Supporting Statement A for Pharmacy Benefit Manager Transparency for Qualified Health Plans
(CMS-10725/OMB control number: 0938-1394)

A. Background

Implementation of section 1150A of the Social Security Act, as added by section 6005 of the Patient Protection and Affordable Care Act (ACA), requires, among other entities, Qualified Health Plans (QHPs) and pharmacy benefit managers (PBMs) that serve QHP issuers to report information on prescription drug benefits to the U.S. Department of Health and Human Services (HHS). PBMs are third-party administrators of prescription programs for a variety of types of health plans, including QHPs. CMS finalized regulations for this reporting at 45 CFR 156.295 and 184.50.

Under these requirements a QHP issuer is required to report issuer and plan level prescription drug data to CMS only when the QHP issuer does not contract with a PBM to administer the prescription drug benefit for their QHPs. Because Stand-alone Dental Plans (SADPs), which are a subset of QHPs, do not generally include a prescription drug benefit or contract with PBMs, we are not seeking data from them at this time.

Section 1150A(a)(1) of the Social Security Act authorizes CMS to collect the same prescription drug and rebate information from Prescription Drug Plan sponsors of a prescription drug plan and Medicare Advantage organizations offering a Medicare Advantage Prescription Drug Plan under part D of title XVIII. Since 2012, CMS has collected these data from Part D sponsors as part of the Medicare Part D Direct and Indirect Remuneration (DIR) reporting requirement, and detailed drug information for each National Drug Code (NDC) from the Prescription Drug Event (PDE) data that plans are required to submit.[1]

CMS is formally requesting an extension of this ICR in connection with submission from QHP issuers that do not contract with a PBM and PBMs (hereinafter referred to as "submitters"). The information required from submitters and the process of submission has changed since the previous PRA package was approved on 04/30/21. The submitters must now be required to complete a web form that reports the allocation methodology (Appendix C) that is selected by the submitters to allocate data, where necessary. Submitters are required to maintain internal documentation of the allocation methodologies chosen, as CMS may need to follow up with the submitters to better understand the methodology. The burden estimates for the ICR included in this package reflects the time and effort for submitters to provide prescription drug benefit information to CMS using the Health Information Oversight System (HIOS) module.

B. Justification

1. Need and Legal Basis

[1] See 77 FR 22094.

Section 1150A(a)(2) of the Social Security Act grants the Secretary the authority to specify the time, form, and manner of this collection. Under section 1150A, a QHP issuer or an entity that provides pharmacy benefits management services on behalf of a health benefits plan that manages prescription drug coverage under a contract with a QHP offered through an Exchange must report the following data to HHS:

1) The percentage of prescriptions they provide through retail pharmacies compared with mail order pharmacies, and the generic dispensing rate.
2) The aggregate amount, and the type of rebates, discounts or price concessions (excluding bona fide service fees) that the QHP issuer or its contracted PBM negotiates that are attributable to patient utilization under the QHP, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the QHP issuer, and the total number of prescriptions that were dispensed. (Bona fide service fees means fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.)
3) The aggregate amount of the difference between the amount the QHP issuer pays the PBM and the amount that the PBM pays retail pharmacies, and mail order pharmacies (commonly referred to as spread pricing).

Section 1150A(a)(2) extends this reporting requirement to PBMs that contract with QHP issuers to manage prescription drug coverage. This requirement applies to PBMs contracting with QHP issuers in all states, regardless of Exchange type. This requirement does not extend to health plans offered by QHP issuers that are not QHPs. This requirement does not apply to SADPs.

45 CFR 156.295(a) currently requires QHP issuers to submit the data prescribed by section 1150A(a)(2). For PBMs that contract with QHP issuers to manage prescription drug coverage to report the data prescribed by section 1150A(a)(2), it is not currently required to collect from PBMs directly.

2. Information Users

HHS will use this information to understand the cost of prescription drugs and the role that PBMs play in the health care delivery process. This information will be used to inform HHS' regulatory efforts. Specifically, we will use the data to gain insight into the prescription drug supply chain and to inform possible policy with regards to prescription drug coverage, given that prescription drug costs make up an increasingly large part of the overall benefits package. Section 1150A of the of the Social Security Act also authorizes CMS to disclose this information (without identifying a specific PBM, issuer, plan, or prices charged for drugs) to the Government Accountability Office (GAO), Congressional Budget Office (CBO), and the states for the purpose of operating an Exchange and to carry out the Medicare Part D program.

3. Use of Information Technology

Submitters use a web form (Appendix A) to collect summary level data and the data collection

instrument (Appendix B) to submit required information related to prescription benefits via HIOS. The web form is located in the HIOS portal. Registration is required in HIOS to the extent users are not already registered. Submitters use the attestation (Appendix D) to attest to the accuracy, completeness, and truthfulness of the data to the best of their knowledge. Submitters provide the completed data collection instrument in an electronic format. Pursuant to 1150A(d), codified at § 156.295, the provisions of subsection (b)(3)(C) of section 1927 of the Social Security Act apply to submitters that fail to provide this information on a timely basis or that knowingly provides false information.

