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Re: Request For Information (RFI) Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs (RIN: 0938-AU66, 1210-AC07, 1545-BQ10, 3206-AO27)

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

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to offer comments in response to the Request for Information (hereinafter referred to as “RFI”) regarding the Consolidated Appropriations Act (CAA) of 2021’s surprise medical billing and transparency provisions to members of the Departments of Health and Human Services (HHS), Labor, and Treasury (hereafter “the Departments”) on July 23, 2021.¹

PCMA is the national association representing America’s pharmacy benefit managers (PBMs), which administer prescription drug plans and operate specialty pharmacies for more than 266

¹ 86 FR 32813 ([2021-13138.pdf \(govinfo.gov\)](https://www.govinfo.gov/justices/2021-13138.pdf))



million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program (FEHBP), and the exchanges established by the Affordable Care Act. Our members work closely with plans and issuers to secure lower costs for prescription drugs and achieve better health outcomes.

Prescription drugs play an important role in our health care system by treating disease and helping patients heal. Dramatic price hikes negatively affect patients and drive-up costs for employers and employees through higher premiums. Division BB, Title II, Section 204 of the CAA requires group health plans and health insurance issuers offering group or individual health insurance coverage to submit to the Departments on an annual basis a report detailing prescription drug cost trends, overall spending on health services and prescription drugs, and information about premiums and the impact of rebates and other remuneration on premiums and out-of-pocket costs (OOP).

PCMA appreciates the opportunity to contribute to the Administration's desire to bring meaningful and actionable transparency to health care purchasers and consumers. Already, PBMs are at the forefront of health care price transparency. Currently, PBMs inform enrollees about their coverage for specific drugs, which pharmacies are available in their plan's network, and their expected OOP costs for their prescriptions through a variety of consumer-friendly means including online tools and consumer hotlines. PBMs also provide real-time information to prescribers at the point of care, including utilization management requirements (e.g., prior authorization and step therapy) and lower-cost therapeutic options available in the plan's formulary. They have also created systems through which prior authorization requests can be resolved electronically, which streamlines enrollee access to prescription drugs.² We stand in support of consumer-facing transparency that helps consumers and their health care providers make the best decisions for their care.

We acknowledge the immense workload imposed upon the Centers for Medicare & Medicaid Services (CMS) and regulated entities by Division BB, Title I of the CAA (also known as the No Surprises Act) and the provisions of Division BB, Title II (entitled Transparency). We appreciate the latitude CMS is prospectively offering regulated entities for several of these provisions, including Division BB, Title II, Section 204, the subject of this letter.³ However, "good faith compliance" in the context of a reporting program that is not fully implemented is not actually feasible. The next iteration of policy on this provision should include a specified delay in enforcement until such time as all requirements are finalized and stakeholders are given ample time to update their systems to comply. The only alternative we see is that any plan or issuer

² 85 Fed. Reg. 86824, December 31, 2020.

³ CMS writes "Until rulemaking to fully implement these provisions [including Section 204] is finalized and effective, plans and issuers are expected to implement the requirements using a good faith, reasonable interpretation of the statute. The Departments intend to issue guidance in the near future regarding their expectations related to good faith compliance with these provisions." 86 Fed. Reg. 36876, July 13, 2021.



currently reporting to a state with substantially similar requirements could be deemed as compliant as of the statutory enforcement date, as we discuss in A.6. below.

Summary of PCMA's Positions on How to Implement Section 204

The Departments' RFI is wide-ranging in its scope and the questions often bypass the specific statutory guardrails that should direct any rulemaking and data collection. However, in an effort to provide as complete a picture as possible to the Departments, we are answering each question as it stands. With that in mind, we wanted to provide a few key principles that prevail regardless of the form of the subsequent proposed rule and subregulatory information collection review processes. These are:

- Congress dictates that plans and issuers should be the sole reporters of these data to the Departments.
- Reporting entities need to know what the Departments want to do with the data before they know how to respond to some of these data collection questions.
- These comments we are filing here are based upon what we know at this point, based on the statutory language and limited insight available in the RFI. Some of our answers are based on questions that stray from the statutory guardrails, which we point out when applicable. More detailed information in a proposed rule and subsequent draft information collection forms may necessitate a change in position if data elements and timing make reporting infeasible.

