



**OFFICE OF PERSONNEL MANAGEMENT**  
**5 CFR Part 890**  
**RIN 3206-AO27**

**DEPARTMENT OF THE TREASURY**  
**Internal Revenue Service**  
**26 CFR Part 54**  
**RIN 1545-BQ10**

**DEPARTMENT OF LABOR**  
**Employee Benefits Security Administration**  
**29 CFR Part 2590**  
**RIN 1210-AC07**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**45 CFR Part 149**  
**[CMS-9905-NC]**  
**RIN 0938-AU66**

**Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs**

**AGENCY:** Office of Personnel Management; Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

**ACTION:** Request for information.

**SUMMARY:** This document is a request for information on issues related to certain reporting requirements under section 204 of Title II of Division BB of the Consolidated Appropriations Act, 2021 (CAA) that are applicable to group health plans and health insurance issuers offering group or individual health insurance coverage. The Departments of Health and Human Services, Labor, and the Treasury (the Departments) are issuing this request for information to gather input from the public regarding implementation considerations for the data collection required under section 204 of Title II of Division BB of the CAA, and the associated impact on group health plans and health insurance issuers. As part of this request for information, the Office of

Personnel Management (OPM) is also seeking input from the public regarding implementation considerations for the data collection required under section 204 of Title II of Division BB of the CAA as it pertains to Federal Employees Health Benefits (FEHB) carriers (whether or not they are also health insurance issuers). The Departments and OPM also seek input on specific data elements, including the level of detail that is feasible to report for entities subject to the data collection requirements and the associated burdens and potential compliance costs. Public comments will inform the Departments' and OPM's implementation of section 204 through rulemaking and the establishment of processes to receive the required information.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [Insert date 30 days after date of publication in the **Federal Register**].

**ADDRESSES:** Written comments may be submitted to the addresses specified below. Any comment that is submitted will be shared among the Departments and OPM. Please do not submit duplicates.

Comments will be publicly posted on Regulations.gov. Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. Comments may be submitted anonymously.

In commenting, refer to file code CMS-9905-NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <https://www.regulations.gov/>. Follow the "Submit a comment" instructions.
2. By regular mail. You may mail written comments to the following address **ONLY**:

Office of Health Plan Standards and Compliance Assistance

Employee Benefits Security Administration

US Department of Labor

Attention: Request for Information Regarding Reporting on Pharmacy Benefits and

Prescription Drug Costs

200 Constitution Avenue NW, Room N-5653

Washington, DC 20210

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Office of Health Plan Standards and Compliance Assistance

Employee Benefits Security Administration

US Department of Labor

Attention: Request for Information Regarding Reporting on Pharmacy Benefits and

Prescription Drug Costs

200 Constitution Avenue NW, Room N-5653

Washington, DC 20210

For information on viewing public comments, see the beginning of the SUPPLEMENTARY INFORMATION section.

**FOR FURTHER INFORMATION CONTACT:** Rina Shah, Office of Personnel Management, at (202) 606-0004.

Christopher J. Dellana, Internal Revenue Service, Department of the Treasury, at (202) 317-5500.

Matthew Litton, Employee Benefits Security Administration, Department of Labor, at (202) 693-8335.

Christina Whitefield, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at (301) 492-4172.

Customer Service Information:

Individuals interested in obtaining information from the Department of Labor (DOL) concerning employment-based health coverage laws may call the Employee Benefits Security Administration (EBSA) Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the DOL's website ([www.dol.gov/agencies/ebsa](http://www.dol.gov/agencies/ebsa)). In addition, information from the Department of Health and Human Services (HHS) on private health insurance coverage and non-Federal governmental group health plans can be found on the Centers for Medicare & Medicaid Services (CMS) website ([www.cms.gov/ccio](http://www.cms.gov/ccio)), and information on health care reform can be found at [www.HealthCare.gov](http://www.HealthCare.gov). Information from OPM on Federal Employees Health Benefits (FEHB) plans can be found on the OPM website ([www.opm.gov/healthcare-insurance](http://www.opm.gov/healthcare-insurance)).

**SUPPLEMENTARY INFORMATION:**

Inspection of Public Comments: Comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. Comments received before the close of the comment period are posted on the following web site as soon as possible after they have been received: <https://www.regulations.gov/>. Follow the search instructions on that web site to view public comments.