4. Duplication of Efforts

This information collection does not duplicate any other federal effort, as no other federal entity collects such prescription drug information from QHP issuers or their PBMs. We are also unaware of any state which collects similar prescription drug information for QHP issuers or their PBMs.

We note that section 1150A(a)(1) authorizes CMS to collect the same prescription drug and rebate information from Prescription Drug Plan sponsors of a prescription drug plan and Medicare Advantage organizations offering a Medicare Advantage Prescription Drug Plan under part D of title XVIII. CMS collects these data from Part D sponsors as part of the DIR reporting requirement, and detailed drug information for each NDC from the PDE data that plans are required to submit.

To lessen burden, this collection utilizes CMS's existing collection efforts to the greatest extent possible. CMS collects most of the financial information required by section 1150A at the sponsor level and collects other information for each individual drug at the NDC level.

5. Small Businesses

This information collection will not have a significant impact on small businesses. HHS is unaware that any of the QHP issuers or PBMs required to report these data are small businesses.

6. Less Frequent Collection

Section 1150A of the Social Security Act grants authority to the Secretary to determine the timing and frequency of collecting these prescription drug data. We collect these data on an annual basis. We will continue to reassess this burden and make every effort to minimize burden in the future.

To that end, section 1150A(b)(1) of the Social Security Act requires HHS to collect, in addition to the information described above, prescription drug data further subcategorized by pharmacy type, to include by independent pharmacies, chain pharmacies, supermarket pharmacies, or mass merchandiser pharmacies that are licensed as a pharmacy by the state and that dispenses medication to the general public. It is our understanding that the health insurance industry at large does not currently have an established method to distinguish between pharmacy types at this level. Therefore, we are not yet proposing to collect this information as part of this ICR.

However, we intend to collect this information in the future. Specifically, we request feedback regarding definitions for these categories and any definitions that may be in use of which we are unaware. We also seek feedback regarding whether existing data systems are capable of breaking out drug data at this level, and the potential burden to break data out at this level if not currently possible.

In addition, section 1150A requires the reporting of the percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate). HHS can calculate the generic dispensing rate using the total number of prescriptions dispensed per NDC and will not require QHP issuers or PBMs to calculate this amount as part of the reporting.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

A 60-day notice will be published in the Federal Register on XX/XX/20XX for the public to submit written comment on the information collection requirements.

No additional outside consultation was sought.

9. Payments/Gifts to Respondents

No payments and/or gifts will be provided to respondents.

10. Confidentiality

Section 1150A of the of the Social Security Act requires the Secretary to keep this information confidential and only disclose it to the GAO, CBO, and states for the purpose of operating an Exchange and to carry out the Medicare Part D program. In disclosing these data to these entities, the Secretary is prohibited from disclosing information in a manner that identifies a specific PBM, issuer, plan, or prices charged for drugs. These are the same confidentiality protections applied to the Medicare Part D DIR Reporting requirements. We expect that the data collected will be considered commercial or financial information that is confidential or privileged and is exempt from Freedom of Information Act (FOIA) requests.

The data collected shall not be disclosed by CMS, except in a form which does not disclose the identity of a specific PBM, issuer, plan, or prices charged for drugs for the purposes of carrying out Section 6005 of the PPACA, which added section 1150A to the Act.

11. Sensitive Questions

There are no sensitive questions included in this information collection effort.

12. Burden Estimates (Hours & Wages)

The burden associated with this data collection is attributed to submitters, and the burden estimates were developed based on our previous experience with QHP information reporting activities. The following section contains estimates of the burden imposed by the associated ICRs. Salaries for the positions cited were taken from the Bureau of Labor Statistics (BLS) web site (https://www.bls.gov). For a description of the median hourly wages for the positions see Table 1.

Table 1. Adjusted Hourly Wages Used in Burden Estimates

Occupation Title	Occupational Code	Median Hourly Wage ($/hour)	Fringe Benefits (100%) ($/hour)	Adjusted Hourly Wage ($/hour)
Business Operations Specialist	13-1199	$ 36.53	$36.53	$ 73.06
Computer Systems Analyst	15-1121	$49.15	$49.15	$98.30
Computer Programmer	15-1251	$47.02	$47.02	$94.04
Computer and Information Systems Manager	11-3021	$78.88	$78.88	$157.76
General and Operations Manager	11-1021	$47.16	$47.16	$94.32
Compliance Officer	13-1041	$34.47	$34.47	$68.94
Pharmacy Technician	29-2052	$18.17	$18.17	$36.34
Secretaries and Administrative Assistants	43-6014	$19.71	$19.71	$39.42
Billing and Posting Clerks	43-3021	$20.58	$20.58	$41.16
Chief Executives	11-1011	$91.12	$91.12	$182.24

Across all 50 states and the District of Columbia, we estimate 8 PBMs and 15 issuers that do not contract with a PBM to administer their prescription drug benefit will be subject to this reporting requirement and will need to submit the web form (Appendix A) and the data collection instrument (Appendix B) on an annual basis.

