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

A. Background

The Patient Protection and Affordable Care Act (P.L. 111-148) and the Health Care and Education Reconciliation Act of 2010 (P.L.111-152) (collectively, the Patient Protection and Affordable Care Act (PPACA)) were signed into law in 2010. The PPACA established competitive private health insurance markets, called Marketplaces or Exchanges, which give millions of Americans and small businesses access to qualified health plans (QHPs), including stand-alone dental plans (SADPs) — private health and dental insurance plans that are certified as meeting certain standards.

The PPACA added section 1150A(a)(2) of the Social Security Act, which requires QHP issuers or their pharmacy benefit managers (PBMs) to report prescription drug benefit information to the 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.

The Centers for Medicare and Medicaid Services (CMS) files this information collection request (ICR) in connection with the prescription benefit information that QHP issuers or PBMs must provide to HHS under section 1150A(a)(2). The burden estimate for this ICR reflects the time and effort for QHP issuers and their PBMs to submit the information regarding prescription drugs.

On January 1, 2020, we displayed a 60-day Paperwork Reduction Act package[1] detailing the proposed collection envisioned by section 1150A. We revised this package to respond to comments we received for that package.

B. Justification

1. Need and Legal Basis

Under section 1150A of the Social Security Act, 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

[1] Pharmacy Benefit Manager Transparency. CMS-10725. Available at: https://www.cms.gov/regulations-and-guidancelegislationpaperworkreductionactof1995pra-listing/cms-10725.

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). While we intend to issue regulatory revisions that would require PBMs that contract with QHP issuers to manage prescription drug coverage to report the data prescribed by section 1150A(a)(2), this is not required in order to collect from PBMs directly, as the statute authorizes us to do so. With this revision, a QHP issuer would be required to report the data prescribed by section 1150A(a)(2) only for plan years for which the QHP issuer does not contract with a PBM to manage prescription drug coverage, though we are unaware of any QHP issuer that does not contract with a PBM to manage prescription drug coverage.

2. Information Users

HHS expects to 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. Section 1150A of the of the Social Security Act also authorizes disclosure of 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

QHP issuers and PBMs will 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. The web form will be located on the Health Insurance Oversight System (HIOS) website, and will require registration. QHP issuers and PBMs will use the ation (Appendix D) to attest to the data's accuracy, completeness, and truthfulness to the best of their knowledge. We anticipate that QHP issuers and PBMs will provide the completed data collection instrument in an electronic format.

We note that the 60-day PRA package did not include the web form (Appendix A), and instead sought to collect summary-level data as part of the data collection instrument (Appendix B). We

will collect summary-level data via a web form to reduce burden and to make the submission process more understandable for QHP issuers and PBMs.

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 an Medicare Advantage Prescription Drug Plan under part D of title XVIII. CMS collects this 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.

To lessen burden, this collection will utilize 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. To maintain consistency across CMS collection efforts and minimize burden, we anticipate HHS's collection of this data will use a similar reporting structure and data collection instrument format.

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 this 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 this prescription drug data. We will collect this 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, and invite comments on how to do so without creating unnecessary burden on QHP issuers or PBMs. 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). We believe that 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 was published in the January 28, 2020 Federal Register (85 FR 4993). Six comment letters were received and are included as Attachment 1. We have addressed these comments in Attachment 2.

A 30-day Notice will be published in the Federal Register on September 11, 2020 (85 FR 56227) 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 Government Accountability Office (GAO), Congressional Budget Office (CBO), and states for the purpose of operating an Exchange and to carry out the Medicare Part D program. In disclosing this 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 QHP issuers and PBMs, and the burden estimates were developed based on our previous experience with QHP information reporting activities.

We are unaware of any QHP issuer that does not contract with a PBM to administer their prescription drug benefit. Thus, we do not estimate any burden for a QHP issuer to submit data directly. The following burden estimate reflects our expectation that all data will be submitted by PBMs.

Across all 50 states and the District of Columbia, we estimate approximately 40 PBMs will be subject to this reporting requirement and will need to submit the web form (Appendix A) and the data collection instrument (Appendix B). We further estimate that these PBMs, taken as a whole, annually contract with approximately 275 QHP issuers, representing approximately 7,000 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 175 plans per PBM. We seek comment on the number of PBMs estimated. We estimate that the 275 QHP issuers will need to identify which plans are QHPs for the PBMs.