Our detailed comments follow below in the format of question-and-response based upon the RFI's specific requests of the public.

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?*

The statute requires plans to report information on the "previous plan year" for both the initial reporting date (due December 27, 2021) and for the subsequent annual reporting date (due June 1, 2022). Reporting requires the creation of data collection forms through an iterative



process informed by ongoing public feedback and support, and thus, a December 27, 2021 date is unrealistic if the Departments intend to ensure stakeholder engagement.

Even for June 1, 2022, PBMs on behalf of their clients need a sufficient amount of time to “close out” the prior plan year. June 1 may not be enough time to close out a 2021 plan year that ends as of December 31, 2021. Assuming data reported on June 1 is “cut off” a month in advance, claims data will be immature. According to CMS, for the Medicare program, based on claims filed in 2010, only 85 to 95% of institutional and outpatient claims are finalized within four months. Only 78% of Part D prescription drug event data is considered “final” after four months.⁴ To ensure 95% completeness for all inpatient/outpatient claims, the Departments would need to allow 11 months. For pharmacy, they would need to allow 17 months.

In the interest of ensuring accurate and meaningful reporting, we recommend at least nine to 12 months, rather than the current schedule allowing for only five months until the first reports are due. In addition to the claims run out described in the preceding paragraph, prescription drug rebates need to be reconciled for the corresponding reporting provision. Rebates are reconciled upon the completion of a contract and are paid retrospectively. There may be a lag between the closing of the plan year and the beginning of the reconciliation process. We believe an important potential use of these data is to identify the success PBMs have had in negotiating lower net costs for drugs. “Rushing” the reporting, as it were, would undermine a key finding, giving ammunition to drug manufacturers. Finally, plans and issuers will need to combine the data provided by their PBMs and other third-party vendors with their own data prior to any reporting. June 1 reporting builds in no time for any of these necessary data cleaning steps.

If the Departments feel compelled to retain the June 1 reporting deadline, we suggest the Departments collect information as follows: initial reporting due by June 1, 2022 (and each June 1 thereafter) for plan years ending on or before December 31, 2020 (and December 31 of each preceding year thereafter).

However, should the Departments feel they have flexibility to move the June 1 date back to accommodate plan year close-outs, they could collect more recent data sooner. Initial reporting could be due by October 1, 2022 (and each October 1 thereafter) for calendar years ending December 31, 2021 (and December 31 of each year thereafter).

These periods will allow plenty of time from the close of a plan year to account for claims reversals and rebates reconciliations. Calendar year reporting is also more meaningful (and less burdensome) for all parties.

⁴ See <https://www.ccwdata.org/documents/10280/19002256/medicare-claims-maturity.pdf>. Table 3 for inpatient/outpatient and Table 7 for Part D.



Additionally, while the statute says: “a group health plan or health insurance issuer,” the Departments should consider collecting the least granular level of detail that would be reasonable to facilitate compliance with reporting requirements. In terms of qualified health plans (QHPs), for example, this would be HIOS-7 which would identify the issuer plus the state. Similar identifiers would need to be developed for use beyond QHPs.

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

FEHB carriers are not subject to the reporting requirements of Section 204, and PCMA is concerned that the Departments are exceeding their statutory authority by reading into the statute that the inclusion of FEHB carriers under Section 204.

Under Title I, which deals with surprise billing, Congress amended 5 U.S.C. § 8902(p) to apply specified provisions of the CAA to FEHB carrier contracts. Congress conspicuously did not include among those requirements section 2799A-10 of the Public Health Service Act (PHSA), which is the provision that was added by Section 204 of the CAA and includes the various reporting provisions at issue here. Moreover, Section 204 of the CAA did not itself amend 5 U.S.C. § 8902 to directly extend its requirements to FEHBs, even while Congress expressly extended such requirements to the PHSA, Employee Retirement Income and Security Act (ERISA), and the Internal Revenue Code (IRC).

In the RFI, the Departments acknowledge this omission, but nonetheless believe that “FEHB carrier compliance with the Departments’ collection pursuant to [section 204] helps accomplish the CAA’s intended purpose of achieving national health data transparency and lower costs.” We disagree with this inclusion and strongly urge the Departments to back away from the inclusion of FEHBs going forward. These plans are already subject to existing reporting protocols that allow for the generation of trend reports.⁵

Accordingly, we request that the Departments do not move forward with including FEHBs as part of their implementation of Section 204.

