

**Supporting Statement for Prescription Drug and Health Care Spending
(CMS-10788/OMB control number 0938-1407)**

A. Background

Title I (No Surprises Act) and Title II (Transparency) of Division BB of the Consolidated Appropriations Act, 2021 (Pub. L. 116-260) (CAA), establish new protections for consumers related to surprise billing and transparency in health care. The Department of Health and Human Services (HHS), the Department of Labor (DOL), and the Department of the Treasury (Treasury) (collectively, the Departments), are responsible for implementation and, along with State regulatory entities, enforcement of these new requirements. These information collection requirements concern the Departments' collection of data related to prescription drug and health care spending required under section 204 of Title II (Transparency) of Division BB of the CAA.

Title II of Division BB was enacted as part of the CAA to promote transparency in health care costs and, particularly, prescription drug costs. Section 204 of the Transparency Title amended the Public Health Service Act (PHS Act), the Employee Retirement Income Security Act of 1974 (ERISA), and the Internal Revenue Code (the Code) by adding new sections that, among other things, authorize the collection of prescription drug and health care spending data from group health plans and health insurance issuers on an annual basis (section 204 data submission). The CAA also requires the Departments to prepare a publicly-available report on prescription drug cost trends. The interim final rules entitled "Prescription Drug and Health Care Spending" (henceforth the 2021 interim final rules) issued by the Departments and the Office of Personnel Management (OPM) specify requirements for group health plans, health insurance issuers, and Federal Employees Health Benefits (FEHB) carriers to submit information regarding prescription drug and health care spending.

Under 5 U.S.C. 8910, OPM must make a continuing study of the operation and administration of the FEHB Program, including surveys and reports on FEHB plans and on the experience of these plans. FEHB carriers are required to furnish reports that OPM finds necessary to properly administer the FEHB Program. Pursuant to its authority under section 8910, OPM has joined the Departments to obtain transparency in FEHB prescription drug and health care spending by requiring FEHB carriers to report information to the Departments, consistent with section 204 of Title II of Division BB of the CAA and the Departments' interim final rules.

The Centers for Medicare & Medicaid Services (CMS) is requesting OMB approval for revisions to the data collection included in this information collection request (ICR).

B. Justification

1. Need and Legal Basis

Section 9825 of the Code, section 725 of ERISA, and section 2799A-10 of the PHS Act require group health plans and health insurance issuers to submit certain information to the Departments about their plan or coverage, including 50 most frequently dispensed brand prescription drugs, the 50 most costly prescription drugs by total annual spending, and the 50 prescription drugs with the greatest increase in plan or coverage expenditures from the preceding plan year. Section

9825 of the Code, section 725 of ERISA, and section 2799A-10 of the PHS Act also require plans and issuers to report total spending on health care services by the plan or coverage broken down by the type of costs (including hospital costs; health care provider and clinical service costs, for primary care and specialty care separately; costs for prescription drugs; and other medical costs, including costs for wellness services); spending on prescription drugs by the plan or coverage as well as by participants, beneficiaries, and enrollees, as applicable; and the average monthly premiums paid by participants, beneficiaries, and enrollees and paid by employers on behalf of participants, beneficiaries, and enrollees, as applicable. Plans and issuers must report rebates, fees, and any other remuneration paid by drug manufacturers to the plan or coverage or its administrators or service providers, including the amount paid with respect to each therapeutic class of drugs and for each of the 25 drugs that yielded the highest amount of rebates and other remuneration under the plan or coverage. Section 9825 of the Code, section 725 of ERISA, and section 2799A-10 of the PHS Act further require plans and issuers to report any reduction in premiums and out-of-pocket costs associated with prescription drug rebates, fees, or other remuneration. Under section 9825 of the Code, section 725 of ERISA, and section 2799A-10 of the PHS Act, plans and issuers must report data by June 1 of each year. Pursuant to 5 U.S.C. 8910 and OPM instruction found in FEHB Carrier Letter 2022-12, FEHB carriers must also report data by June 1 of each year.