**I. Background**

*A. Purpose*

In recent years, there has been a broad effort toward promoting greater price transparency in health care as a means to promote competition and bring down overall costs. Section 204 of Title II of Division BB of the CAA added parallel provisions at section 2799A-10 of the Public Health Service Act (PHS Act), section 725 of the Employee Retirement Income Security Act of 1974 (ERISA), and section 9825 of the Internal Revenue Code (Code). These provisions include

certain reporting requirements for group health plans (plans) and health insurance issuers offering group or individual health insurance coverage (issuers). The reporting requirements primarily relate to prescription drug expenditures, requiring that plans and issuers submit the relevant information to the Departments. The provisions also require the Departments to issue biannual public reports on prescription drug reimbursements under group health plans and individual health insurance coverage, prescription drug pricing trends, and the impact of prescription drug costs on premium rates, aggregated in such a way so that no drug or plan specific information will be made public.

Title I of Division BB also amended 5 U.S.C. 8902(p) to include specified provisions of the CAA into FEHB carrier contracts. Although section 204 is not enumerated as a specified provision in section 8902(p), FEHB carrier compliance with the Departments' collection pursuant to this section helps accomplish the CAA's intended purpose of achieving national health data transparency and lower costs. Therefore, references to "plans" for purposes of this request for information include FEHB health benefits plans.

The Departments and OPM are requesting input from the public regarding implementation of the data collection, the data elements to be collected, and the associated impact on plans and issuers. Public input will inform the Departments' and OPM's implementation through rulemaking and establishment of processes to receive the information that must be reported. Using the information obtained through this data collection, the Departments and OPM intend to analyze trends in overall spending on prescription drugs and other health care services by plans and issuers and to publish the analysis in the required reports in a format that the Departments and OPM intend to enable plans and issuers to ultimately negotiate fairer rates and lower costs for participants, beneficiaries, and enrollees.

#### *B. Reporting Requirements*

By December 27, 2021, and not later than June 1 of each year thereafter, plans and issuers must submit to the Departments certain information with respect to the health plan or

coverage for the previous plan year. This includes general information on the plan or coverage, such as the beginning and end dates of the plan year, the number of participants, beneficiaries, or enrollees, as applicable, and each state in which the plan or coverage is offered. Plans and issuers must also report the 50 most frequently dispensed brand prescription drugs, and the total number of paid claims for each such drug; the 50 most costly prescription drugs by total annual spending, and the annual amount spent by the plan or coverage for each such drug; and the 50 prescription drugs with the greatest increase in plan expenditures over the plan year preceding the plan year that is the subject of the report, and, for each such drug, the change in amounts expended by the plan or coverage in each such plan year. Additionally, plans and issuers must report total spending by the plan or coverage broken down by the type of health care 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 from drug manufacturers during the plan year. Finally, plans and issuers must report any reduction in premiums and out-of-pocket costs associated with these rebates, fees, or other remuneration.

### *C. Public Report and Privacy Protections*

Not later than 18 months after the date on which plans and issuers must first submit the information described in section B and biannually thereafter, the Departments and OPM will publish on the internet reports on prescription drug reimbursements under group health plans and group and individual health insurance coverage, prescription drug pricing trends, and the role of prescription drug costs in contributing to premium increases or decreases under such plans or coverage, aggregated so that no drug or plan specific information is made public. Furthermore,

these reports will not include any confidential or trade secret information submitted pursuant to the reporting requirements of PHS Act section 2799A-10, ERISA section 725, and Code section 9825.

## **II. Solicitation of Comments**

The Departments and OPM request comments from all interested stakeholders to gain a better understanding of the issues related to compliance with this provision, including reporting on premiums, enrollment, pharmacy drug benefits, and prescription drug costs, and to estimate the impact of any potential rules, both generally and with respect to the following specific areas:

### *A. General Implementation Concerns*

1. What, if any, challenges do plans and issuers anticipate facing in meeting the statutory reporting obligations? For example, do plans or issuers currently have access to all the information they are required to report under PHS Act section 2799-10, ERISA section 725, and Code section 9825? If not, which statutory data elements are not readily accessible to plans and issuers, and how could plans and issuers obtain the information necessary to comply with the reporting requirements? Are there ways in which the Departments and OPM could structure the reporting requirements to facilitate compliance?
2. Are FEHB carriers (including those that are also issuers) able to report data separately for each FEHB plan?
3. After the Departments and OPM finalize rulemaking and publish the reporting format and instructions, how much time will plans and issuers need to prepare their data and submit it to the Departments and OPM? What data sources are readily available and which data may take longer to compile? Are there operational, formatting, or technical considerations that the Departments and OPM should be aware of that may impact plans' and issuers' abilities to meet the statutory deadline for reporting?

