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The Honorable Xavier Becerra
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Re: Tri-Department Interim Final Rule: Prescription Drug and Health Care Spending (CMS-9905-IFC)

Dear Acting Associate Director DeHarde, Deputy Commissioner O'Donnell, Acting Assistant Secretary Khawar, and Secretary Becerra:

On November 23, 2021, the U.S. Department of Health and Human Services (HHS), U.S. Department of Treasury, U.S. Department of Labor (together "the Departments") and the Office of Personnel Management (OPM) published an interim final rule with comment period (IFC) entitled "Prescription Drug and Health Care Spending."[1] This Interim Final Rule (IFR) followed an identically titled Request for Information (RFI) published five months earlier, on which the Pharmaceutical Care Management Association (PCMA) provided timely comments.[2] This IFC implements Division BB, Title II, Section 204 of the Consolidated Appropriations Act of 2021 (CAA), which requires group health plans and health insurance issuers to provide annually a narrowly delineated set of aggregated healthcare spending data to the Departments. Under this

[1] 86 Fed. Reg. 66662, November 23, 2021. The Departments have also opened an Information Collection Request under this title, on which PCMA is providing separate written comments.
[2] 86 Fed. Reg. 32813, June 23, 2021. PCMA's comments are available at https://www.regulations.gov/comment/EBSA-2021-0005-0035.

Section, the Departments will produce reports every two years describing prescription drug spending and pricing trends.[3]

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 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.

As noted in our original comments on the RFI, PCMA is supportive of many efforts by this Administration to bring meaningful and actionable transparency to health care purchasers and consumers. **This interim final rule is a positive step in that direction. With minimal changes, this rule will provide the Departments with the insights they need to pinpoint that drug manufacturer pricing and anti-competitive behaviors directly lead to higher prescription drug spending. These data will also demonstrate the important role that plans and issuers and their pharmacy benefit managers (PBMs) play in reducing overall prescription drug costs.**

Two months following the publication of the RFI, the Departments and OPM have issued guidance delaying the reporting of these data under this provision by one year, until December 27, 2022.[4] The IFR acknowledges that much of the information an issuer needs is held instead by third-party administrators including PBMs.

In this letter, we first thank the Departments for incorporating much of PCMA's input on the RFI questions based on our initial public comments. We raise a number of concerns related to timing and data elements exceeding statutory authority. We have highlighted areas where we believe the Departments and OPM have veered from the 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). As we explain further in these comments, Section 204 is very prescriptive in its definition of the data points to be reported. Based on what is exactingly required by the statute, we object to the expansion of data reporting to now also include: (1) rebates, fees, and other remuneration retained by PBMs; (2) manufacturer cost-sharing assistance; and (3) *bona fide* service fees. Each of these elements is well beyond the bounds of the data identified by Congress in Section 204 and, further, lacks any true meaning

[3] Public Law 116-260, December 27, 2020, added parallel provisions at section 9825 of the Internal Revenue Code (the Code), section 725 of the Employee Retirement Income Security Act (ERISA), and section 2799A-10 of the Public Health Service Act (PHS Act).
[4] U.S. Department of Labor. FAQS 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.

within the context of the statute which is designed to track the role of prescription drug costs in contributing to premium increases or decreases.

1. **PCMA Thanks CMS for Heeding our Recommendations with Respect to Reporting Timelines and Data Aggregation.**

The IFR requires group health plans and health insurance issuers to report specified information to each of the Departments beginning December 27, 2022, and annually by June 1 of each year thereafter, in a specified form and manner. PCMA appreciates the Departments' exercise of enforcement discretion with respect to the reporting of CY 2020 and CY 2021 information to alleviate burdens related to timing and increase the completeness of reported data. We will revisit timeframes later in this document to discuss remaining industry concerns in this area. This reported data will capture both pharmacy and medical benefit drugs. However, we appreciate that medical benefit drugs will not be reflected in the "top-50" lists, as being outside the purview of typical pharmacy benefits. We appreciate the Departments' receptivity to receiving our feedback and believe many of the data elements included in the IFR are well-reasoned and flow directly from concepts first discussed in the RFI, accounting for stakeholder input.

