMS system.

16. Publication/Tabulation Dates

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

17. Expiration Date

This expiration date will be displayed in the Quick Reference Guide in HPMS.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collection of Information Employing Statistical Methods

There are no statistical methods.