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?*

⁵ See <https://www.opm.gov/our-inspector-general/publications/management-advisory-reports/1h-01-00-18-039.pdf> as an example of the analyses OPM is already able to perform under existing reporting requirements.



First, we object to any rulemaking by the U.S. Office of Personnel Management (OPM) on this matter. We will not repeat this for each question, but it applies to every question in which “OPM” appears.

Second, and aligned with the discussion in A.1. above, reporting should not begin until at least nine to 12 months after all final guidance is published for this provision (meaning the culmination of any required Paperwork Reduction Act (PRA) process) in order to allow plans and PBMs sufficient time to develop policies, procedures, and internal capability to collect and accurately report this data. Additionally, we note that regulated entities are entitled to advance notice of the exact contents of the data they are required to disclose and to have sufficient time to build the systems necessary to do so. Our PBM members rightly hesitate to build-out IT systems “at risk” based on a proposed rule or even an early round of information collection forms.

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?

We suggest the Departments consider starting with reporting for fully insured plans and then phasing in third-party administrators (TPA) and administrative service only (ASO) plans. As a starting point, most health plans, irrespective of type, do not maintain all the data outlined in Section 204 of the No Surprises Act on their own servers, and instead rely on trusted third-party vendors, such as PBMs or other TPAs, to manage a portion of covered benefits. These third-party vendors maintain their own records and data and may share only high-level information with their clients. Requiring each health plan to report all the data elements listed in Section 204 would require plans to renegotiate contracts with each third-party vendor to receive or access the required data. Plans would then have to build and maintain new data storage infrastructure, aggregate data from its vendors, and then build and submit the reports.

Additionally, many self-funded employer plans contract with a third party to provide administrative services for the plan. The Departments will need to determine whether the employer group or the carrier providing administrative services is the “plan.” We recommend it be the carrier so that reporting can be better aggregated.

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?*

To simplify the administration of this reporting program, PCMA recommends that the Departments consider all reporting move through the Health Insurance Oversight System (HIOS). HHS would need to grant access to the Departments of Labor and Treasury. We believe a single platform for all reporting by all entities will be simpler to stand up and administer than multiple programs.

If this data submission is required via machine-readable files, our members would require additional time to develop the machine-readable file formats. Additionally, the development of these files would have a cost impact as well. Given the cost and extra burden of machine-readable file development, the Departments must ensure that detailed templates and data dictionaries are provided for consistency and ease of adoption.

For operational ease, we recommend excel, which can be problematic for large amounts of data, or CSV as options for data collection format. Additionally, using flat files like CSV provides multiple advantages in analyzing the data by inserting it into a database. However, for high volume data, machine readable is the best option.

In either case, it is critical that the data be reported directly to the three Departments and not using a third-party data storage like DropBox. Many corporations block access to these for security reasons. Direct submission to a .gov portal or by email will simplify the process considerably.

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?*

With the implementation of this provision, similar reporting will now in many ways duplicate other state reporting requirements. Some examples include the following:

- California: Insurance Code Section 10123.205
- Connecticut: Sec. 38a-479qqq



- Minnesota: MN Statutes 62K.07
- Texas: TIC 1369.503
- Utah: Utah Code Section 31A-48-103
- Washington: Rev. Code Wash. (ARCW) § 43.71C.020

The Departments should contact these states (and others) to understand their requirements, rather than relying on the public to interpret the various applicable state laws and regulations. We also recommend that the Departments consider using waivers for plans already subject to like reporting requirements at the state level and to allow for the use of those submissions to meet obligations under Section 204. This would eliminate duplicate data submission burdens.

We would like to note that the federal reporting requirements specifies that the data should be provided for “each state in which the plan or coverage is offered.” This requirement seems to contradict reporting at a federal level. If the expectation of having the data reported for each state is maintained, then the recommendation of allowing waivers makes sense to avoid duplication. Also, we recommend that a single method of reporting is used for both the federal and state levels.