Each PBM that administers pharmacy benefits for a QHP issuer will be required to complete the web form (Appendix A) and the data collection instrument (Appendix B). The web form will collect data aggregated at the QHP issuer level, for all plans and products offered by the QHP issuer combined. The web form will also require the reporting of the allocation methodology (described in Appendix C) that is selected by the QHP issuer or the PBM to allocate data, where necessary. This requirement was not included in the previous PRA package. 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.

PBMs must prepare and submit one PBM Transparency Collection Data Collection Instrument (Appendix B) per QHP issuer by Health Insurance Oversight System (HIOS) ID. Each data collection instrument will contain information regarding each plan the issuer offers. PBMs must report financial data elements related to rebates, price concessions, and spread pricing at both the QHP issuer and plan level (by National Drug Code (NDC). PBMs will also be responsible for reporting multiple prescription drug data elements for each NDC, for each QHP offered in the requested data submission timeframe. We estimate that an average PBM will report information for 5,200 NDCs for each QHP. The reports must include the data for all of 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 QHP issuers and PBMs 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 previous PRA package. We seek comment on the descriptions in Appendix C.

Additionally, we seek comment on the extent to which PBMs currently have access to the information required to be reported in Appendices A and B. Alternatively, we seek comment on the extent to which the reporting requirement will require PBMs to work closely with their issuers to obtain the information.

Each PBM that administers pharmacy benefits for a QHP issuer will also be required to complete the PBM attestation (Appendix D). PBMs must prepare and submit one attestation (Appendix D) per QHP issuer by HIOS ID. In the event a QHP issuer does not contract with a PBM to administer the drug benefit for their QHPs, each QHP issuer will be required to complete the QHP issuer attestation (Appendix E). If a QHP issuer does contract with a PBM to administer the drug benefit for their QHPs, the QHP issuer will not complete the QHP issuer attestation (Appendix E).

PBM Wage Estimates

The mean hourly wages for the positions of Project Management Specialists and Business Operations Specialist (Occupation Code 13-1198), Computer System Analyst (Occupation Code 15-1121), Computer Programmer (Occupation Code 15-1251), Computer and Information Systems Manager (Occupation Code 11-3021), General and Operations Manager (Occupation Code 11-1021), Compliance Officer (Occupation Code 13-1041), Pharmacy Technician (Occupation Code 29-2052), Secretaries and Administrative Assistants (Occupation Code 43-6014), and Billing and Posting Clerks (Occupation Code 43-3021), and Chief Executives (11-1011) were obtained from the Bureau of Labor Statistics (BLS) Web site: https://www.bls.gov/oes/current/oes_stru.htm. The respective adjusted hourly wage for each Occupational Title is the total of the mean hourly wage of the occupation plus 100% fringe benefit rate of the position, as set out in Table 1, below:

Table 1. Adjusted Hourly Wages for PBMs Used in Burden Estimates

Occupation Title	Occupational Code	Mean Hourly Wage ($/hour)	Fringe Benefits (100%) ($/hour)	Adjusted Hourly Wage ($/hour)
Project Management Specialists and Business Operations Specialist	13-1198	$38.57	$38.57	$77.51
Computer System Analyst	15-1121	$46.23	$46.23	$92.46
Computer Programmer	15-1251	$44.53	$44.53	$89.06
Computer and Information Systems Manager	11-3021	$75.19	$75.19	$150.38
General and Operations Manager	11-1021	$59.15	$59.15	$118.30
Compliance Officer	13-1041	$35.03	$35.03	$70.06
Pharmacy Technician	29-2052	$16.95	$16.95	$33.90

Occupation Title	Occupational Code	Mean Hourly Wage ($/hour)	Fringe Benefits (100%) ($/hour)	Adjusted Hourly Wage ($/hour)
Secretaries and Administrative Assistants	43-6014	$18.84	$18.84	$37.68
Billing and Posting Clerks	43-3021	$19.53	$19.53	$39.06
Chief Executives	11-1011	$93.20	$93.20	$186.40

For each reporting PBM, we anticipate it would take the indicated occupations the approximate hours listed in Table 2 below to make a one-time technical build 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*) burden associated with this one-time technical build is (*rate*) * (*time*) per PBM.