Section 9825 of the Code, section 725 of ERISA, and section 2799A-10 of the PHS Act additionally require the Departments to publish on the internet a report (Section 204 public report) on prescription drug reimbursements for plans and coverage, prescription drug pricing trends, and the role of prescription drug costs in contributing to premium increases or decreases under the plans or coverage, with information that is aggregated so that no drug or plan specific information is made public. This Section 204 public report must be published no later than 18 months after the date on which plans and issuers are required to first submit the information and biannually thereafter.¹

This ICR is being revised for 2023 and later reference years to add clarifications in response to questions received from the respondents.

2. Information Uses

The data collected under this ICR will provide the Departments and OPM with a better understanding of prescription drug and health care spending in the United States. This information will also inform the development of the biannual Section 204 public reports that will be published by the Departments.

3. Use of Information Technology

The information related to prescription drug and health care spending, premiums, and enrollment under the plan or coverage will be submitted electronically by plans, issuers, and FEHB carriers to the Departments.

¹ The section 204 public report may not include any confidential or trade secret information submitted pursuant to the reporting requirements.

4. Duplication of Efforts

There is no duplication of efforts for these information collections. The Departments are currently the only agencies with the statutory authority to collect this information.

5. Small Business

We do not anticipate that small businesses will be significantly burdened by this data collection.

6. Less Frequent Collection

The statute requires data to be reported to the Departments annually. A less frequent collection is therefore not a consideration for this information collection.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

CMS published the notice of the revised Prescription Drug and Health Care Spending (RxDC) PRA package in the Federal Register on January 31, 2024 (89 FR 6118). The 60-day comment period closed on April 1, 2024. CMS received four comments on a number of specific issues from industry organizations representing health insurance issuers, third-party administrators, and pharmacy benefit managers. A summary of the comments and the Departments' responses is attached.

9. Payments/Gifts to Respondents

No payments or gifts are associated with these information collections.

10. Confidentiality

Privacy of the information provided will be protected to the extent provided by law.

11. Sensitive Questions

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

12. Burden Estimates (Hours & Wages)

The following subsections of this document contain estimates of the burdens imposed by these data collection requirements. These burdens reflect the time and effort for group health plans, third-party administrators (TPAs), FEHB carriers, and pharmacy benefit managers (PBMs) to collect and submit the prescription drug and health care spending data in the required format to the Departments.

The Departments and OPM used the Contract Awarded Labor Category (CALC)² database tool to derive estimates of costs related to the ICRs. The hourly wages used to derive the cost estimates are presented in Table 1.

TABLE 1: CALC Hourly Wages Used in Burden and Cost Estimates

Occupation:	Hourly Wage Rate
Project Manager/Team Lead	\$110
Scrum Master	\$110
Senior Business Analysis	\$134
Technical Architect/Sr. Developer	\$207
DevOps Engineer/Security Engineer	\$143
Application Developer	\$111

ICRs Regarding Reporting Requirements of Prescription Drug and Health Care Spending for Group Health Plans and Health Insurance Issuers (45 CFR Parts 149.720, 149.730, and 149.740)

The 2021 interim final rules require plans, issuers, and FEHB carriers to annually report certain information regarding prescription drug and health care spending, premiums, and enrollment under the plan or coverage to the Departments. The burden estimates are based on the expected time and effort for reporting entities to prepare and submit the required data. The Departments and OPM assume that for self-funded group health plans the costs will be incurred by TPAs, and that prescription drug information will be submitted by PBMs on behalf of plans, issuers, and FEHB carriers. Costs incurred by TPAs and PBMs are likely to be passed on to plans, issuers, and FEHB carriers. The Departments and OPM acknowledge that some large self-funded plans may report the required information to HHS without the use or assistance of a TPA or other third-party entity. In those instances, the self-funded plan will directly incur the burden and cost to meet the requirements of the 2021 interim final rules. The Departments and OPM also acknowledge that in 2022, which was the first year of implementation, some plans needed to report premium and enrollment information without the use of an issuer, TPA, or other third-party entity. However, it is the Departments’ and OPM’s understanding that in 2024 and beyond, this information will generally be reported by issuers and TPAs.

The Departments and OPM estimate there are 473 health insurance issuers and 46 FEHB carriers offering individual and group health insurance,³ 205 TPAs⁴ (generally submitting on behalf of

² The CALC tool (<https://calc.gsa.gov/>) was built to assist acquisition professionals with market research and price analysis for labor categories on multiple U.S. General Services Administration (GSA) & Veterans Administration (VA) contracts. Wages obtained from the CALC database are fully burdened to account for fringe benefits and overhead costs.