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?*

Rebates and other remuneration should not include amounts received by enrollees from manufacturers. The statute is clear that this term only includes amounts received by plans and their service providers. To the extent that a PBM administers a point-of-sale rebate program for their client (in whole or in part), these should be reflected as rebates received by the plan and then passed on to the enrollee, etc., negotiated by the PBM.

Coupons (as well as cash discounts, free goods contingent on a purchase agreement, and goods in kind) may directly benefit enrollees at the point-of-sale without reducing the issuer’s expenses. These are not remuneration to the plan or PBM. We raise this in part due to the inability of PBMs to track all payments of this nature made to or on behalf of enrollees, since manufacturers and other third parties continue to innovate in their ways to offset plan-required



cost sharing. Therefore, coupons that do not yield actual reductions in total plan cost for the issuer are not price concessions and should not be considered.

PCMA opposes the reporting of bona fide service fees on the basis that these are fair market value payments for services actually performed *and* for which a fee is not passed on, in whole or in part, to a client or customer of the entity. Further bona fide service fees are determined *by the manufacturer* not the PBM. There is no existing mechanism for a PBM to know that the fees they collect meet the definition; the onus is on the manufacturer not to obscure discounts as fees, not *vice versa*. The several regulatory definitions of bona fide service fees across CMS programs all define these fees as fees paid by a manufacturer to an entity and meeting a set of specific conditions. (see 42 C.F.R. § 423.501 (Part D definition), 42 C.F.R. § 414.702 (Part B definition), 42 C.F.R. § 447.502 (Medicaid definition)).

The Departments risk disrupting existing arrangements that provide significant value to consumers should they require reporting of bona fide service fees. PBMs, by way of example, currently perform a wide array of service on behalf of entities including manufacturers, such as:

- improving outcomes for patients taking chronic medications, controlled substances, or drugs with potentially serious adverse events;
- administering REMS;
- medication compliance and management programs;
- medical education of pharmacists and prescribers;
- medication monitoring; and
- data management.

Treatment of such amounts as “remuneration” under Section 204 is both inaccurate, and, more concerning, risks interrupting or increasing the costs of these vital services.

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?*

We recommend the Departments provide guidance that the costs associated with drugs administered in hospitals both inpatient and outpatient, by primary care or specialty care providers, or as part of other medical costs be included within those categories and not within the prescription drug category. For the most part, cost and access to these drugs are not managed in the same way that retail and mail-order prescription drugs are managed, and in relation to new subparagraphs (8), (9), and (10) of Section 2799A-10 etc., the Departments should compare “apples to apples.”

We recommend that the Departments do not attempt to define “pharmacy.” A unique definition could cause additional burden in reporting if certain pharmacy types are excluded. The Departments should focus this reporting requirement on the pharmacy *benefit* – and may want to define “pharmacy” as “pharmacy benefit provider” using the National Council for Prescription Drug Programs (NCPDP) transaction standard (vs. medical benefit providers who file claims via ANSI X12 standards). The Departments should acknowledge that drugs reimbursed under both the pharmacy benefit and the medical benefit can be dispensed or administered in retail pharmacies, mail-service pharmacies, specialty pharmacies, physician offices and out-patient hospital settings, and that the highest cost drugs are often dispensed or administered in a physician’s office or hospital setting. However, for the purposes of this reporting, we must acknowledge that for most health insurers/issuers, the pharmacy benefit is somewhat siloed. While some issuers are beginning to integrate the two benefits, to keep reporting requirements clean, the reports should reflect the benefit as offered by most issuers today. Hence, reports should reflect all drugs reimbursed under the pharmacy benefit, with no differentiation as to 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?*

For these data to be most meaningful, the Departments should not collect data at the National Drug Code (NDC) level, but less granularly at the drug name or trade name level. For reporting by volume, the Departments would benefit from knowing which ingredients form the most commonly dispensed drugs, rather than which of a specific manufacturer’s dosage form, strength, and quantity is most often dispensed.

Similarly, for spending and price changes, it would be important for the Departments to know the costliest drug names or trade names rather than the specific NDC dispensed. Manufacturers often market multiple dosages, forms, and strengths which may otherwise not reveal total spending unless combined at the drug name level.

Therefore, we recommend reporting at the brand name level or using MediSpan Generic Product Identifier (GPI) 8-level which is similar.

- 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?

