4120-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 423

[CMS-4218-NC]

RIN 0938-AW09

Request for Information (RFI): Pharmacy Benefit Manager Compensation and Data Collection

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: This request for information (RFI) solicits technical input on the services and business practices of pharmacy benefit managers ("PBMs") and their affiliates to inform implementation of recent legislation. It specifically focuses on gathering information to inform two specific legislative requirements that are effective beginning calendar year 2028: restrictions on the remuneration that PBMs and their affiliates may receive for services in connection with the utilization of covered Part D drugs; and data reporting requirements.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by 5 p.m. on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: In commenting, refer to file code CMS-4218-NC.

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

1. *Electronically*. You may submit electronic comments on this regulatory document to https://www.regulations.gov/docket/CMS-2026-2212. Follow the "Submit a comment" instructions.

2. *By regular mail*. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-4218-NC,

P.O. Box 8013,

Baltimore, MD 21244-8013.

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

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

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-4218-NC,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

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

FOR FURTHER INFORMATION CONTACT: Claire Schreiber, (410) 786-8939.

Katie Perez, (667) 290 8648.

PartDPBM@cms.hhs.gov, For general questions related to section 6224 of the CAA, 2026, ("Modernizing and Ensuring PBM Accountability").

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the

close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that website to view public comments. CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

This request for technical input is narrowly focused on gathering information on current business practices to inform two specific requirements added to the Social Security Act (the Act) by section 6224 of the Consolidated Appropriations Act, 2026 (CAA, 2026): restrictions on the remuneration that PBMs and their affiliates may receive for services in connection with the utilization of covered Part D drugs and data reporting requirements, both effective beginning in calendar year (CY) 2028. CMS is also implementing other provisions of the CAA, 2026, including other provisions of section 6224 of CAA, 2026, such as compliance and enforcement mechanisms, as well as requirements in section 6223 of CAA, 2026, including those related to Part D pharmacy contracting standards and affiliate pharmacy and pharmacy incentive payment reporting requirements. Those topics are not the focus of this request for technical input.

II. Solicitation of Public Comments

While we invite all relevant input, we are soliciting information from interested parties regarding the topics described in this section for the purpose of informing rulemaking on section 6224 of the CAA, 2026. In preparing submissions, respondents should clearly identify which section(s) of this RFI they are responding to and the circumstances to which their responses relate. We encourage commenters to provide specific examples, data, or documentation where possible.

A. Definition of "Pharmacy Benefit Manager"

Section 1860D-12(h)(7)(C) of the Act defines “pharmacy benefit manager” broadly to include any person or entity that, directly or through an intermediary, acts as a price negotiator or group purchaser on behalf of a prescription drug plan (PDP) or PDP sponsor or manages the prescription drug benefits provided by such plan or sponsor. The definition expressly encompasses entities that perform one or more functions, including claims processing, utilization review, prior authorization, appeals adjudication, pharmacy network contracting, and cost control, regardless of whether the entity calls itself a pharmacy benefit manager.

- Section 1860D-12(h)(7)(C) of the Act includes a reference to "the provision of related services" in addition to the specific functions listed previously.

++ What "related services" do PBMs, or entities that perform functions identified as PBM services under section 1860D-12(h)(7)(C) of the Act, typically provide?

++ Are there additional functions commonly performed by PBMs, or otherwise considered to be PBM services, that are not expressly identified in the Act?

- Section 1860D-12(h)(7)(C) of the Act states that the PBM definition applies "irrespective of whether such person or entity calls itself a “pharmacy benefit manager”." Are there categories of entities that normally perform one or more of the functions specified in that provision or a function as identified in the first bulleted paragraph, but do not self-identify as PBMs, that would qualify as PBMs under this definition?

- Section 1860D-12(h)(7)(C) of the Act applies the PBM definition to entities that provide functions “directly or through an intermediary.”

++ Are there categories of entities that commonly provide functions through an intermediary on behalf of a PDP sponsor or prescription drug plan?

- For each category of intermediary listed in the fourth bulleted paragraph, please provide available information on the following:

++ Ownership/control: The typical ownership or governance relationship that exists between the intermediary and the PBM or PDP sponsor.

