BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

1310 G Street, N.W.
Washington, D.C. 20005
202.626.4800
www.BCBS.com

July 23, 2021

Carol Weiser
Benefits Tax Counsel
U.S. Department of the Treasury
1500 Pennsylvania Avenue, NW
Washington, DC 20220

Rachel Leiser Levy
Associate Chief Counsel (EEE)
Internal Revenue Service
Office of Chief Counsel
1111 Constitution Avenue, NW
Washington, DC 20224

Ali Khawar
Acting Assistant Secretary - Employee Benefits Security Administration
U.S. Department of Labor
200 Constitution Ave, NW
Washington, DC 20210

Amber Rivers
Director - Office of Health Plan Standards and Compliance Assistance
U.S. Department of Labor
200 Constitution Ave, NW
Washington, DC 20210

Jeffrey Wu
Deputy Director for Policy
Center for Consumer Information and Insurance Oversight
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Submitted via the Federal Regulations Web Portal, http://www.regulations.gov

RE: Request for Information (RFI) Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs

Dear Mr. Khawar, Ms. Levy, Ms. Rivers, Ms. Weiser and Mr. Wu:

The Blue Cross Blue Shield Association (BCBSA) appreciates the opportunity to provide comments on the RFI regarding Reporting on Pharmacy Benefits and Prescriptions Drug Costs included in Section 204 of Title II of Division BB of the Consolidated Appropriations Act, 2021 (CAA) as issued in the Federal Register on June 23, 2021 (86 Fed. Reg. 32813).

BCBSA is a national federation of 35 independent, community-based and locally operated Blue Cross and Blue Shield companies (Plans) that collectively provide health care coverage for one in three Americans. For more than 90 years, Blue Cross and Blue Shield companies have offered quality health care coverage in all markets across America – serving those who purchase coverage on their own as well as those who obtain coverage through an employer, Medicare and Medicaid.

We appreciate the opportunity to provide comments and recommendations on this new reporting requirement to the Departments of Health and Human Services, Labor, and Treasury (the Departments) and the Office of Personnel Management (OPM). Our objective in these recommendations is to provide the Departments with information under Sec. 204 for the public reporting requirement in a manner that reduces burden on the Departments and reporting entities. We also support a reporting system that is administratively efficient and protects proprietary and confidential information.

BCBSA's key recommendations include:

- Providing reporting entities with adequate time following receipt of the Departments' guidance to comply with the requirements
- Requiring reporting by line of business (LOB), specifically, non-group coverage, small group coverage, large group coverage and self-funded plans
- Creating a reporting system allowing health insurance issuers, employers and pharmacy benefit managers (PBMs) to submit data that would protect competitively sensitive information
- Requesting the Departments provide the greatest level of detail possible in defining terms, for reporting prescription drug and other health care spending by category, so as to ensure consistency in reporting across reporting entities
- For the purpose of Federal Employees Health Benefits (FEHB) Carriers reporting of pharmacy benefit data, requesting OPM to choose one of two exclusive approaches: (1) direct FEHB Carriers to continue to report FEHB-specific pharmacy benefits data under current OPM requirements; or (2) direct FEHB Carriers to report FEHB pharmacy data under the reporting process to be established under Sec. 204

We appreciate your consideration of our recommendations. We look forward to continuing to work with the Departments on implementation issues under the CAA. If you have any questions, please contact me at 202.626.4814 or at kris.haltmeyer@bcbsa.com.

Sincerely,

Kris Haltmeyer
Vice President, Legislative and Regulatory Policy
Blue Cross and Blue Shield Association

DETAILED COMMENTS ON RFI REGARDING REPORTING ON PHARMACY BENEFITS AND PRESCRIPTION DRUG COSTS (CMS-9905-NC)

Questions Related to 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?*

Recommendation:

BCBSA recommends requiring reporting by line of business (LOB) to achieve the objectives of the public report required under Sec. 204 of the CAA.

Rationale:

While Sec. 204 is not precise about the level at which data must be reported, referring only to "information with respect to the health plan or coverage," BCBSA understands the congressional intent is to inform the Departments on prescription drug trends in the commercial market to produce a report on (as cited in the CAA):

> "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 in such a way as no drug or plan specific information will be made public."