For each reporting submitter, a one-time technical build will be required to implement the changes necessary for this collection, which will involve activities such as planning, assessment, budgeting, contracting, and reconfiguring systems to generate data extracts that conform to this collection's requirements. The total estimated burden is 3,970 hours at a cost of $8,531,840.80 for all respondents. Table 2 displays the burden estimates for the one-time technical build.

Pursuant to 45 CFR 156.295(a) and 184.50(a), it requires PBMs to report prescription drug benefit information related to QHP issuers.

Table 2. Burden per Submitter: One-Time Technical Build

Labor Category	Number of Respondents	Hourly Labor Costs (Hourly rate + 100% Fringe benefits)	Burden Hours	Total Burden Costs (Per Respondent)	Total Burden Cost (All Respondents)
Business Operations Specialist	23	$73.06	500	$36,530.00	$840,190.00
Computer Systems Analyst	23	$98.30	1,300	$127,790.00	$ 2,939,170.00
Computer Programmer	23	$94.04	2,080	$195,603.20	$4,498,873.60
Computer and Information Systems Manager	23	$157.76	40	$6,310.40	$145,139.20
General and Operations Manager	23	$94.32	50	$4,716.00	$108,468.00
Total – One-Time			**3,970**	**$370,949.60**	**$8,531,840.80**

Submitters will be required to complete the web form (Appendix A) and the data collection instrument (Appendix B) each year. The web form collects data aggregated at the QHP issuer level, for all plans and products offered by the QHP issuer combined. The web form also requires the reporting of the allocation methodology (described in Appendix C) that is selected by the submitter to allocate data, where necessary. This requirement was not included in the ICR associated with this collection that we displayed in 2020. As explained in Appendix C, submitters should maintain internal documentation of the allocation methodologies chosen, as CMS may need to follow-up with the submitter to better understand the methodology.

Submitters must prepare and submit one PBM Transparency Collection Data Collection Instrument (Appendix B) per QHP issuer by HIOS ID annually. Each data collection instrument contains information regarding each plan the issuer offers. Submitters must submit data at the HIOS Plan ID level to include financial data elements related to rebates and multiple prescription drug data elements for each NDC (at the 11-digit NDC level using the National Drug Code Directory), for each QHP offered in the requested data submission timeframe. We estimate that a submitter will report information for 5,200 NDCs for each QHP annually. The reports must include the data for all the plans that the QHP issuer offered in their QHPs in the applicable plan year, even if they have no financial information to report for that plan year.

Appendix C provides instruction to submitters on how to report the data. A detailed description of each field in Appendices A and B can be found in Appendix C. As noted previously, to the greatest extent possible, we have attempted to mirror the terminology and definitions already used in the industry to report DIR. We have removed terminology that is not applicable to this collection, including the removal of the bona fide services field, which was included in the ICR

associated with this collection that we displayed in 2020.

Submitters are required to complete the attestation. PBMs must prepare and submit one attestation (Appendix D) per QHP issuer by HIOS ID annually. A QHP issuer that does not contract with a PBM to administer the drug benefit for their QHPs, will be required to complete the QHP issuer attestation (Appendix E) annually.

Each submitter is required to annually compile the data and prepare the required data collection instrument, as well as register an account in HIOS. The total estimated burden is 1,278 hours at a cost of $1,554,207.06 for all respondents. Table 3 displays the burden estimates for the annual submission of prescription benefit information.

Pursuant to 45 CFR 156.295(a) and 184.50(a), it requires PBMs to report prescription drug benefit information related to QHP issuers.

