July 28, 2022

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Mr. William N. Parham, III
Director, Paperwork Reduction Staff
Office of Strategic Operations and Regulatory Affairs
U.S. Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Mr. Parham:

Re: Prescription Drug and Health Care Spending (CMS-10788, OMB Control Number 0938-1405)

On June 22, 2022, the Centers for Medicare & Medicaid Services (CMS) published a notice of an information collection review (ICR) in the *Federal Register* under the Paperwork Reduction Act (PRA) regarding revised information for the implementation of Title II, Division BB, Section 204 of the Consolidated Appropriations Act of 2021.[1] The public has been allotted 30 days to respond to this ICR, titled "Prescription Drug and Health Care Spending." The provision is jointly administered by the Department of Health and Human Services (HHS), through CMS; the Department of Labor (DOL), through the Employee Benefits Security Administration (EBSA); the Department of Treasury through the Internal Revenue Service (IRS), and the U.S. Office of Personnel Management (OPM). (Jointly, we refer to these entities as "the Departments" hereafter.)

The Pharmaceutical Care Management Association (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 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and qualified health plans (QHPs) sold through 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.

[1] 87 Fed. Reg. 38411, June 28, 2022. PRA materials are posted at https://www.cms.gov/httpswwwcmsgovregulations-and-guidancelegislationpaperworkreductionactof1995pra-listing/cms-10788.

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The Prescription Drug Data Collection (RxDC) program will require pharmacy benefit managers (PBMs) and issuers to report to the Departments the top 50 prescription drugs by spending and by volume, along with other important contextual details, such as rebates collected by PBMs by therapeutic class and the effect of rebates on plan premiums. PCMA has been engaged with the Departments on this provision since its enactment.[2] We support Congress's intention to provide the Departments with sufficient data to better understand the role of drug manufacturers in the high and rising price of their drugs.

Following a public request for information (RFI) in June 2021,[3] the Departments issued an Interim Final Rule with comment period (IFC) late the same year.[4] The Departments did not adequately describe why they skipped formal notice-and-comment rulemaking. They had already deferred enforcement of the provision to December 27, 2022 in previous guidance.[5] In response to the IFC, we pointed out that the Departments have veered from this clear statutory language set forth by Congress, impermissibly expanding the scope of the data Congress intended to be reported by health plans and health insurance issuers such as the extension of these requirements to Federal Employees Health Benefits (FEHB) program. Section 204 is prescriptive in its definition of the data points to be reported. Based on what is exactingly required by the statute, we object to the collection of rebates, fees, and other remuneration retained by PBMs, manufacturer cost-sharing assistance, and *bona fide* service fees. Each of these elements is well beyond the bounds of the data identified by Congress for reporting.

Beyond this continued objection, PCMA also wishes to raise several other issues arising from the most recent instructions published by CMS. There are several instances where either the initial data collection forms, unmodified, or the modified new forms and process, make reporting technically more difficult. Since reporting will not begin until December, we believe the Departments have ample time to address these issues, in order to collect the most meaningful data, in as accurate a manner as possible. These two topics are addressed further below.

1. **The Departments Should Scale Back Data Collection to Match the Intent of Congress.**

   The revised data collection forms retain the requirement to report data beyond the statutory framework created by Congress. Included among these novel reporting elements are: (1)

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[2] See PCMA's May 2021, July 2021, and January 2022 letters, all attached as part of this Regulations.gov submission.
[3] 86 Fed. Reg. 32813, June 23, 2021.
[4] 86 Fed. Reg. 66662, November 23, 2021.
[5] U.S. Department of Labor. "Facts About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49." August 20, 2021. Available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf.

rebates, fees, and other remuneration retained by PBMs; (2) manufacturer cost-sharing assistance; and (3) *bona fide* service fees. The rule should also not apply to FEHB carriers, either. Such information is far outside of what is required or even intended to be required by Section 204 which, as plainly drafted by Congress, consists of a series of 10 distinct data elements and clearly related sub-elements.[6] As is well understood under the *expressio unius* canon of statutory construction, it is reasonable to conclude that Congress intentionally excluded specific data elements from the reporting requirements. While well-intentioned, the Departments and OPM clearly lack the statutory authority to regulate beyond the narrow bounds of the statutory terms and programs.

a. PCMA is concerned that the Departments are exceeding their statutory authority by reading into the statute the inclusion of FEHB carriers under Section 204.