We believe reporting by LOB, specifically, non-group coverage, small group coverage, large group coverage and self-funded plans will achieve this end. The term "coverage" in the excerpt of the statute above can refer to a single individual policy or in the plural to an entire market (e.g., individual coverage, small group coverage, large group coverage). It is unlikely the congressional intent would be for health insurance issuers to compile a report for each individual market policy, so we can imply that some level of aggregation is required for the non-group coverage market. Indeed, the data collected from a single individual or small employer group would not be meaningful, and would – potentially – involve privacy disclosure issues. Aggregating the reporting for small group coverage, large group coverage and self-funded plans is not a logical leap and would meet the statutory criteria of "information with respect to the health plan **or** coverage," (emphasis added) while easing administrative, competitive and privacy concerns.

From an operational perspective, it would be impractical for health insurance issuers to produce reports for each employer plan sponsor. Information at such a granular level will not assist in the prescription drug cost tracking that the statute envisions, and reporting by LOB will produce information relevant for, and more easily used by, the public. For example, a single employer group health plan's information may not be representative, may not be actuarially credible, may provide a distorted picture of costs, and has the potential to disclose protected health information (PHI). Aggregated information, on the other hand, can provide more representative, credible and actionable information without the risk of disclosing PHI. Finally, reporting at a LOB level would help ensure that no confidential or trade secret information is disclosed (subsection (c)).

2. *Are FEHB carriers (including those that are also issuers) able to report data separately for each FEHB plan?*

Recommendation:

BCBSA, the carrier of the Blue Cross and Blue Shield Service Benefit Plan, also known as the Federal Employee Program (or simply FEP), with the collaboration of our PBM contractors, is able to report data separately for the three FEP plans: Standard Option, Basic Option, and FEP Blue Focus.

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?*

Recommendation #1:

BCBSA recommends delaying the reporting deadline one year after the release of guidance (e.g., PRA package).

Rationale:

Meeting this statutory deadline (12/27/2021) for reporting under Sec. 204 will be extremely difficult. Health plan pharmacy teams have other significant regulatory reporting commitments, including the Transparency in Coverage prescription drug machine-readable file and the Qualified Health Plan (QHP) prescription drug reporting requirements, plus operationalizing other No Surprises Act provisions that have direct consumer impact. A delay will allow time for reporting entities to review the Departments' standards (once finalized), aggregate data from various sources, test the templates for data submission and submit the final reports, as well as identify, train and credential employees on the reporting requirements.

Recommendation #2:

BCBSA recommends sufficient time between the end of a calendar year and the reporting deadline to account for the claims lag (the period of time between delivery of health care to a patient and receipt of the claim by the health plan) and time to aggregate data.

Rationale:

The data elements in Sec. 204 require aggregating data from internal and external sources. Health plans will need to procure data from external entities, incorporate with internal data sources, and produce and submit the final reports. Moving the reporting deadline to after July 1 would allow health plans to report on the previous year. For example, a reporting deadline of Oct. 1, 2022, would facilitate health plan reporting of 2021 data.

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?*

Recommendation #1:

BCBSA recommends the Departments rely on other internal agency data or external research or data under subsection (a)(8).

Rationale:

Health insurance issuers do not have the data needed to populate all of the reporting elements of Sec. 204 without seeking information from employers and PBMs.

Some information is held by the employer only, such as the "average monthly premium" paid by employer/employees (subsection (a)(8)). In general, health insurance issuers and third-party administers (TPAs) receive all funding for a group health plan directly from the health plan sponsor, but they do not know what portion comes from the employer vs. the employee. Employers with self-funded coverage collect premiums from enrollees and pay claims, but the TPA does not see the costs paid by the employee.

It would be a very difficult task to collect, store, and develop reporting on the premium paid by employer/employees from all employer accounts (small, mid-sized, large, self-funded), as that is not collected today by plans from employers. We recommend the Departments rely

on other internal agency data or external research for the data under subsection (a)(8) (e.g., KFF Employer Health Benefits Survey or Form 5500s).

Recommendation #2:

To protect competitively sensitive information, we recommend a reporting system that allows employers, health insurance issuers and PBMs to report information separately on certain self-funded group health plans.