Table 2. Burden per PBM: 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	40	$77.51	500	$38,755.00	$1,550,200
Computer System Analyst	40	$92.46	1,300	$120,198.00	$4,807,920
Computer Programmer	40	$89.06	2,080	$185,244.80	$7,409,792
Computer and Information Systems Manager	40	$150.38	40	$6,015.20	$240,608.00
Operations Manager	40	$118.30	50	$5,915.00	$236,600.00
Total – One-Time			3,970	$356,128.00	$14,245,120

For each plan serviced for the respective issuer by the reporting PBM, we anticipate it would take the indicated occupations the approximate hours listed in Table 3 below to compile the data and to prepare the required data collection instrument. The (*total*) burden associated with this information collection is (*rate*) * (*time*) * (# *plans*), or (*total*) / (# *PBMs*) per PBM.

Table 3. Burden per PBM: 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	40	$70.06	570	$39,934.20	$1,597,368.00
Pharmacy Technician	40	$33.90	350	$11,865.00	$474,600.00
Secretaries and Administrative Assistants	40	$37.68	175	$6,594.00	$263,760.00
Billing and Posting Clerks	40	$39.06	175	$6,835.50	$273,420.00
Chief Executives	40	$186.40	8	$1,491.20	$59,648.00
Total – Annual			1,278	$66,719.90	$2,668,796.00
Total – Three Years			3,834	$200,159.70	$8,006,388.00

Thus, the total estimated annual burden for all PBMs is $2,668,796. This burden estimate will vary by PBM, since each PBM will report for a different number of plans, depending on the issuer. On average, a PBM will report 175 plans, for which the average estimated aggregate burden per PBM is $66,719.90.

QHP Issuer Wage Estimates

The mean hourly wage for the position of Secretaries and Administrative Assistants (Occupation Code 43-6014) was obtained from the Bureau of Labor Statistics (BLS) Web site: https://www.bls.gov/oes/current/oes_stru.htm. The respective adjusted hourly wage for this Occupational Title is the total of the mean hourly wage of the occupation plus 100% fringe benefit rate of the position, as set out in Table 4, below:

Table 4. Adjusted Hourly Wages for QHP Issuers Used in Burden Estimates

Occupation Title	Occupational Code	Mean Hourly Wage ($/hour)	Fringe Benefits (100%) ($/hour)	Adjusted Hourly Wage ($/hour)
Secretaries and Administrative Assistants	43-6014	$18.84	$18.84	$37.68

For each QHP issuer with plans serviced by a reporting PBM, we anticipate it would take the indicated occupations the approximate hours listed in Table 5 below to identify which plans are QHPs for the PBMs. The (*total*) burden associated with this information collection is (*rate*) * (*time*) * (*# plans*), or (*total*) / *(# QHP Issuers*) per QHP issuer.

Table 5. 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	275	$37.68	7	$263.76	$72,534.00
Total – Annual			7	$263.76	$72,534.00
Total – Three Years			21	$791.28	$217,602.00

Thus, the total estimated annual burden for all QHP issuers is $72,534.00. This burden estimate will vary by QHP issuer, since each QHP issuer will need to identify a different number of plans, depending on the issuer. On average, a QHP issuer will identify about 26 plans, for which the average estimated aggregate burden per QHP issuer is $263.76.

Table 6. Total Annual Burden for All Information Collections

Information Collection	Number of Respondents	Number of Responses	Burden Hours	Total Burden Costs (Per Respondent)	Total Burden Costs (All Respondents)
PBM Burden	40	275	1,278	$66,719.90	$2,668,796.00
QHP Issuer Burden	275	275	7	$791.28	$217,602.00

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 $17,494.38. 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/2020/DCB_h.pdf.

Table 7. Administrative Burden Costs for the Federal Government Associated with the PBM Transparency Collections

Task	**Estimated Cost**
Receiving and Analyzing Data	
5 GS-13: 5 x $49.19 x 50 hours	$12,297.50
Managerial Review and Oversight	
2 GS-15: 2 x $68.38 x 38 hours	$5,196.88
Total Costs to Government	$17,494.38

15. Changes to Burden

There are no changes to the burden as this is a new data collection.

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.

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.