HDA
Healthcare Distribution Alliance
HEALTH DELIVERED

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Dr. Mehmet Oz
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4218-NC
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Request for Information: Pharmacy Benefit Manager Compensation and Data Collection, CMS-4218-NC

Dear Administrator Oz,

The Healthcare Distribution Alliance (HDA) appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS) Request for Information (RFI) soliciting input on pharmacy benefit manager (PBM) services to inform implementation of Section 6224 of the Consolidated Appropriations Act of 2026 (CAA).[1]

HDA represents primary pharmaceutical distributors[2]—the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently.[3]

HDA seeks to be a constructive resource to CMS as it implements the requirements set forth in the CAA, with particular attention to the distinct role of pharmaceutical distributors within the supply chain. In developing CAA regulations, HDA urges CMS to focus on the statute's core purpose: improving transparency and accountability for intermediaries that represent Part D plan (PDP) sponsors in the management, development, and design of prescription drug benefits.

[1] 91 Fed. Reg. 36776 (June 18, 2026), https://www.govinfo.gov/content/pkg/FR-2026-06-18/pdf/2026-12344.pdf.
[2] As defined in 21 U.S.C. § 360eee(29).
[3] HDA, Policy Overview (last accessed June 29, 2026), https://www.hda.org/policy-overview/. HDA's policy priorities are centered on preserving a reliable prescription drug supply chain and supporting efficient patient access to medicines. HDA has long supported policy solutions that strengthen the safety, security, resilience, and efficiency of the pharmaceutical supply chain, including through work on pharmaceutical traceability, DSCSA implementation, supply chain preparedness, and secure distribution practices.

HDA members purchase pharmaceutical products from manufacturers and deliver those products to pharmacies, hospitals, physician practices, and other dispensing providers through safe, secure distribution networks governed by the Drug Supply Chain Security Act (DSCSA) and other applicable state and federal laws. Importantly, distributors do not perform any of the functions that define a "pharmacy benefit manager" under Section 1860D-12(h)(7)(C), nor do they perform any such functions on behalf of PDPs or PDP sponsors. Distributors do not set wholesale acquisition cost ("WAC"), set prices on behalf of Part D plans, design or administer formularies, determine beneficiary cost-sharing, negotiate rebates in exchange for formulary placement, adjudicate pharmacy claims, establish pharmacy reimbursement methodologies, or make coverage determinations. Instead, distributors arrange for the safe physical transport of medicines across the U.S. on behalf of healthcare providers and drug manufacturers. Because distributors neither manage nor influence the Part D prescription drug benefit, they occupy a fundamentally different role in the pharmaceutical supply chain than PBMs.

Our responses to the RFI follow below.

I. Wholesale Distributors Focus on Physical Distribution of Prescription Drugs

Congress has already established a comprehensive federal regulatory framework governing wholesale pharmaceutical distribution through the DSCSA. The DSCSA expressly defines "wholesale distributor" and related terms and regulates wholesale distributors based on their role in taking physical possession of, handling, storing, and distributing prescription drugs. Because wholesale distributors take custody of prescription drugs, the DSCSA subjects them to a distinct set of licensing, product tracing, verification, and other supply chain security requirements.

- "Wholesale distributor" means "a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution." 21 U.S.C. § 360eee(29).

- "Wholesale distribution" means the distribution (or receipt) of prescription drugs to a person other than a consumer or patient, subject to specified statutory exceptions. *See* 21 U.S.C. § 353(e)(4).

- "Distribute" or "distribution" means "the sale, purchase, trade, delivery, handling, storage, or receipt of a product," excluding dispensing pursuant to a prescription. 21 U.S.C. § 360eee(5).

The DSCSA thus recognizes wholesale distributors as a distinct category of regulated supply chain participant whose responsibilities are centered on the physical custody and movement of prescription drugs. Those responsibilities are fundamentally different from the benefit management functions performed by PBMs.

CMS should interpret Section 6224 consistently with this established statutory framework. Nothing in the CAA suggests that Congress intended to redefine wholesale distribution or supplant the existing federal regulatory regime governing wholesale distributors.

