

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

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. This information collection concerns the 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 amends the Public Health Service Act (PHS Act), the Employee Retirement Income Security Act of 1974 (ERISA), and the Internal Revenue Code (the Code) to, 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. section 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.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act, HHS has submitted the following for emergency review to the Office of Management and Budget (OMB). We are requesting emergency review and approval of the information collection requests (ICRs) related to the provisions of section 2799A-10 of the PHS Act, as enacted by section 204 of Title II of Division BB of the CAA. In accordance with 5 CFR 1320.13(a)(2)(i) and 5 CFR 1320.13(a)(2)(iii), we believe that public harm is likely to result and the collection of information is likely to be delayed if the standard, non-emergency clearance procedures are followed.

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 the plan or coverage, as well as the information about the 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 also 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.

Section 9825 of the Code, section 725 of ERISA, and section 2799A-10 of the PHS Act require plans and issuers to report data no later than 1 year after the date the CAA was enacted, and not later than June 1 of each year thereafter. The Departments interpret these statutory provisions to require plans and issuers to submit calendar year 2020 information by December 27, 2021, calendar year 2021 information by June 1, 2022, calendar year 2022 information by June 1, 2023, and so forth.

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

2. Information Uses

The reporting requirements in these interim final rules will provide the Departments and OPM

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

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.

4. Duplication of Efforts

There is no duplication of efforts for these ICRs.

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

The 2021 interim final rules with requests for comment will be published on November 23, 2021 (86 FR 66662).

The Departments and OPM published a Request for Information in the June 23, 2021 Federal Register (86 FR 32813). The Departments also held several listening sessions with employers, group health plans, issuers, and pharmacy benefit managers (PBMs) to gather public input. OPM also held a listening session with FEHB carriers. The Departments further consulted with stakeholders through regular contact with states, issuers, plans, trade groups, employers, and other interested parties. The Departments and OPM considered all public input received in the development of the 2021 interim final rules.

9. Payments/Gifts to Respondents

No payments or gifts are associated with these ICRs.

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 ICRs. These burdens reflect the time and effort for group health plans, third-party administrators (TPAs), FEHB carriers and 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 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

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.

may seek to make needed information technology (IT) changes and 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 assume that all costs will be incurred in 2022 and beyond.

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

In 2022, reporting entities will incur a one-time cost to make changes to their IT systems to include the development of programs, processes, and systems for reporting the data. In 2023 and beyond, each entity will incur annual costs to update and maintain reporting capabilities and to report the required data to the Departments.

For issuers and FEHB carriers, the Departments and OPM estimate that in 2022, each issuer and FEHB carrier will incur a one-time first-year cost and hour burden to design, develop, and implement needed IT systems changes to collect and submit the required data to the Departments as set forth in the 2021 interim final rules, including obtaining information on employer and employee premium contributions from employers offering group health coverage. The Departments and OPM estimate that for each issuer and FEHB carrier, on average, it will take Project Managers/Team Leads 2,080 hours (at \$110 per hour), Scrum Masters 1,560 hours (at \$110 per hour), Senior Business Analysts 1,040 hours (at \$134 per hour), Technical Architects/Sr. Developers 2,080 hours (at \$207 per hour), Application Developers 2,080 hours (at \$111 per hour), and DevOps Engineers/Security Engineers 520 hours (at \$143 per hour) to complete this task. The Departments and OPM estimate the total burden per issuer and FEHB carrier will be approximately 9,360 hours, with an equivalent cost of approximately \$1,275,560. For all 519 issuers and FEHB carriers, the total first-year burden is estimated to be 4,857,840 hours with an equivalent total cost of approximately \$662,015,640.

In addition to the one-time first-year cost and burden, issuers and FEHB carriers will incur an additional one-time cost and burden in the second year of implementation to maintain and update their IT systems and to submit 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 Analysts 260 hours (at \$134 per hour), 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 second-year burden for each issuer or FEHB carrier will be 2,340 hours, with an equivalent cost of approximately \$323,180. For all 519 issuers and FEHB carriers, the total one-time second-year implementation and reporting burden is estimated to be 1,214,460 hours with an

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.