Rationale:

Health insurance issuers would need to collaborate with PBM contractors (if used) to capture certain data sources, such as "top 50" prescription drug data calls and questions about manufacturer rebates. This collaboration is practical where the employer selects a combined health plan-PBM contract.

However, some self-funded accounts have multiple service providers. A TPA may hold the medical benefit contract, while the plan contracts separately and directly with a PBM for pharmacy benefits (pharmacy benefits are "carved-out"). To protect competitively sensitive information, we recommend the entity serving as the TPA for the self-funded account submit a report based on the information it holds, and the PBM submit a separate report.

This may necessitate a system that allows employers, health insurance issuers and PBMs to report information separately on certain group health plans. Moreover, some employers utilize multiple carriers in some regions, direct contracting strategies with providers, custom networks, private exchanges, or individual choice HRAs (ICHRAs). All of these things will add complexity to data reporting and should be clarified before reporting begins.

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?*

Recommendation #1:

BCBSA recommends the Departments simplify and streamline the process for creating new user accounts and not require an issuer's senior leaders to create a unique user account if the agencies select the Health Insurance Oversight System (HIOS) platform for reporting.

Rationale:

The Center for Consumer Information and Insurance Oversight (CCIIO) previously suggested the use of the HIOS platform for submitting reports under Sec. 204 for the initial

reporting year. The HIOS security system for creating new user accounts and logging in is lengthy, and health insurance issuers have experienced challenges successfully uploading documents that are CMS approved and without errors. Issuers have noted concerns with the need to create new user accounts to grant staff access to HIOS for Sec. 204 reporting.

Recommendation #2:

BCBSA recommends providing issuers with sufficient time to review and test any new reporting templates, particularly for any new medical loss ratio (MLR) templates if the agencies select the HIOS platform.

Rationale:

The MLR templates in the HIOS platform do not collect the data required under Sec. 204, so new templates would be needed, tailored to these specific reporting requirements. Issuers would need the submission templates and instructions for Sec. 204 reporting with sufficient time to review and test.

Recommendation #3:

BCBSA recommends providing self-funded accounts and FEHB carriers with appropriate training and time if requiring these accounts to report during the first year.

Rationale:

Self-funded accounts and certain FEHB carriers do not have access to HIOS, so a new interface would be needed to allow them to create user accounts to upload reports. If the Departments and OPM are collecting reports from self-funded accounts and FEHB carriers, respectively, in the first reporting year, there will need to be appropriate training and time as this is an unfamiliar platform for self-funded accounts and certain FEHB carriers.

Similarly, if the Departments allow a self-funded account to delegate reporting to its PBM (as BCBSA recommends above when the pharmacy benefit is "carved-out" of the health plan), an interface would be needed for PBMs as well.

Recommendation #4:

If the use of HIOS, or a new module within HIOS, is used for the first reporting year, we request the Departments and OPM review using HIOS, or a new module within HIOS, to determine if it is a viable application for future Sec. 204 reporting or if a new application/system is more appropriate.

Rationale:

Use of HIOS, or a new module within HIOS, may be appropriate for the first year of reporting to comply with the Sec. 204 mandates. Over the long-term, another mechanism may be

more useful and reduce administrative burden for all stakeholders. To ensure efficient and effective reporting, we request the Departments and OPM to review to determine if HIOS is a viable application for future Sec. 204 reporting or if a new application/system is more appropriate. BCBSA is willing to be a partner to support the review and provide BCBS company perspectives.

Recommendation #5:

BCBSA recommends the Departments not create a new platform for reporting if the HIOS platform is not chosen for the pharmacy benefit reporting requirements.

Rationale:

The creation of a new platform would substantially increase administrative burden for the Departments and reporting entities. The Departments would need the requisite time to develop, establish and test any new platform. Additionally, reporting entities would need sufficient time to understand how to use and be credentialed on the new reporting platform. We believe submitting data (e.g., flat files, CSV) would be the most appropriate format for submission, not a new reporting platform that will take time and significant resources to establish.

Questions Related to 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?*

Recommendation #1:

Under subsection (a)(9), we recommend consistent formatting across all requirements and clarity in the data guide regarding the requirements in this data field, including defining "therapeutic class."