We would like to emphasize and note that 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(p) 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). Therefore, we suggest that FEHB carriers be excluded from Section 204 reporting requirements.

b. Given the clear statutory guardrails imposed by Section 204, we urge the Departments to exclude from any final reporting requirements amounts retained by PBMs.

New section 149.740((b)(7)(ii) requires the reporting by plans and issuers of "prescription drug rebates, fees, and other remuneration" *including* "amounts retained by the entity providing pharmacy benefit management services to the plan or issuer." Yet, Section 204 (as codified in section 9825 of the Code, section 725 of ERISA, and section 2799A-10 of the PHS Act) by its plain language limits reporting of rebates, fees, and other remuneration to those amounts that have "any impact on premium" and "any reduction in premiums and out-of-pocket costs."[7] As a form of PBM compensation, amounts retained by PBMs and not passed through to the plan have a net-zero impact

[6] *See O'Melveny & Myers v. FDIC*, 114 S. Ct. 2048, 2054 (1994) ("The expression of one thing implies the exclusion of others (expressio unius est exclusio alterius))". The *expresio unius* canon is strongest when the items expressed are members of an 'associated group or series,' justifying the inference that items not mentioned were excluded by deliberate choice, not inadvertence*." Barnhart v. Peabody Coal Co.*, 537 U.S. 149, 168 (2003) (quoting *United States v. Vonn*, 535 U.S. 55, 65 (2002)).
[7] *See*, e.g., PHS Act § 2799A–10(a)(9)–(10).

on premiums.[8] In order to comply with the statutory mandate, these data elements should be removed from the file templates. The Departments' justification of this move in the IFC remains uncompelling. Congress very clearly conditions the reporting of rebates, fees, and remuneration on their being a premium impact. Of course, this reading is also inconsistent with the statutory purpose of Section 204, which is focused specifically on "the role of prescription drug costs in contributing to premium increases or decreases under such plans or coverage."

In addition, even if the PBM were able to identify what portion of the rebates were "reasonably" related to various national drug codes, it does not provide any productive way to attribute those dollars to premiums or out-of-pocket (OOP) costs paid by members. Ultimately, a plan or plan sponsor will more often than not receive a lump sum of rebates that they use to reduce various costs for plan members.[9] When making those determinations, the plan must establish premiums, maximum OOP thresholds, deductibles, and other cost sharing such as premiums and deductibles. Any metric that specifically assigned rebate dollars to any one element of coverage would be arbitrary and fail to provide any meaningful insight.

Given that a number of these data elements are well beyond the statutory authority included in Section 204 and have significant policy concerns and logistical hurdles, we have included an appendix (Data Elements Exceeding Statutory Authority) of these data elements by form at the end of these comments.

c. PCMA recommends that the Departments exclude manufacturer direct cost-sharing assistance from total annual spending.

PCMA appreciates the Departments' adoption of our recommendation to exclude from the definition of rebates and other price concessions, drug manufacturer cost-sharing assistance provided directly to enrollees on the basis that such amounts are not credited, or potentially even knowable, by the plan or coverage (or its service providers). However, we are disquieted that the Departments are moving forward with requiring the reporting of these amounts in terms of total spending.

[8] PBMs are compensated by plans and issuers for their services under any number of models. They may retain rebates negotiated with manufacturers or pharmacies or pass those rebates back to the plans and be paid administrative fees by the plans instead. Other compensation models include risk mitigation contracting with pharmacies. In any case, PBM compensation is about the same under any model, with the same level of effect of premiums, so calling out one method of compensation for reporting will yield artificial results.