⁵ Source: National Association of Insurance Commissioners, last updated on March 16, 2021. Available at https://content.naic.org/cipr_topics/topic_pharmacy_benefit_managers.htm.

equivalent total cost of approximately \$167,730,420. The cost and burden associated with the second year will be incurred in 2023.

In addition to the one-time first-year and second-year costs and burdens, issuers, and FEHB carriers will incur ongoing annual costs, to be incurred from 2024 onward, 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 Departments and OPM estimate the three-year average annual total burden for all 519 issuers and FEHB carriers to develop, build, and maintain needed IT systems changes to collect and aggregate the required data, and submit that data to the Departments, will be 2,345,880 hours with an average annual total cost of \$322,399,340. The total annual burden for all respondents is 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 1,055,646 burden hours with an equivalent cost of approximately \$145,079,703.

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

Year	Estimated Number of Respondents	Estimated Number of Responses	Burden Per Response (hours)	Total Estimated Annual Burden (Hours)	Total Estimated Labor Cost (\$)
2022	234	234	9,360	2,186,028	\$297,907,038
2023	234	234	2,340	546,507	\$75,478,689
2024	234	234	1,860	434,403	\$61,853,382
Three-year average	234	234	4,520	1,055,646	\$145,079,703

For TPAs, the Departments and OPM estimate that in 2022, each TPA will incur a one-time first-year cost and burden to design, develop, and implement needed IT systems changes to collect and submit, generally on behalf of self-funded group health plans, the data required under the

2021 interim final rules, including obtaining information on employer and employee premium contributions from employers offering group health coverage. The Departments and OPM estimate that for each TPA, on average, it will take Project Managers/Team Leads 2,080 hours (at \$110 per hour), Scrum Masters 1,560 hours (at \$110 per hour), Senior Business Analysts 1,040 hours (at \$134 per hour), Technical Architects/Sr. Developers 2,080 hours (at \$207 per hour), Application Developers 2,080 hours (at \$111 per hour), and DevOps Engineers/Security Engineers 520 hours (at \$143 per hour) to complete this task. The Departments and OPM estimate the total burden per TPA will be approximately 9,360 hours, with an equivalent cost of approximately \$1,275,560. For all 205 TPAs, the total one-time first-year implementation and reporting burden is estimated to be 1,918,800 hours with an equivalent total cost of approximately \$261,489,800.

In addition to the one-time first-year cost and burden, TPAs will incur an additional one-time cost and burden in the second year of implementation to maintain and update their IT systems and to submit the 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 260 hours (at \$134 per hour), 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 total second-year burden for each TPA will be 2,340 hours, with an equivalent cost of approximately \$323,180. For all 205 TPAs, the total one-time second-year implementation and reporting burden is estimated to be 479,700 hours with an equivalent total cost of approximately \$66,251,900. The cost and burden associated with the second year will be incurred in 2023.

TPAs will also incur ongoing annual costs, in 2024 and subsequent years, 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 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.

The Departments and OPM estimate the 3-year average annual total burden for all 205 TPAs to develop, build, and maintain needed IT systems changes to collect and aggregate the required data, and submit that data to the Departments, will be 926,600 hours with an average annual total cost of \$127,344,633. As HHS, DOL, the Department of the Treasury, and OPM share jurisdiction, HHS will account for 45 percent of the burden, or approximately 416,970 burden hours with an equivalent cost of approximately \$57,305,085.