Table 3. Burden per Submitter: Annual Submission of Prescription Benefit Information

Labor Category	Number of Respondents	Hourly Labor Costs (Hourly rate + 100% Fringe benefits)	Burden Hours	Total Burden Costs (Per Respondent)	Total Burden Cost (All Respondents)
Compliance Officer	23	$68.94	570	$ 39,295.80	$ 903,803.40
Pharmacy Technician	23	$36.34	350	$ 12,719.00	$ 292,537.00
Secretaries and Administrative Assistants	23	$39.42	175	$6,898.50	$ 158,665.50
Billing and Posting Clerks	23	$41.16	175	$ 7,203.00	$ 165,669.00
Chief Executives	23	$182.24	8	$ 1,457.92	$ 33,532.16
Total – Annual			**1,278**	**$67,574.22**	**$1,554,207.06**
Total – Three Years			**3,834**	**$202,722.66**	**$4,662,621.18**

We further estimate that these PBMs, taken as a whole, annually contract with 240 QHP issuers, representing around 5,800 total plans. Some of these PBMs will contract with more QHP issuers than others and, as such, the reporting requirement will vary per PBM. We have estimated reporting on an average of 725 plans per PBM each year. We estimate that the 240 QHP issuers will need to identify which plans are QHPs for the PBMs each year. We further estimate that the 15 issuers that do not contract with a PBM represent around 1400 total plans and these issuers will need to identify which plans are QHPs for each year.

An estimated total of 255 QHP issuers (240 QHP issuers who contract with a PBM and 15 issuers that do not contract with a PBM), are required annually to identify which plans are QHPs.

The total estimated burden is 7 hours at a cost of $70,364.70 for all issuers. Table 4 displays the burden estimates for identifying QHP plans.

Pursuant to 45 CFR 156.295(a) and 184.50(a), PBMs must report prescription drug benefit information related to QHP issuers.

Table 4. Burden per QHP Issuer: Identification of QHPs

Labor Category	Number of Respondents	Hourly Labor Costs (Hourly rate + 100% Fringe benefits)	Burden Hours	Total Burden Costs (Per QHP Issuer)	Total Burden Cost (All QHP Issuers)
Secretaries and Administrative Assistants	255	$39.42	7	$275.94	$70,364.70
Total – Annual			**7**	**$275.94**	**$70,364.70**
Total – Three Years			**21**	**$827.82**	**$211,094.10**

Table 5. Summary of Total Annual Burden

Table Number: Name	CFR Section	Burden Hours	Burden Cost
Table 2: Burden per Submitter: One-Time Technical Build	45 CFR § 156.295(a) & 45 CFR § 184.50(a)	3,970	$8,531,840.80
Table 3: Burden per Submitter: Annual Submission of Prescription Benefit Information	45 CFR § 156.295(a) & 45 CFR § 184.50(a)	1,278	$1,554,207.06
Table 4: Burden per QHP Issuer: Identification of QHPs	45 CFR § 156.295(a) & 45 CFR § 184.50(a)	7	$70,364.70
Total		**5,255**	**$10,156,412.56**

13. Capital Costs

There are no anticipated capital costs associated with this information collection.

14. Cost to Federal Government

The anticipated burden to the Federal government for implementing and maintaining this information collection is $1,345,480.84. The calculations for CMS employees' hourly salary was obtained from the OPM website: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2023/GS_h.pdf

Table 6. Administrative Burden Costs for the Federal Government Associated with the PBM Transparency Collections

Task	Estimated Cost
Implementation (One-Time Burden)	
Designing and Implementing PBM module to HIOS	
3 GS-13 (step 7): 3 x $97.22[1] x 60 hours	$17,499.60
Managerial Review and Oversight	
2 GS-15 (step 7): 2 x $135.14[1] x 20 hours	$5,405.60
Costs to add PBM module to HIOS	$613,000.00
Subtotal One-Time Costs	$635,905.20
Maintenance (Annual Burden)	
Receiving and Analyzing Data	
3 GS-13 (step 7): 5 x $97.22[1] x 50 hours	$24,305.00
Managerial Review and Oversight	
2 GS-15 (step 7): 2 x $135.14[1] x 38 hours	$10,270.64
Costs to maintain PBM module to HIOS	$150,000.00
Modification of PBM Module in the HIOS portal	$525,000.00
Subtotal Annual Costs	$709,575.64
Total Costs to Government	**$1,345,480.84**

[1] Hourly basic rate + 100% fringe benefit rate.

15. Changes to Burden

There is an overall decrease in the financial burden from the 2021 PRA package because of a decrease in the number of submitters from 40 to 23 and the number of QHP issuers from 275 to 255. The total burden hours remain the same at 5,255 hours.

16. Publication/Tabulation Dates

Under current statutes, prescription information collected under this ICR will be kept confidential, and may only be disclosed to the GAO, CBO, and states for the purpose of operating an Exchange and to carry out Medicare Part D. In disclosing these data to these entities, the Secretary is prohibited from disclosing information in a manner that identifies a specific PBM, issuer, plan, or prices charged for drugs. Accordingly, the data collected shall not be disclosed by CMS, except in a form which does not disclose the identity of a specific PBM, issuer, plan, or prices charged for drugs for the purposes of carrying out Section 6005 of the PPACA, which added section 1150A to the Act.

17. Expiration Date

The expiration date and OMB control number will appear on the first page of the instrument (top-right corner). The PRA disclosure statement will be included at the bottom of the first page of the instrument.