³ Based on data from MLR annual reports for the 2019 MLR reporting year, available at <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr>.

⁴ Estimates for Non-issuer TPAs are based on data derived from the 2016 Benefit Year reinsurance program contributions.

self-funded group health plans), and 66 PBMs⁵ (submitting on behalf of plans, issuers, and FEHB carriers) that will submit the required data annually.

For issuers and FEHB carriers, the Departments and OPM estimate that in 2024, each issuer and FEHB carrier will incur ongoing annual costs related to ensuring submission accuracy, providing quality assurance, conducting maintenance and making updates, enhancing or updating any needed security measures, and submitting the required data to the Departments. The Departments and OPM estimate that for each issuer and FEHB carrier it will take Project Managers/Team Leads 520 hours (at \$110 per hour), Scrum Masters 260 hours (at \$110 per hour), Senior Business Analyst 40 hours (at \$134 per hour), Technical Architects/Sr. Developers 520 hours (at \$207 per hour), Application Developers 260 hours (at \$111 per hour), and DevOps Engineers/Security Engineers 260 hours (at \$143 per hour) to perform these tasks. The total annual burden for each issuer and FEHB carrier will be 1,860 hours, with an equivalent cost of approximately \$264,840. For all 519 issuers and FEHB carriers, the total annual maintenance and reporting burden is estimated to be 965,340 hours with an equivalent total cost of approximately \$137,451,960. The Departments and OPM consider this to be an upper-bound estimate and expect maintenance costs to decline in succeeding years as issuers and FEHB carriers gain efficiencies and experience in updating, managing, and submitting the required data. The total annual burden for all respondents is also likely overestimated because the estimate does not reflect process efficiencies for FEHB carriers that are also issuers. As HHS, DOL, the Department of the Treasury, and OPM share jurisdiction, HHS will account for 45 percent of the burden, or approximately 434,403 burden hours with an equivalent cost of approximately \$61,853,382.

TABLE 2: Estimated Annual Burden and Costs for Issuers and FEHB Carriers in the Individual and Group Markets to Update and Maintain Needed IT Systems and Submit Required Data

Estimated Number of Respondents	Estimated Number of Responses	Burden Per Response (hours)	Total Estimated Annual Burden (Hours)	Total Estimated Labor Cost (\$)
234	234	1,860	434,403	\$61,853,382

For TPAs, the Departments and OPM estimate that in 2024, each TPA will incur ongoing annual costs related to ensuring submission accuracy, providing quality assurance, conducting maintenance and making updates, enhancing or updating any needed security measures, and submitting the required data to the Departments. The Departments and OPM estimate that for each TPA it will take Project Managers/Team Leads 520 hours (at \$110 per hour), Scrum Masters 260 hours (at \$110 per hour), Senior Business Analysts 40 hours (at \$134 per hour), Technical Architects/Sr. Developers 520 hours (at \$207 per hour), Application Developers 260 hours (at \$111 per hour), and DevOps Engineers/Security Engineers 260 hours (at \$143 per hour) to perform these tasks. The total annual burden for each TPA will be 1,860 hours, with an equivalent cost of approximately \$264,480. For all 205 TPAs, the total annual ongoing maintenance and reporting burden is estimated to be 381,300 hours with an equivalent total cost

⁵ Source: National Association of Insurance Commissioners, last updated on June 1, 2023. Available at https://content.naic.org/cipr_topics/topic_pharmacy_benefit_managers.htm.

of approximately \$54,292,200. The Departments and OPM consider this to be an upper-bound estimate and expect maintenance costs to decline in succeeding years as TPAs gain efficiencies and experience in updating, managing, and submitting the required data. As HHS, DOL, the Department of the Treasury, and OPM share jurisdiction, HHS will account for 45 percent of the burden, or approximately 171,585 burden hours with an equivalent cost of approximately \$24,431,490.