4. Are there different considerations regarding data reporting by health insurance issuers versus group health plans that would affect their ability to comply with the statutory reporting obligations? Among group health plans, are there different considerations for reporting by fully-insured versus self-insured plans, or for insured plans with small group versus large group coverage? Are there different considerations for reporting FEHB carrier data versus other plans and issuers? Are there different considerations for reporting of premiums, spending, and other data by partially-insured group health plans, such as those that utilize minimum premium, stop-loss, or similar coverage? Are there special considerations the Departments should take into account for multiemployer plans, or that OPM should take into account for policies offered by FEHB carriers that are not issuers?
5. What data reporting tools and systems should the Departments and OPM consider when deciding on the format of the data collection? What are the operational advantages and disadvantages of various reporting formats, such as Excel spreadsheets, fillable PDF forms, or flat files? How can the Departments and OPM reduce the need for manual data entry? What are the ways in which the Departments and OPM could implement the reporting requirements to facilitate compatibility with the systems most commonly used by plans and issuers?
6. Are there state laws with similar reporting requirements that could serve as models for implementing the requirements under PHS Act section 2799A-10, ERISA section 725, and Code section 9825? If so, in what ways are these state laws directly comparable to PHS Act section 2799A-10, ERISA section 725, and Code section 9825, and what should the Departments and OPM consider when deviating from the state requirements?

#### *B. Definitions*



1. What considerations should the Departments and OPM take into account in defining “rebates, fees, and any other remuneration”? Should bona fide service fees—for example, administrative fees, data sharing fees, formulary placement fees, credits, and market share incentives—be included in this definition? Are there additional fees that the Departments and OPM should include in this definition? How should manufacturer copay assistance programs and coupon cards be accounted for? How should copay accumulator programs be accounted for?
2. What considerations should the Departments and OPM take into account in defining the term “pharmacy”? Are there different considerations for retail pharmacies versus mail order or specialty pharmacies? Are there different considerations for prescription drugs dispensed in an inpatient, outpatient, office, home, or other setting?
3. What considerations should the Departments and OPM take into account in defining the term “prescription drug”? Should prescription drugs be identified by National Drug Codes (NDCs)? Are there other prescription drug classification systems that should be considered, such as the first nine digits of the NDC, the RxNorm Concept Unique Identifier (RxCUI), or the United States Pharmacopeia Drug Classification (USP-DC)? How does the choice of prescription drug classification influence plan and issuer operational costs?
4. Should there be different definitions of “prescription drug” for different elements of the PHS Act section 2799A-10, ERISA section 725, and Code section 9825 data collection, such as the 9-digit NDC for identifying the 25 drugs with the highest rebates and the RxCUI for identifying the 50 most costly drugs? What classification systems do plans and issuers currently use for internal needs and compliance with reporting requirements other than those under PHS Act section 2799A-10, ERISA section 725, and Code section 9825?

5. What considerations should the Departments and OPM take into account in defining the term “therapeutic class”? How do plans and issuers currently classify prescription drugs by therapeutic class? Does the classification method rely on proprietary software, and how would the choice of therapeutic classification method influence plan and issuer operational costs?
6. What considerations should the Departments and OPM take into account in defining “health care services”? It is preferable to define the term as a service or bundle of services necessary to treat an illness (for example, by Diagnosis-Related Group code)? Or would it be preferable to disaggregate by particular services (for example, by Current Procedure Technology code)? In what ways could this definition help reduce burdens or increase the utility of data reporting?