2. **PCMA Recommends Additional Changes Related to Timing of Data Submission.**

   a. **The Departments should delay annual reporting from June 1 to August 1 (or later) to ensure full calendar year data is available.**

Under the IFR, data submissions will generally be due each June 1, beginning with data reporting for CY 2022 (due June 1, 2023). While this date is presumably designed to adequately capture any data collection lag associated with the reporting year, PCMA believes that an annual reporting deadline of August 1 will better accommodate for lag time between the closing of the plan year and the beginning of the reconciliation process and allow for plan year close-outs prior to reporting. Based on information received from our member companies, June 1, 2022 may not (for example) 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.[5] Based on this data, a minimum of eight months is required, with a preference of 11 to 17 months for true data completeness.

The following example illustrates the importance of providing for a sufficient lag time in ensuring completeness of data, as discussed above. Rebates are currently reconciled upon the completion of a contract and are paid retrospectively. There may be a lag between the

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

closing of the plan year and the beginning of the reconciliation process, especially in the context of an outcomes-based agreement where patient data is also being collected. 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, thereby, would undermine a key finding and misrepresent the data through omission. 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. The June 1 reporting builds in no time for any of these necessary data cleaning steps.

3. The Departments Should Eliminate from the Final Regulations Any Data Reporting that is Beyond Its Statutory Authority.

In the IFR, the Departments propose to require plans to report not only drug pricing information delineated in the statute, but also a much broader scope of data far outside of the plain language of the statute. Included among these novel reporting elements are: (1) 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, the Departments and OPM, while well-intentioned, clearly lack the statutory authority to regulate beyond the narrow bounds of the delineated 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

[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)).

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 on premiums.[8] In order to comply with the statutory mandate, these data elements should be removed in the rule and from the file templates in the guidance before any submissions are made.

In the preamble, the Departments attempt to justify this improper expansion of the statute based on an incorrect reading of the statute. According to the rule: "[t]he Departments interpret 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 to require plans and issuers to report the total amount of rebates, fees, and any other remuneration, *and separately*, the extent to which rebates, fees, and any other remuneration impact premiums and out-of-pocket costs."[9] This is either a poor attempt at legal justification or a misreading of the statute, which very clearly conditions the reporting of rebates, fees, and remuneration in both sections (9) and (10) on 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

[7] *See*, e.g., PHS Act § 2799A–10(a)(9)–(10).
[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] 86 Fed. Reg. 66662, 66669 (November 23, 2021) (Emphasis added).

that they use to reduce various costs for plan members.[10] 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 completely 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.

Additionally, due to the dual reporting mechanism included in the IFR, there is no effective way for PBMs and plan sponsors to communicate on how to report these data elements. PBMs would be able to report total rebate dollars, but plan sponsors would then be unable to use those figures to provide any further detail.

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.

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 type 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.[11]

[10] 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)
[11] NCPDP Upstream Reporting of Copay Assistance Issues Brief

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",[12] 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, they completely leave out 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 IFR 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."

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' 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 out-of-pocket costs.

Just like PBM-retained rebates, BFSFs are fair-market value payments for services actually performed. They have no bearing on premiums or out-of-pocket 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

[12] 86 Fed. Reg. at 66670.

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 Qualifies Health Plan (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 (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)). 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 in categories of 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:

- 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.

Recommendation: **CMS should address and respond to the data reporting concerns raised and clarify their perspective regarding the relevance and rationale for including statutorily out-of-scope data reporting requirements.**

Conclusion

PCMA supports the IFR's intent to gather specific information regarding pharmacy benefits and prescription drug costs. However, we caution against collecting pricing and discount data that will adversely affect beneficiary experience. We thank the Departments for the opportunity to provide comments prior to full implementation, 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

cc: Carol Weiser
Rachel Leiser Levy
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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
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