[9] Overall net drug prices in Medicare and Medicaid fell from 2009 to 2018 while brand-name drug prices rose sharply, according to a report released by the Congressional Budget Office Wednesday. **Link:** Prescription Drugs: Spending, Use, and Prices | Congressional Budget Office (cbo.gov)

As the Departments concede, health plans and issuers (and PBMs) do not have direct access to financial assistance provided by manufacturers directly to beneficiaries. Reporting on these will be incomplete since PBMs do not have access to this data. For example, many "eVoucher" and "switch" operations take visibility away from the PBM on these types of funds, essentially evading capture and reporting by PBMs. These claims are being paid without our detection, though we know this is occurring. Moreover, as National Council for Prescription Drug Programs noted in their report on copay assistance, contractual modifications and patient consent are needed to address privacy, data sharing and member rights prior to sharing such data.[10] Even within the RxDC program this creates significant issues: the data to be reported by issuers in elements D3-D8 *could* contain manufacturer cost-sharing assistance but the PBMs responsible for extracting these dollars would have no way of knowing—the issuers won't know either.

While the Departments acknowledge that such reporting will only be required "to the extent information regarding the amount of these reductions is available to the plan",[11] given the acknowledged incompleteness of this data, as well as its lack of relevancy to the statutory purpose of Section 204, PCMA urges the Departments to remove this data element from the required reporting fields. This requirement exceeds the congressional mandate of the agencies in both letter and spirit. It pulls in supply chain transactions explicitly excluded within the statute and has no rational basis in the law. By including transactions associated with other supply chain entities, the rules go far beyond the statutory authority by inferring the inclusion of entire other entities left unnamed in the statute. Additionally, the statute does not contemplate these entities as filers, an implicit recognition that they were never meant to be included in the first place.

d. PCMA urges the exclusion of *bona fide* service fees (BFSF) since these amounts do not increase or decrease the costs of the drugs paid for by the plan.

The IFC requires plans to report the total amount of *bona fide* service fees but are not proposing to require that such amounts be reported separately for each therapeutic class or for each drug on the top 25 list. PCMA appreciates the Departments recognition that BFSF are not intended to directly affect the cost or utilization of specific prescription drugs. We further appreciate the limited reporting of this information. However, we continue to oppose the reporting of any BFSF amounts, as well as the inclusion of BFSFs in the definition of "prescription drug rebates, fees, and other remuneration."

[10] NCPDP. "Upstream Reporting of Copay Assistance, Issues Brief. June 208. Accessible at https://ncpdp.org/NCPDP/media/pdf/20180604_Upstream_Reporting_of_Copay_Assistance_Issues_Brief.pdf

[11] 86 Fed. Reg. at 66670.

PCMA opposes the reporting of BFSF on the basis that these are fair market value payments for services actually performed on behalf of drug manufacturers, unrelated to the processing of prescription drug claims, *and* for which a fee is not passed on, in whole or in part, to a client or customer of the entity. In line with Congress's goal of bringing transparency to health care items and services, it would be inconsistent to report on information that has no bearing on the price of health care items and services. Consistent with our comments above, section 9825(a)(9)–(10) of the Code, section 725(a)(9)–(10) of ERISA, and section 2799A–10(a)(9)–(10) of the PHS Act require that plans and issuers report rebates, fees, and other remuneration *only* to the extent that such amounts have any impact on premiums or result in the reduction in premiums and OOP costs.

Just like PBM-retained rebates, BFSFs are fair-market value payments for services actually performed. They have no bearing on premiums or OOP costs. Including such amounts is inconsistent with the statutory directive that these amounts be reported "with respect to prescription drugs prescribed to enrollees in the plan or coverage." BFSFs are regularly paid for services performed without respect to a particular drug and thus clearly fall outside of this statutory directive. Further, treating BFSFs as rebates, fees, and other remuneration is inconsistent and should be excluded for consistency with the requirements under the Medical Loss Ratio (MLR) rule, the Exchange Establishment rule and the QHP PBM Transparency rule, as well as the definitions used by the Medicare and Medicaid programs.

While there is no single definition of BFSFs, largely as a result of a complex interplay among drug manufacturer federal price reporting requirements, the regulatory definition of *bona fide* service fees has been replicated across federal health care programs.[12] In each of these cases, HHS defines these fees as fees paid by a manufacturer to an entity for meeting a set of specific conditions, distinct from rebates, fees, and other remuneration.