### *C. Entities That Must Report*

1. Are there special considerations for certain types or sizes of group health plans, such as individual coverage health reimbursement arrangements and other account-based plans, that make it challenging or not feasible for these plans to satisfy the reporting requirements? What are those specific challenges? If exemptions are provided for certain plans, how might that affect the value of the required public analysis?
2. Should the Departments expect that self-insured and partially-insured group health plans will contract with third-party administrators or other service providers to submit the required data on their behalf? Is there any relevant information or data that may be helpful in determining how widespread this approach may be?
3. Are there ways for issuers and plan service providers to submit data on behalf of multiple plans and coverage options, consistent with the statutory requirements? What benefit would there be to issuers and plan service providers having the ability to submit aggregated data as opposed to reporting information separately for each group health plan, to the extent consistent with the statutory requirements? What

considerations exist with respect to issuers that participate in the FEHB Program submitting FEHB-specific data separately as opposed to including FEHB data in their general book of business?

4. What role, if any, will Pharmacy Benefits Managers (PBMs) play in furnishing necessary information to plans and issuers, or to the Departments or OPM? If permitted, would plans and issuers rely on PBMs to help satisfy their reporting obligations, such as by retaining PBMs to conduct some or all of the reporting? Could PBMs obtain all the information required to be reported, including general information on the plan or coverage, such as the number of participants, beneficiaries, and enrollees; each state in which the plan or coverage is offered; monthly premiums paid by employers and by participants, beneficiaries, and enrollees; total spending on health care services broken down by type; and the impact on premiums of prescription drug rebates, fees, and any other remuneration paid by drug manufacturers to the plan or coverage or its administrators or service providers? If not, would allowing separate reporting forms, modules, or data collection systems for PBMs and issuers and plan administrators to report such information be administratively and operationally feasible? How would separate reporting forms change the costs or burdens associated with compliance?

*D. Information Required to be Reported*

1. What considerations are important for plans and issuers in determining the 50 brand prescription drugs that are most frequently dispensed by pharmacies for claims paid by the plan or coverage, and the total number of paid claims for each drug? Should the determination be based on the number of claims, the number of days' supply, or something else? Should the unique number of participants, beneficiaries, or enrollees that received a prescription be taken into account, and, if so, how?

2. What considerations are important for plans and issuers in determining the 50 prescription drugs with the greatest increase in plan expenditures? Should the increase be measured based on the absolute increase in dollars; percentage increase in price; the increase relative to another measure, such as overall spending by the plan or issuer; or something else? What factors should the Departments and OPM consider in selecting an approach? If the Departments and OPM define the increase in proportion to the change in overall spending, should the increase be measured in comparison to total spending or only to spending on prescription drugs?
3. If the top prescription drugs are identified by RxCUI (or any classification other than NDC), is it feasible for plans and issuers to report the required information separately by NDC for each NDC associated with the given RxCUI?
4. Which data elements can be directly tied to a specific prescription drug or class of prescription drugs, and which data elements must be allocated among prescription drugs or prescription drug classes? If an amount must be allocated, what allocation method(s) are preferable, and why?
5. What considerations are important for plans and issuers in determining the 25 drugs that yielded the highest amount of rebates and other remuneration from drug manufacturers during the plan year? Should rebates and other remuneration be measured by total dollar amount? Should rebates and other remuneration be measured in comparison to another measure, such as total spending on a drug or a unit price? If a price measure is used, which price measure should be used and why?
6. PHS Act section 2799A-10, ERISA section 725, and Code section 9825 require plans and issuers to report total spending on health care services separately for hospital costs, health care provider and clinical service costs (for primary care and specialty care separately), prescription drug costs, and other medical costs, including wellness services. Which cost elements should be included in each category? Should the