II. Section 6224 Defines "PBMs" and "Affiliates" Based on Benefit Management Functions and Common Ownership Relationships, Not Wholesale Distribution Activities

a. Definition of "PBM": Wholesale Distributors Do Not Meet the Statutory Definition of a PBM

Section 1860D-12(h)(7)(C) defines a "pharmacy benefit manager," in part, as an entity that (1) acts as a price negotiator or group purchaser on behalf of a PDP, or (2) **manages** the prescription drug benefits provided by such PDP. Wholesale distributors satisfy neither requirement.

The statute is directed to entities that exercise authority over the Part D benefit on behalf of a PDP—not entities that participate elsewhere in the pharmaceutical supply chain. As discussed above, distributors take title to prescription drugs and distribute those products to dispensing providers across every corner of the U.S., including rural America. They do not negotiate drug prices or purchasing arrangements on behalf of PDP sponsors, nor do they manage prescription drug benefits on behalf of PDP sponsors or perform the functions enumerated in Section 1860D-12(h)(7)(C), such as administering formularies, adjudicating claims, conducting utilization management, or establishing pharmacy reimbursement on behalf of PDP sponsors.

Because distributors neither act on behalf of PDP sponsors in managing benefits nor otherwise perform the statutory PBM functions, they do not fall within the statutory definition of a PBM.

b. Definition of "Affiliate": Wholesale Distributors Are Not PBM Affiliates Solely Because They May Contract With PBMs or PDPs

The definition of "affiliate" in Section 1860D-12(h)(7)(A) should be interpreted consistently with the statute's definition of "pharmacy benefit manager." The statute provides that a contractor, principal, or agent to a PBM or PDP sponsor is an affiliate only "insofar as" it performs the functions described in Section 1860D-12(h)(7)(C). Accordingly, a contractual relationship with a PBM or PDP sponsor, standing alone, is insufficient to render an entity an affiliate for purposes of Section 6224. Rather, the entity must perform one or more of the statutory PBM functions on behalf of the PBM or PDP sponsor.

Wholesale distributors do not satisfy that standard. Pharmaceutical distributors provide logistics infrastructure and their services are directed to the physical distribution of prescription drugs, including purchasing inventory, warehousing products, processing orders, supporting returns and recalls, maintaining secure distribution networks, and delivering medicines to authorized dispensers. Those activities facilitate the physical movement of products through the supply chain; they do not constitute the benefit management functions identified in Section 1860D-12(h)(7)(C).

A traditional distributor may fulfill orders or distribute drugs to a PBM-owned pharmacy, as it would to any other licensed pharmacy, but such services do not constitute benefit management functions identified in Section 1860D-12(h)(7)(C) on behalf of a PBM or PDP Sponsor. Accordingly, a distributor does not become an "affiliate" merely because it has a commercial relationship or contractual arrangement with a PBM or PBM-owned specialty pharmacy, any more than a shipping company, warehouse operator, software as a service company, or other supply chain participant would become an affiliate solely by providing services to a PBM that do not fall within the benefit management functions identified in Section 1860D-12(h)(7)(C). The statute's limiting phrase "insofar as" precludes such an expansive, arbitrary, and capricious interpretation.

III. The Statutory Structure Confirms Congress Did Not Intend for Distributors to be Treated as "PBMs" or Automatically Considered "Affiliates"

The structure of Section 6224 reinforces the conclusion that Congress did not intend pharmaceutical distributors to be treated as PBMs or their affiliates. Multiple provisions of the statute distinguish entities that administer Part D benefits from those that participate in the physical distribution of prescription drugs.

First, Section 6224 directs the Comptroller General to study the effects of the CAA on "drug wholesalers" and "pharmacy benefit managers" as separate categories of market participants. Congress's decision to identify wholesalers independently from PBMs reflects its recognition that they perform fundamentally different functions within the pharmaceutical supply chain. CMS should interpret the statute consistently with that distinction. Doing so otherwise would be arbitrary and capricious.