TABLE 3: Estimated Annual Burden and Costs for TPAs to Develop and Maintain Needed IT Systems Changes 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 (\$)
2022	92	92	9,360	863,460	\$117,670,410
2023	92	92	2,340	215,865	\$19,813,355
2024	92	92	1,860	171,585	\$24,431,490
Three-year Average	92	92	4,520	416,970	\$57,305,085

For PBMs, the Departments and OPM estimate that in 2022, each PBM will incur a one-time first-year cost and burden to design, develop, and implement needed IT systems changes to collect and submit, on behalf of plans and issuers, the data required under the 2021 interim final rules. The Departments and OPM estimate that for each PBM, on average, it will take Project Managers/Team Leads 2,080 hours (at \$110 per hour), Scrum Masters 2,080 hours (at \$110 per hour), Senior Business Analysts 1,560 hours (at \$134 per hour), Technical Architects/Sr. Developers 2,080 hours (at \$207 per hour), Application Developers 4,160 hours (at \$111 per hour), and DevOps Engineers/Security Engineers 780 hours (at \$143 per hour) to complete this task. The Departments and OPM estimate the total burden per PBM will be approximately 12,740 hours, with an equivalent cost of approximately \$1,670,500. For all 66 PBMs, the total one-time first-year implementation and reporting burden is estimated to be 840,840 hours with an equivalent total cost of approximately \$110,253,000.

In addition to the one-time first-year cost and burden, PBMs will incur additional one-time cost and burden in the second year of implementation to maintain and update their IT systems and to submit the required data to the Departments. The Departments and OPM estimate that for each PBM it will take Project Managers/Team Leads 1,040 hours (at \$110 per hour), Scrum Master 1,040 hours (at \$110 per hour), Senior Business Analysts 780 hours (at \$134 per hour), Technical Architects/Sr. Developers 1,040 hours (at \$207 per hour), Application Developers 2,340 hours (at \$111 per hour), and DevOps Engineers/Security Engineers 260 hours (at \$143 per hour) to perform these tasks. The total second-year burden for each PBM will be 6,500 hours, with an equivalent cost of approximately \$845,520. For all 66 PBMs, the total one-time second-year implementation and reporting burden is estimated to be 429,000 hours with an equivalent total cost of approximately \$55,804,320.

In addition to the one-time first-year and second-year costs and burdens, PBMs 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.

The Departments and OPM estimate the three-year average annual total burden for all 66 PBMs to develop, build, and maintain needed IT systems changes to collect and aggregate the required data, and submit that data to the Departments, will be 469,920 hours with an average annual total cost of \$61,813,840. As HHS, the DOL, the Department of the Treasury, and OPM share jurisdiction, HHS will account for 45 percent of the burden, or approximately 211,464 hours, with an equivalent cost of approximately \$27,816,228.

TABLE 4: Estimated Annual Burden and Costs for PBMs to Develop and Maintain Needed IT Systems Changes 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 (\$)
2022	30	30	12,740	378,378	\$49,613,850
2023	30	30	6,500	193,050	\$25,111,944
2024	30	30	2,120	62,964	\$8,722,890
Three-year Average	30	30	7,120	211,464	\$27,816,228

The total annual burden for all 356 issuers, FEHB carriers, TPAs, and PBMs to develop and maintain needed IT systems changes and submit required data is estimated to be 1,684,080 hours with an equivalent cost of approximately \$230,201,016.

TABLE 5: Estimated Annual Burden and Costs for Issuers, FEHB Carriers, TPAs, and PBMs to Develop and Maintain Needed IT Systems Changes 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 (\$)
Issuers and FEHB Carriers	234	234	4,520	1,055,646	\$145,079,703
TPAs	92	92	4,520	416,970	\$57,305,085
PBMs	30	30	7,120	211,464	\$27,816,228
Total	356	356		1,684,080	\$230,201,016

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 million in 2021, \$5.6 million in 2022 and \$4.6 million in 2023 to build 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. The average cost over 3 years is approximately \$4.7 million.

15. Changes to Burden

This is a new information collection request.

16. Publication/Tabulation Dates

The data collected will be used by the Secretary of HHS to prepare a publicly-available report.

17. Expiration Date

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

ATTACHMENT:

RxDC Section 204 Reporting Instructions