Rationale:

Subsection (a)(9) calls for reporting the "impact on premiums by rebates…" with two subsections on "(A) the amounts so paid for each therapeutic class of drugs; and (B) the amounts so paid 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." The intent of this subsection is unclear, including whether this constitutes three reporting elements or only those under subsection (A) and (B). If the Departments require a quantitative response to this subsection, we ask for clarity and uniformity for that response

(i.e. range of data that equates to describing an impact) to ensure consistency across reporting entities. Without further direction, the question will generate many different types of responses based on each reporting entities' assumptions.

We also ask for clarification on how the Departments will define "therapeutic class" (e.g., USP classification, American Hospital Formulary Service standard definition or otherwise).

Recommendation #2:

BCBSA recommends safeguards ensuring health plan level data and competitively sensitive data are not included in publicly available reports.

Rationale:

As noted under the Consolidated Appropriations Act, the public report from the Departments is to produce aggregate reports on prescription drug spending with no drug or plan specific information being made public. We support this level of aggregation in any public report, and understand it extends to health plan level data under subsection (a)(9) that may include competitively sensitive data on the negotiation of rebates and the use of rebates to lower premiums and/or member cost-sharing under a group health plan or individual market coverage.

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?*

Recommendation #1:

For the reporting elements that reference "prescription drugs," we recommend this term refer only to drugs covered under the plan's pharmacy benefit. Drug spending under the medical benefit should be classified as hospital costs (under the 7(A)(i)) or health care provider and clinical service costs (under 7(A)(ii)).

Rationale:

Health insurance issuers and PBM contractors have ready access to spending, utilization and trends for member-filled drugs covered under the pharmacy benefit. Drugs covered under the medical benefit are much more complex to capture. For example, drugs administered at an inpatient hospital setting are often covered under a diagnosis-related group (DRG) or bundled payment arrangement, and it is more difficult to extrapolate for this type of reporting structure.

Recommendation #2:

We call on the Departments to estimate drug spending under the medical benefit based on publicly available reports for the public reporting requirement.

Rationale:

We believe it is important to incorporate estimates of the percent of drug spending under the medical benefit (hospital costs (under the 7(A)(i)) or health care provider and clinical service costs (under 7(A)(ii)) in the public report. This approach will ease the reporting burden as noted above, while at the same time provide information to the public on the growing drug spending under the medical benefit. The Departments can rely on publicly available reports estimating the percent of drug spending under hospital and physician claims and include estimates in the public report.

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?*

Recommendation:

We encourage the Departments to classify drugs by using the 9-digit NDC for the reporting requirements identifying the top "number of drugs" (e.g., highest rebate, most costly, most frequently dispensed) in a manner that captures and aggregates drugs at the drug name level.

Rationale:

The NDC classification is the most common format for payers in identifying prescription drugs and is most appropriate for this reporting standard that requires collaboration between insurers and PBMs. The 9-digit NDC classification will capture drugs more closely at the molecular level to group drugs with varying strengths and dosage forms (injectable pen or syringe), so the top "number of drugs" categories are identifying unique "drug name" prescription drugs. We support a classification system that is utilized across payers and results in categories that reflect unique molecules.

As to the option to use RxCUI, health plans are required to use the RxCUI classification system in the Medicare and exchange markets, but this is not common across all commercial markets and therefore not practicable for Sec. 204 reporting.

6. *What considerations should the Departments and OPM take into account in defining "health care services"? Is it 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?

Recommendation:

BCBSA recommends using data from uniform billing (UB) or a health insurance claim form to determine "health care services."

Rationale:

Subsection (a)(7)(A) of the CAA calls for reporting total spending by 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 wellness services. For this reporting element, we recommend:

- *Hospital costs* refer to services with a uniform billing (UB) claim form
- *Health care provider and clinical service costs, for primary care and specialty care separately* refer to services with a health insurance claim form (a "HCFA 1500" or "CMS 1500" form), with:
    - *Primary care* referring to where the provider of a service is a primary care clinician (e.g., general practitioner, family practice, family nurse practitioner)
    - *Specialty care* referring to all other practitioners
- *Costs of prescription drugs* refer to drugs covered under the pharmacy benefit (as described above)
- *Other medical costs, including wellness services* refer to all other claims not included in a category above

Use of the UB and health insurance claims forms will accurately capture health care services and align with the objectives of the reporting requirements.