We recommend the Departments adhere to a single industry standard. There are several in use today, each being proprietary to their owners and the PBMs that subscribe to them. See MediSpan⁶, First Databank⁷, U.S. Pharmacopeia (USP⁸), American Society of Health-System Pharmacists (AHFS⁹), and Anatomical Therapeutic Chemical (ATC),¹⁰ for example. We recommend that the total rebates and remuneration be paid by GPI-8 or drug name.

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?*

We recommend the Departments adhere to a single industry standard. There are several in use today, each being proprietary to their owners and the PBMs that subscribe to them. They range from MediSpan, First Databank, USP, AHFS, and ATC.¹¹ Therefore, we recommend a crosswalk from RxCUI to USP to operationalize therapeutic classifications.

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?*

Given that this question addresses areas that are outside the purview of PBMs, we defer to organizations with expertise in health care services to provide suggestions regarding health care service definitions.

⁶ See <https://www.wolterskluwer.com/en/solutions/medi-span/about/gpi>

⁷ See <https://www.fdbhealth.com/applications/drug-formulary-management>

⁸ See <https://www.fda.gov/regulatory-information/fdaaa-implementation-chart/usp-therapeutic-categoriesmodel-guidelines>

⁹ See <https://www.ashp.org/Products-and-Services/Database-Licensing-and-Integration/AHFSTherapeutic-Classification?loginreturnUrl=SSOCheckOnly>

¹⁰ See <https://www.who.int/tools/atc-ddd-toolkit/atc-classification>

¹¹ See footnotes 6 to 10 above.

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?*

We suggest starting with fully insured plans and then phasing in TPA/ASOs. Additionally, many self-funded employer plans contract with a third party to provide administrative services for the plan. We recommend the Departments spell out that the claims administrator is responsible for reporting to the agencies, rather than the employer. Alternatively, the Departments will need to address privacy issues that will arise when smaller plans report their data.

- 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?*

The statute requires that reporting be made by plans and issuers. The Departments have discretion as to whether the employer as a plan should report in contrast to its carrier or claims administrator, for self-funded plans. Otherwise, this question exceeds the Departments' statutory authority. Privacy issues will arise if smaller plans (e.g., individual employers) report their data. Higher level of reporting will reduce any privacy concerns with compiling and submitting this information to the Departments. If adopted, CMS should establish a minimum threshold of 20 claims for reporting under Section 204 in order to protect the privacy of an employer plan's enrollees.

- 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?*

It is clear from the plain statutory text of Section 204 that Congress' desire in collecting information from issuers and plans was to identify "prescription drug pricing trends" and to understand "the role of prescription drug costs in contributing to premium increase or decrease." Congress was explicit that publicly reported information be "aggregated" and that no confidential or trade secret information be disclosed. PCMA thus believes that reporting at the plan or issuer

level is both inconsistent with the plain statutory text, administratively burdensome, and potentially harmful to competition.

The administrative complexity of gathering the required data increases as the level of granularity increases. In other words, reporting at the plan level would be significantly more administratively complex than reporting at the business segment level. CMS should require plans and issuers to report by state or by business segment. Reporting at these higher levels would allow CMS to detect significant trends with respect to prescription drugs that are increasing consumers' premiums and OOP costs. For data elements that would be provided by the group health plan (employer), we recommend that CMS allow issuers to conduct surveys of a randomized sample of employers in that line of businesses to determine the average monthly premium and the average contribution from both the employer and employee (as required under element 8 in the appendix).

- 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?*

The statute clearly requires plans and issuers to report these data. PBMs will of course hold most of the relevant prescription drug data, which can be reported to their client plans or issuers. The Departments do not need to impose separate reporting requirements on PBMs for plans and issuers to comply with the law.

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?

Plans will need to be able to advise the PBM on how to aggregate the data and crosswalk to the PBM hierarchy to pull in the pharmacy claims specific to the plan. If the Departments include medical benefit drugs in the reporting, then aggregation of medical drug costs and appending to the pharmacy costs may be difficult and may require pulling data that extends beyond the top 50 drugs for each.

For appropriate determinations, we recommend that the Departments provide specific details and answer the following question: Is "most frequently dispensed" intended to be defined by script count, 30-day equivalent script count, allowed claims, net claims, or net claims net of Rx rebate? We recommend creating a standard definition of 30-day equivalent logic for all issuers to use.