Because these fees are not passed on or retained by the client or customer of an entity (in this case, the issuer or health plan), existing federal programs generally treat such fees as unique and separate from other fees and remuneration. For example, in the Medicare Part D program, BFSFs that meet the safe harbor definition are not reported as direct and indirect remuneration and are not included as administrative expenses for Part D plan sponsors.

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

[12] See 42 C.F.R. § 423.501 (Part D definition), 42 C.F.R. § 414.702 (Part B definition), and 42 C.F.R. § 447.502 (Medicaid definition)

- 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 inaccurate. Their inclusion in any reports would undercut the delicate balance between PBMs who perform these services and manufacturers who pay for them. Further, the fair market value (FMV) determination is made by the manufacturer – not the PBM – so a PBM would only know a fee is paid to them, not whether the manufacturer considers it to be FMV for the service.

***In conclusion,* the Departments should remove any reporting obligation for items outside of Congress's specific instructions to them in the statute.**

2. The Departments Should Modify the Current Collection to Address PBM Technical Reporting Concerns.

In reviewing the original data collection templates and the revised templates, we have identified the following technical concerns. The Departments should understand these as mission critical recommendations in order to make the reporting program work as intended and provide the Departments with the data that Congress has authorized it to view and report publicly on. We stand ready to work with the Departments to clarify any of the points below, in advance of the December 27, 2022 initial submission period.

a. To best minimize burden and take advantage of existing reporting programs, the Departments should conduct annual reporting beginning in August of each year, not June.

PCMA has made this recommendation repeatedly since the CAA's enactment. Much of the physician and hospital spending data the Departments seek to collect as context requires at least six months of "run out" before it is reasonably complete. It is likely the most costly and complicated cases that will take the longest to fully settle. Further, the Medical Loss Ratio data – on which much of this reporting could borrow – is not due until July of each year, and the industry takes great pains to file these accurately. The Departments would thus be missing valuable context by rushing issuers and PBMs into annual reporting in June.

b. The instructions need to allow for good faith efforts or include language about inclusion "to the extent known."

The RxDC platform would collect, for example, prescription drug spending amounts that are not applied to the deductible or patient OOP maximum. While in some cases this could be because the PBM has adjudicated a claim for a non-covered product, for example, a drug for cosmetic use only, in other cases the patient may have gone *outside* of their pharmacy benefit and paid cash for a prescription for any number of reasons. PBMs have no way of collecting that information and thus no way to satisfy the requirement to report it.

c. The requirement to report drug spending associated with bundled or capitated payment arrangements will lead to inaccurate information.

The sole intention of one-size payments for a wide variety of services is to incentivize the provider to make the most cost-effective choice, given the patient's needs. While encounter data may include National Drug Codes for drugs, the provider is expressly not being paid for the product, but for their clinical judgment. In both cases the prescription drug spending cannot be teased out from the bundled or capitated payment without devising an allocation methodology that will systematically undercount or overcount drug spending. The Departments should remove reporting for drugs provided in bundles or capitated arrangements. This would bring the RxDC platform in line with the Departments' other recent rules, that exclude such spending from line-item reporting.[13]

d. There remains some risk in duplicate reporting in elements D3-D8, including reporting based on divergent levels of aggregation.

We appreciate that the Departments have made meaningful improvements in who reports which data elements, given that the relationship between the PBM and issuer is often contractual rather than ownership in nature. For example, PBMs will no longer need to report element D2 since the Departments will have that information at the appropriate level and be able to aggregate it. More specifically, there is the potential for two different entities to be submitting the D2 vs D3-D8 files in HIOS. The D3- D8 files could be inadvertently aggregated at a higher level than the D2 file aggregation. PBMs submitting on behalf of plans will be reliant on accurate information being provided by their clients. If the medical D2 file is submitted at the plan level this will also result in greater burden as the individual plan D3-D8 files will need to be separated within

[13] See 85 Fed. Reg. 72158, November 12, 20202. The Transparency in Coverage final rule and reporting framework for machine-readable files excludes the prices for drugs that would be paid for under bundled or capitated arrangements, from the prescription drug file, as originally finalized. The prescription drug file requirement is currently not being enforced pursuant to the FAQ 49 issued by the Departments in August 2021. (See link at footnote 5.)

individual plan rankings. As the PBM is the main subject of, and has the vast majority of the data required for the reporting, one option would be to allow PBMs to set the benchmark for aggregation for their clients. Additionally, the Department could allow the files to be aggregated per reporting entity, eliminating the administrative burden and need to coordinate how the data is presented.

e. The new aggregation restriction rules present a risk to disclosure of proprietary data.