TABLE 3: Estimated Annual Burden and Costs for TPAs to Update and Maintain Needed IT Systems and Submit Required Data

Estimated Number of Respondents	Estimated Number of Responses	Burden Per Response (hours)	Total Estimated Annual Burden (Hours)	Total Estimated Labor Cost (\$)
92	92	1,860	171,585	\$24,431,490

For PBMs, the Departments and OPM estimate that in 2024, each PBM will incur ongoing annual costs related to ensuring submission accuracy, providing quality assurance, conducting maintenance and making updates, enhancing or updating any needed security measures, and submitting the required data to the Departments. The Departments and OPM estimate that for each PBM it will take Project Managers/Team Leads 520 hours (at \$110 per hour), Scrum Masters 260 hours (at \$110 per hour), Senior Business Analysts 40 hours (at \$134 per hour), a Technical Architects/Sr. Developers 520 hours (at \$207 per hour), Application Developers 520 hours (at \$111 per hour), and DevOps Engineers/Security Engineers 260 hours (at \$143 per hour) to perform these tasks. The Departments and OPM estimate the total annual burden for each PBM will be 2,120 hours, with an equivalent cost of approximately \$293,700. For all 66 PBMs, the total annual maintenance and submission burden is estimated to be 139,920 hours with an equivalent total cost of approximately \$19,384,200. The Departments and OPM consider this to be an upper-bound estimate and expect maintenance costs to decline in succeeding years as PBMs gain efficiencies and experience in updating, managing, and submitting the required data. As HHS, the DOL, the Department of the Treasury, and OPM share jurisdiction, HHS will account for 45 percent of the burden, or approximately 62,964 hours, with an equivalent cost of approximately \$8,722,890.

TABLE 4: Estimated Annual Burden and Costs for PBMs to Update and Maintain Needed IT Systems and Submit Required Data

Estimated Number of Respondents	Estimated Number of Responses	Burden Per Response (hours)	Total Estimated Annual Burden (Hours)	Total Estimated Labor Cost (\$)
30	30	2,120	62,964	\$8,722,890

The total annual burden for all 356 issuers, FEHB carriers, TPAs, and PBMs to update and maintain needed IT systems and submit required data is estimated to be 668,952 hours with an equivalent cost of approximately \$95,007,762.

TABLE 5: Estimated Annual Burden and Costs for Issuers, FEHB Carriers, TPAs, and PBMs to Update and Maintain Needed IT Systems and Submit Required Data

Audience	Estimated Number of Respondents	Estimated Number of Responses	Burden Per Response (hours)	Total Estimated Annual Burden (Hours)	Total Estimated Labor Cost (\$)
Issuers and FEHB Carriers	234	234	1,860	434,403	\$61,853,382
TPAs	92	92	1,860	171,585	\$24,431,490
PBMs	30	30	2,120	62,964	\$8,722,890
Total	356	356		668,952	\$95,007,762

13. Capital Costs

There are no additional capital costs associated with these ICRs.

14. Cost to Federal Government

HHS will incur costs of approximately \$4.2 million in 2024 to update and maintain a system to receive, store, and analyze the information submitted by issuers, FEHB carriers, TPAs, and PBMs and to prepare the section 204 public reports. This includes costs to the Centers for Medicare and Medicaid Services and the Office of the Assistant Secretary for Planning and Evaluation.

15. Changes to Burden

Burden hours have decreased from 1,684,080 hours to 668,952 hours. The three-year average burden has been updated to remove the one-time first- and second-year implementation burdens that were incurred only in 2022 and 2023. Reporting instructions (document title: RxDC Reporting Instructions) have been revised to add clarifications in response to comments and questions from the respondents; however, these revisions did not result in a burden hour change.

16. Publication/Tabulation Dates

The data collected will be used by the Secretary of HHS to prepare a publicly-available report. Section 9825 of the Code, section 725 of ERISA, and section 2799A-10 of the PHS Act, which require this data collection, also require the Departments to publish on the internet a report on prescription drug reimbursements for plans and coverage, prescription drug pricing trends, and the role of prescription drug costs in contributing to premium increases or decreases under the plans or coverage. Following initial publication, this public report will be published biannually.

17. Expiration Date

The expiration date and OMB control number will appear on the first page of the instrument (top-right corner).

18. Certification Statement

There are no exceptions to the certification statement.

ATTACHMENT:
RxDC Reporting Instructions for 2023