- 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?*

The statute requires that plans and issuers report the 50 drugs with the largest year-over-year spending growth. While intended to capture "watch outs" in therapeutic classes with rising costs, as written in the statute, the Departments are likely to capture many drugs with large increases in utilization from the prior year, rather than those with price increases. We recommend a more meaningful measure of prescription drug pricing dynamics which would be the 50 drugs with the largest year-over-year spending growth attributed to manufacturer price increases. This calculation could be made at the drug name or trade name level by comparing prior year's units and unit prices to current year's values. Additionally, the Departments should specify how data should reflect new drugs to market. In comparison to the prior data period, these drugs would have highest annual percentage increase as no cost from previous period when that drug was not yet available.

We recommend that clarification is provided as to how the end data is going to be used by the Departments. What specifically is intended to be reported? What conclusions do the Departments expect to draw? We also suggest that the increase in dollars be reported as drug contribution to total prescription cost increase in plan expenditure as a year-over-year percentage increase.

- 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?*

The Departments should not collect data at the NDC level, but less granularly at the drug name or trade name level such as GPI-8. For reporting by volume, the Departments would benefit from knowing which ingredients form the most commonly dispensed drugs, rather than which of a specific manufacturer's dosage form, strength, and quantity is most often dispensed. Manufacturers often market multiple dosages, forms, and strengths which may otherwise not reveal total spending unless combined at the drug name level.

- 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?*

The Departments should collect the least granular level of detail that would be reasonable. In terms of QHPs, this would be HIOS-7 which would identify the issuer plus the state. Similar identifiers would need to be developed for use beyond QHPs.

Allocation of data elements like rebates at the drug claim level will provide specific data where the data is better understood generally. A PBM will negotiate across a drug's NDCs, not a specific one. Therefore, we recommend rolling up to the drug name or label name (GPI-8 or label name).

- 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?*

We recommend the Departments adhere to a single industry standard such as MediSpan or GPI-8. There are several in use today, each being proprietary to their owners and the PBMs that subscribe to them. See our discussion in B.5. above. We recommend the Departments rely upon these definitions for total rebates and remuneration paid by GPI-8 or drug name.

Rebates and other remuneration should be measured by total dollar amount rather than a percentage of the allowed amount.

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?*

Since this question addresses areas outside the purview of PBMs, we differ to organizations in this space such as plans and insurers.

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?*

We suggest starting with fully insured plans and then phasing in TPA/ASOs and keep reporting at a high level (by line of business) in order to detect larger trends and reduce burden on PBMs. We also recommend reporting be made at the issuer and state level as the default.

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?*

A plan or issuer may not know the actual allocation of premium payments by the employer or its employees. Clients may not want to disclose this to their issuers. These arrangements will need to be worked out, necessitating a longer time period for implementation than contemplated by Congress.

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, 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?*

Rebates and other remuneration should not include amounts received by enrollees from manufacturers. The statute is clear that this term only includes amounts received by plans and their service providers. To the extent that a PBM administers a point-of-sale rebate program for their client (in whole or in part), these should be reflected as rebates received by the plan and then passed on to the enrollee, etc., negotiated by the PBM. Additionally, from a plan pricing perspective, aggregate prescription drug rebates are sufficient.

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?

We discuss bona fide service fees in B.1. above. Other administrative fees paid to manufacturers are rare. What the Departments should be aware of are value-based contracts. Rather than closing out in nine to 12 months, their horizon may be more like three to five years. Hence, any reporting on rebates for these drugs would be under-reporting in the initial performance period of any contract.

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?

See our discussion on question B.1.

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, which requires issuers of QHPs or their PBMs to report prescription drug information to HHS.

We believe the heavy administrative burden placed on PBMs outweighs the benefits derived from receiving the data. However, CMS can tailor the data collection system to reduce this burden. Therefore, we recommend and support removing other reporting requirements to reduce burdens on the PBM industry.



The overlap with several state-level reporting requirements should also be noted. We ask that the Departments recognize the burden of disparate duplicative reporting and remove some of the other reporting requirements.