++ Contractual relationship: The typical nature of the contractual relationship between the intermediary and the PBM or PDP sponsor.

++ Services performed: The functions or activities the intermediary typically carries out.

++ Payments received: The types of payments the intermediary typically receives.

++ Source of payments: Which entity makes the payments (for example, PBM, PDP sponsor, manufacturer).

++ Payment variability: Whether and how payments vary based on factors such as utilization (for example, covered Part D drugs), formulary status, rebate value, pricing benchmarks (for example, wholesale acquisition cost (WAC), average wholesale price (AWP)), pharmacy channel, product selection.

B. Definition of "Affiliate"

Section 1860D-12(h)(7)(A) of the Act defines "affiliate" to include any entity that, directly or indirectly, owns or is owned by, controls or is controlled by, or is otherwise related in any ownership structure to the PBM or PDP sponsor, or that acts as a contractor, principal, or agent to the PBM or PDP sponsor insofar as it performs any of the pharmacy benefit management functions described in the provision. Under this definition, any entity in an ownership relationship with a PBM or that performs certain functions on behalf of a PBM on a contractual or other basis is considered an affiliate and is subject to the bona fide service fee (BFSF) restrictions with respect to services provided in connection with the utilization of covered Part D drugs.

- CMS welcomes stakeholder input on whether the following entities are affiliates under the affiliate definition as defined in section 1860D-12(h)(7)(A) of the Act. Why or why not?

++ Affiliated provider group

++ Data vendors

++ Group purchasing organization/rebate aggregator

++ Long-term care pharmacy

++ Mail-order pharmacy

++ Payment facilitator

++ Pharmaceutical relabeler

++ Pharmaceutical wholesaler

++ Pharmacy benefit consultant

++ Retail pharmacy

++ Specialty pharmacy

- What other types of entities might meet the section 1860D-12(h)(7)(A) affiliate definition? Please also include an explanation of why it is appropriate to conclude that this type of entity is an affiliate of a PBM or PDP sponsor.

- For each affiliate type listed in the first bulleted paragraph and for any additional entities identified under the second bulleted paragraph, please provide available information on the following:

++ Ownership/control: The typical ownership or governance relationship that exists between the affiliate and a PBM or PDP sponsor.

++ Contractual relationship: The typical nature of the entity's contract with the PBM or PDP sponsor.

++ Services performed: The functions or activities the entity carries out.

++ Payments received: The types of payments the entity typically receives.

++ Source of payments: Who makes the payments (for example, PBM, PDP sponsor, manufacturer)?

++ Payment variability: Whether and how payments vary based on factors such as utilization (for example, covered Part D drugs), formulary status, rebate value, pricing benchmarks (for example, WAC, AWP), pharmacy channel, product selection.

- Are there other regulatory or statutory definitions of "affiliates," or similar concepts, administered by HHS or another federal or state agency, that currently apply to entities that have

an ownership, control, or contractual relationship with entities performing PBM functions?"? How do those definitions align with, or differ from, the definition of "affiliate" in section 1860D-12(h)(7)(A) of the Act?

C. Definition of "Bona Fide Service Fee"

Section 1860D-12(h)(7)(B) of the Act defines "bona fide service fee" as a fee that is reflective of fair market value for a bona fide, itemized service actually performed on behalf of an entity, that the entity would otherwise perform or contract for in the absence of the service arrangement, and that is not passed on in whole or in part to a client or customer. The fee must be a flat dollar amount and shall not be directly or indirectly based on or contingent upon drug price, rebate amounts, formulary placement decisions, referral volume, or other amounts or methodologies prohibited by the Secretary.

- What existing types of remuneration agreements with PBMs or affiliates of a PBM are not tied to a "service actually performed on behalf of an entity"?

- Section 1860D-12(h)(7)(B) of the Act requires that a qualifying service be one that the paying entity "would otherwise perform (or contract for) in the absence of the service arrangement. Are there examples of services provided by PBMs or their affiliates for which a contracting entity provides remuneration, but which the contracting entity would not otherwise perform or contract for?