- Departments and OPM collect prescription drug spending information separately based on the setting of care?
7. Should the Departments collect information separately by market, state, or employer size? If so, are there data elements that must be allocated among the categories? What allocation methods should be used? Are there differences in the capacities of different size entities to comply with the Departments' and OPM's reporting requirements, or in the costs and burdens of compliance?
  8. What considerations are important for plans and issuers in measuring the impact of drug manufacturer rebates on premiums and out-of-pocket costs? What quantitative or qualitative analyses might plans and issuers perform? What analyses do plans and issuers currently perform?
  9. Should the Departments and OPM collect information on rebates, fees, and any other remuneration at the total level or broken out by relevant subcategories? For example, in the PBM Transparency for Qualified Health Plans (QHPs) data collection,<sup>1</sup> PBMs will report information for retained rebates, rebates expected but not yet received, PBM incentive payments, price concessions for administrative services from manufacturers, all other price concessions from manufacturers, amounts received and paid to pharmacies, and spread amounts for retail and mail order pharmacies. Should the Departments use the same or similar subcategories for the reporting requirements under PHS Act section 2799A-10, ERISA section 725, and Code section 9825?
  10. Are there types of payments that flow from plans, issuers, or PBMs directly to drug manufacturers? If so, how should these payments be treated? Should they be netted against rebates and other price concessions that are received from drug manufacturers?

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<sup>1</sup> Section 1150A of the Social Security Act, and its implementing regulations at 45 CFR 156.295 and 45 CFR part 184, require issuers of QHPs or their PBMs to report certain prescription drug information to HHS.

11. Are there types of rebates and price concessions that are passed directly to the participant, beneficiary, or enrollee? If so, how should they be treated? Should they be included or acknowledged in this data collection?

*E. Coordination with Other Reporting Requirements*

1. Are there opportunities to remove other reporting requirements applicable to plans and issuers or to leverage or combine those requirements with the reporting requirements under PHS Act section 2799A-10, ERISA section 725, and Code section 9825 to reduce administrative burdens or costs associated with complying with the new requirements? For example, the Departments are aware that there may be some overlap between the data subject to collection under PHS Act section 2799A-10, ERISA section 725, and Code section 9825 and the data subject to collection in the PBM Transparency for QHPs data collection,<sup>2</sup> which requires issuers of QHPs or their PBMs to report prescription drug information to HHS.

*F. Public Report and Privacy Protections*

1. In what ways can the Departments and OPM facilitate use of the reports by a variety of interested parties, such as government entities, academics, industry entities, and consumers and their advocates?
2. Should OPM issue a public report specifically for FEHB carriers?
3. Would the Departments' and OPM's reports have greater value and utility if data were collected on a calendar year basis, by plan or policy years, or by some combination, to the extent consistent with the statutory requirements? If data were to be collected by plan or policy year, are there any considerations the Departments and OPM should take into account when determining the plan or policy year effective dates for reporting periods? For example, what is the last plan or policy year end date that should be included in data submitted by June 1 of each year?

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<sup>2</sup> *Id.*

4. Are there any examples of similar reports published by state agencies? If so, what are any strengths or limitations of the reports published by the state agencies that would be relevant to the Departments and OPM? In what ways should the Departments and OPM consider adapting or differentiating the process under PHS Act section 2799A-10, ERISA section 725, and Code section 9825 from any similar state reporting processes?
5. Should the public report include a comparative analysis of prescription drug costs for plans and issuers, relative to costs under Medicare or in other countries?

*G. Regulatory Impact Analysis*

1. What benefits, costs, and other impacts do plans, issuers, or other stakeholders anticipate from the reporting requirements of PHS Act section 2799A-10, ERISA section 725, and Code section 9825?
2. Are there benefits to academics or other researchers? How will consumers benefit?
3. What data, research, or other information is available to help quantify the benefits, costs, and other impacts of the reporting requirements? Are there existing data, research, or reporting analogues that could be extrapolated from to predict market impacts?
4. What actions could the Departments and OPM take to minimize the compliance costs of the reporting requirements?
5. Operationally, which types of employees will be necessary to ensure compliance with the reporting requirements? Will staff specialized in medical billing coding be needed for the purpose of reporting?
6. Will new or additional technology be needed for the collection, maintenance, or storage of the data to be reported?
7. Will there be coordination costs or benefits from simultaneously complying with state regulations that require the reporting of medical services costs or prescription drug costs?

8. Would greater alignment with other Federal reporting requirements reduce associated compliance costs, and if so, how?

### **III. Collection of Information Requirements**

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements under the Paperwork Reduction Act of 1995 (PRA). However, Section II of this document does contain a general solicitation of comments in the form of a request for information. In accordance with the implementing regulations of the PRA, specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA. Consequently, there is no need for review by the Office of Management and Budget under the authority of the PRA.



Signed at Washington DC.

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Signed at Washington DC.

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