F. Public Report and Privacy Protections

Global comment for **Section F**: The data regarding pharmacy benefits and prescription drug costs is extremely complicated and if not clearly understood, it could be misinterpreted and misunderstood. Therefore, we recommend that the Departments exercise caution when advocating for public reporting and providing other groups this data.

- 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?*

The data regarding pharmacy benefits and prescription drug costs is extremely complicated and if not clearly understood, it could be misinterpreted and misunderstood. Therefore, we recommend that the Departments exercise caution when advocating for public reporting and providing other groups this data.

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

FEHB carriers are not subject to the reporting requirements of Section 204, and PCMA is concerned that the Departments are exceeding their statutory authority by reading into the statute provisions that Congress plainly decided to omit, namely, a requirement that FEHB carriers also be required to comply with the requirements of Title II of the CAA.

- 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?*

Calendar year is preferred and easier to report since plan year includes a full picture of the year, but every plan has a different plan year which will complicate the reporting. For plans that do not match the calendar year, they should use their latest end date which should be during the preceding calendar year.

- 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?*

As noted in our response to question A.6., we are aware of several state programs that collect similar information to Section 204. Some of these programs include public reporting of these data. The Departments should contact these states and others directly to better understand how their reports are generated, if applicable.

- 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?*

The data regarding pharmacy benefits and prescription drug costs is extremely complicated and if not clearly understood, it could be misinterpreted and misunderstood. Therefore, we recommend that the Departments exercise caution when advocating for public reporting and providing other groups this data or comparative analysis data.

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?*

Most health plans do not maintain all the data outlined in Section 204 on their own servers. Many use third-party vendors, such as PBMs or TPAs, to manage a portion of covered benefits. These third-party vendors maintain their own records and data and may share only high-level information with their clients. Requiring each health plan to report all the data elements listed in Section 204 would require plans to renegotiate contracts with each third-party vendor to receive or access the required data. Plans would then have to build and maintain new data storage infrastructure, aggregate data from its vendors, and then build and submit the reports. The heavy administrative burden placed on plans outweighs the benefits derived from receiving the data. However, CMS can tailor the data collection system to reduce this burden.

- 2. Are there benefits to academics or other researchers? How will consumers benefit?*

The statute does not provide for access to these data to academics or other researchers. While we expect that well-credentialed contractors may help the Departments analyze the data reported to them, that is a different relationship than this question seems to imply. The

Departments explicitly cannot provide the data reported by plans and issuers to anyone outside of a nondisclosure contracting agreement.

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?*

The Departments (mainly CMS) have imposed a number of similar information collections on the regulated public including PBMs in the past several years (QHP PBM transparency, Transparency in Coverage final rule). It should start from those analyses and take into account the fact that many of the same individuals responsible for *those* programs will need to work on Section 204, possibly in parallel. Firms will need to hire rapid response teams of IT contractors to meet all of these reporting obligations.

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

Requiring the data be reported at a higher aggregate level (issuer and state, GPI-8) will reduce the file sizes associated with each reporting.

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?*

Compliance and reporting requirements will necessitate the addition of employees who specialize in data analytics, compliance, and coding. Many of these roles are already hired for, and overburdened by, existing and in process reporting programs.

6. *Will new or additional technology be needed for the collection, maintenance, or storage of the data to be reported?*

Currently, there are no PBM reporting systems other than HIOS. Therefore, collecting required data will necessitate the development of new systems to create reports for individual clients and mapping the insurers identifiers to the PBM claim hierarchy. Moreover, collection and management of the insurer's identifier will be an additional effort on an annual basis to ensure data integrity.

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?*



First, greater alignment with other reporting requirements would reduce compliance costs. Second, we recommend and reiterate the removal of duplicative reporting requirements. The Departments should contemplate a non-enforcement grace period if a plan or issuer is reporting similar data to states.

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

The Departments should consider which reporting programs came from Congress most recently when determining how to prioritize their own staff time and the resources of the regulated public in driving compliance to multiple, competing, and overlapping programs.

Conclusion

PCMA supports the RFI's intent to gather specific information regarding pharmacy benefits and prescription drug costs. We thank the Departments for the opportunity to provide our answers and clarifications, as we move toward a future of greater transparency. If you have any questions, please do not hesitate to reach out to me at tdube@pcmanet.org.

Sincerely,

Tim Dube

Tim Dube
Vice President, Regulatory Affairs