- Section 1860D-12(h)(7)(B) of the Act specifies that bona fide service fees "shall not be directly or indirectly based on, or contingent upon— (i) drug price, such as wholesale acquisition cost or drug benchmark price (such as average wholesale price); (ii) the amount of discounts, rebates, fees, or other direct or indirect remuneration with respect to covered Part D drugs dispensed to enrollees in a prescription drug plan, except as permitted pursuant to paragraph (1)(A)(ii); (iii) coverage or formulary placement decisions or the volume or value of any referrals or business generated between the parties to the arrangement; or (iv) any other amounts or methodologies prohibited by the Secretary." What are examples of fees that are

contingent on amounts or methodologies other than those listed in (i) through (iii) of the previous sentence?

- Section 1860D-12(h)(1)(A)(ii) of the Act specifies that "an incentive payment (as determined by the Secretary) paid by a PDP sponsor to a pharmacy benefit manager or an affiliate of a pharmacy benefit manager that is performing services on behalf of such sponsor shall be deemed a 'bona fide service fee' (even if such payment does not otherwise meet the definition of such term]" if it meets certain requirements, which are very similar to a subset of the requirements for BFSFs. It also authorizes the Secretary to define any additional requirements. What types of remuneration between PDP sponsors and PBMs or affiliates currently provide an incentive for PBM or affiliate performance, and how do they differ from the definition of 'bona fide service fee'?

D. Determination of "Fair Market Value"

Section 1860D-12(h) of the Act requires the Secretary to define "fair market value" through notice-and-comment rulemaking. Fair market value serves as the standard against which BFSFs and incentive payments are assessed, and as the benchmark for evaluating remuneration arrangements between PBMs, affiliates, and other supply chain entities under the Secretary's review authority.

- What methods for determining fair market value for services provided by PBMs or their affiliates are most commonly used? What are the benefits and limitations to those methods?

- Do standard practices for determining fair market value differ depending on the entity type (that is, a PBM vs. a PBM affiliate such as a rebate aggregator, pharmacy, wholesaler, health plan, etc.)?

- How do standard practices for determining fair market value take into account, if at all, the concentration and vertical integration of the PBM market?

E. Pharmacy Payment

Section 1860D-12(h)(4) of the Act states that "Nothing in this subsection shall be construed as—(A) prohibiting flat dispensing fees or reimbursement or payment for ingredient costs (including customary, industry-standard discounts directly related to drug acquisition that are retained by pharmacies or wholesalers) to entities that acquire or dispense prescription drugs; or (B) modifying regulatory requirements or sub-regulatory program instruction or guidance related to pharmacy payment, reimbursement, or dispensing fees."

- What current pharmacy payment or compensation arrangements meet either description (A) or description (B) in the previous paragraph?
- What current pharmacy payment or compensation arrangements do not meet either description (A) or description (B) in the first paragraph of this section?

F. Data Collection

Not later than July 1 of each year, beginning in 2028, PBMs must submit an annual report covering the prior plan year to both the PDP sponsor and the Secretary. The report, which, per section 6224 of the CAA, 2026, is not subject to the Paperwork Reduction Act of 1995 (Chapter 35 of title 44, United States Code, must include detailed information on drug utilization and dispensing activity, drug costs and pricing, enrollee out-of-pocket spending, direct and indirect remuneration (DIR), pharmacy reimbursement, overall plan spending, and revenue retained by the PBM or its affiliates. What additional data elements beyond those PBMs are required to report under section 1860D-12(h)(1)(C) would help inform CMS' implementation and monitoring of the provisions of Section 6224 of the CAA, 2026?

III. Collection of Information Requirements

This is an RFI only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information

pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, we are not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. We note that not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. In addition, we note that CMS will not respond to questions about the policy issues raised in this RFI.

We will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. We may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in the responders' written responses. Contractor support personnel may be used to review responses to this RFI. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. In addition, we may publicly post the public comments received, or a summary of those public comments.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on June 15, 2026.

Robert F. Kennedy, Jr.

Secretary,

Department of Health and Human Services.

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