In our interpretation of the revised Appendix 2 data entry instructions, we foresee a far greater burden than anticipated on the reporting teams with regard to file processing and data transfers. It was expected that most issuers, when submitting their own P files and D1-D2 files, could be aggregated at the PBM level for the D3-D8 information. However, it now seems that the PBM data – originally submitted in the aggregate – would now need to be broken out by issuer. To better meet the reporting process, PBMs may instead need to send their proprietary data to the issuer to submit on their behalf, *contra* the intent of the aggregate reporting decision in the first place.

In each of these cases, PCMA believes that reverting to the prior instructions will alleviate the reporting burden and better allow PBMs and issuers to report the data needed by the Departments in the most usable manner possible.

Conclusion

We appreciate the opportunity to provide comments on this PRA information collection notice. PBMs support the Administration's efforts to provide meaningful operational data to regulatory authorities, to better inform policymaking with regard to prescription drug benefits. We look forward to working with the Departments as it continues refining the Prescription Drug Data Collection program prior to its rollout later this year. If you need additional information, please contact me at tdube@pcmanet.org.

Sincerely,

Tim Dube

Tim Dube
Vice President, Federal Regulatory Affairs

Enclosure: Appendix, Attachments

APPENDIX
Data Elements Exceeding Statutory Authority

ICR File	Data Element	Rationale
D2	Disallowed amounts for non-covered services or for prescription drugs not on a plan or coverage's formulary	(a)(1)-(10) only refer to plan spending, and do not cover non-covered drugs or services
D2	Cost-sharing amounts not applied to the deductible or OOP maximum	(a)(1)-(10) do not include any elements related to deductibles or OOP maximums
D3	Manufacturer Cost Sharing Assistance by Drug	(a)(9) only refers to transfers between manufacturers and a plan or PBM, and does not include transfers from a manufacturer to a member or pharmacy
D4	Manufacturer Cost Sharing Assistance by Drug	(a)(9) only refers to transfers between manufacturers and a plan or PBM, and does not include transfers from a manufacturer to a member or pharmacy
D5	Manufacturer Cost Sharing Assistance by Drug	(a)(9) only refers to transfers between manufacturers and a plan or PBM, and does not include transfers from a manufacturer to a member or pharmacy
D7	Manufacturer Cost Sharing Assistance by Drug	(a)(9) only refers to transfers between manufacturers and a plan or PBM, and does not include transfers from a manufacturer to a member or pharmacy
D8	Manufacturer Cost Sharing Assistance by Drug	(a)(9) only refers to transfers between manufacturers and a plan or PBM, and does not include transfers from a manufacturer to a member or pharmacy
D6	Bona Fide Service Fees as a Separate Element	(a)(9) only refers to transfers between manufacturers and a plan or PBM that are related to a member prescription. Bona fide service fees are not reasonably related
D7	Net Transfer of Remuneration from Manufacturers to Plans/Issuers/Carriers/PBMs by Therapeutic Class	(a)(9)(A) only requires a total transfer figure
D7	Net Transfer of Remuneration from Pharmacies, Wholesalers, and Other Entities to Issuers/Plans/Carriers/PBMs	(a)(9) only refers to transfers between manufacturers and a plan or PBM, and does not include transfers between other entities
D7	Restated Prior Year Rebates, Fees and Other Remuneration	(a)(1)-(10) only refer to reporting for individual years

ICR File	Data Element	Rationale
D8	Net Transfer of Remuneration from Manufacturers to Plans/Issuers/Carriers/PBMs by Drug	(a)(9)(B) only requires a total transfer figure
D8	Net Transfer of Remuneration from Pharmacies, Wholesalers, and Other Entities to Issuers/Plans/Carriers/PBMs	(a)(9) only refers to transfers between manufacturers and a plan or PBM, and does not include transfers between other entities