<u>Questions Related to Entities That Must Report</u>

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?*

Recommendation #1:

BCBSA recommends initially implementing the Sec. 204 reporting requirements for fully insured line of business (LOB) and delay reporting for self-funded LOB.

Rationale:

We mention above the complications with self-funded employers that carve-out pharmacy benefits from the health plan contract. The compilation of Sec. 204 reports under this scenario – sharing contractual data on drug manufacturer rebates and other data from competitors – risks disclosing competitively sensitive information. Subsection (c) prohibits the HHS Secretary from disclosing any confidential or trade secret information, and we believe that those protections naturally extend to not being required to disclose such information to competitors. We recommend the Departments implement the Sec. 204 reporting requirements for fully insured LOBs first and delay reporting by the self-funded LOB in order to provide time to identify a solution that meets the needs of the Departments and reporting entities.

Recommendation #2:

BCBSA recommends individual coverage health reimbursement arrangements (ICHRA) be excluded from the pharmacy benefit reporting requirements.

Rationale:

Health plans may not have the necessary information to report for ICHRA because plans may not know when an ICHRA is in use. The prescription drug reporting for ICHRA is not distinct from other individual policies. Issuers would not necessarily know if an ICHRA funds an individual policy. Employees will be selecting from multiple carriers since they can choose any individual policy they prefer. Therefore, there is no need to separately report or identify ICHRA for Sec. 204 reporting.

Questions Related to Public Report and Privacy Protections

2. *Should OPM issue a public report specifically for FEHB carriers?*

Recommendation:

BCBSA recommends OPM collaborate with BCBSA and other interested FEHB carriers to maintain confidential business information.

Rationale:

BCBSA recognizes that OPM, as the federal agency responsible for administering the FEHB Program, has the discretion to issue a FEHB-specific public report. However, recognizing that FEP currently serves over 50 percent of the individuals covered under the FEHB Program, BCBSA is concerned that unintentionally, but unavoidably, a FEHB-specific report may disclose confidential information regarding FEP's pharmacy benefits program.

For this reason, BCBSA requests that if OPM does decide to pursue issuing a FEHB-specific public report, for OPM to collaborate with BCBSA and other interested FEHB Carriers to ensure the FEHB-specific report does not disclose any FEHB Carrier's confidential business information.

Questions Related to Regulatory Impact Analysis

4. What actions could the Departments and OPM take to minimize the compliance costs of the reporting requirements?

Recommendation #1:

BCBSA recommends OPM select only one reporting requirement for FEHB carriers and not require both current pharmacy data reporting requirements and those established under Sec. 204 in the CAA.

Rationale:

OPM has already established robust FEHB pharmacy benefit data reporting standards, which most likely will not be consistent with the pharmacy benefit data reporting standards established under Sec. 204. To minimize compliance costs and avoid the incurrence of unreasonably excessive reposting costs by FEHB Carriers, we strongly urge OPM to explicitly adopt one of the following two approaches:

- Direct FEHB Carriers to continue reporting pharmacy benefit data in compliance with OPM's current requirements, with perhaps a few minor adjustments to bring the requirements in closer alignment with the reporting requirements established under Sec. 204; or
- Direct FEHB Carriers to report FEHB pharmacy benefit data in compliance with the reporting requirements established under Sec. 204.

We strongly discourage OPM requiring FEHB Carriers to continue to comply with OPM's current pharmacy data reporting requirements and, in addition, comply with the reporting requirements established under Section 204. By OPM selecting one reporting pathway over another, it aligns with the intent of the RFI to identify methods to reduce administrative burden and costs.

Recommendation #2:

BCBSA recommends the Departments remove data elements from the qualified health plan (QHP) reporting requirements on the pharmacy benefit if those same data elements apply to commercial plans under Sec. 204 of the CAA.

Rationale:

Pharmacy benefit managers will be required to report prescription drug information on QHPs. If there are data elements that overlap between the Sec. 204 reporting requirements and those for QHPs, we call on the Departments to remove those reporting standards where there is an overlap to help reduce administrative burden and support efficient submission.