Second, Congress expressly preserved "customary, industry-standard discounts directly related to drug acquisition that are retained by pharmacies or wholesalers." Section 1860D-12(h)(4)(A). That rule of construction recognizes that wholesale distribution involves longstanding commercial arrangements related to acquiring and distributing prescription drugs—not the manufacturer compensation arrangements associated with pharmacy benefit management. Reading Section 6224 to encompass traditional wholesale distribution activities would undermine this express statutory distinction and blur the separate roles Congress established for distributors and PBMs.

Finally, Congress has also distinguished wholesale distribution activities in other provisions of the Social Security Act and the DSCSA. For example, the Medicaid Average Manufacturer Price (AMP) statute specifically addresses manufacturer-paid "distribution service fees" and "inventory management fees" paid to "wholesalers." 42 U.S.C. § 1396r-8(k)(1)(B)(i)(II). When Congress intends to regulate manufacturer compensation associated with wholesale distribution, it knows how to do so expressly. The absence of comparable language in Section 6224 is therefore significant.

Rather than regulating manufacturer payments to wholesalers, Section 6224 focuses on compensation paid to PBMs and their affiliates in connection with pharmacy benefit management functions performed on behalf of PDP sponsors. The statutory text thus

indicates that Congress did not intend the statute to reach "wholesalers" or wholesale distribution services to providers and drug manufacturers.

IV. CMS Should Not Conflate Wholesale Distribution With PBM Business Models

A central issue in this RFI is how CMS should understand and implement PBM compensation restrictions and data reporting requirements. The RFI seeks technical input on services, fees, and payment structures involving PBMs and PBM affiliates in connection with Medicare Part D drug utilization.[4]

As discussed above, PBMs operate in connection with prescription drug benefit management, including by designing formularies, performing drug utilization review, or acting as a price negotiator or group purchaser on behalf of PDPs or PDP sponsors. By contrast, distributors operate in a different part of the pharmaceutical supply chain. Thus, as CMS evaluates PBM compensation, HDA urges the agency to avoid overbroad terminology or arbitrary or capricious reporting concepts that could sweep in business models that are unrelated to the policy concerns presented by PBM compensation and data collection.

For example, "fees for access" (i.e., formulary access to ensure coverage and reimbursement for a certain pharmaceutical) are different from distributors' "fees for service" because these fees compensate distributors for securely storing, handling, and physically moving product to healthcare providers.

Instead, distributor compensation should be understood through the lens of bona fide services. Existing CMS regulations define a bona fide service fee (BFSF) as a fee paid by a manufacturer to an entity that reflects fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer, where the manufacturer would otherwise perform or contract for the service, and that is not passed on to the entity's client or customer.[5]

Manufacturer-distributor arrangements support a wide range of services that are necessary for product movement and supply chain operations. These may include:

- order processing and customer account support;
- warehousing and inventory management;
- pick, pack, and ship functions;
- transportation and delivery;
- cold-chain and specialty handling;

[4] 91 Fed. Reg. 36776 (June 18, 2026).
[5] 42 C.F.R. § 447.502.

- chargeback administration and contract operations support;
- returns processing and reverse logistics;
- recall support;
- data reporting related to channel operations;
- credit and financial services associated with distribution;
- compliance support related to licensing, product traceability, and authorized trading partner requirements;
- provide one-stop-shopping convenience for pharmacists and physicians where they can make one call or log into one system to order any medicine from any manufacturer in the world and have that product delivered the next day; and
- other services required to maintain a secure and efficient distribution system.

This framework is well-suited to distributor arrangements because distributors perform concrete, necessary services for manufacturers to move products in the supply chain. These arrangements are separate and distinct from PBM arrangements and fall outside the scope of this RFI.

V. CMS Should Clarify That its Fair Market Value Guidance Will Apply Only to Arrangements Governed by Section 6224

HDA urges CMS to clarify that the fair market value (FMV) principles articulated in any forthcoming guidance apply solely for purposes of implementing Section 6224 of the CAA and are not intended to modify, replace, or inform FMV standards established under other federal statutes or regulations. Numerous federal health care laws—including the Anti-Kickback Statute and the physician self-referral law (Stark Law)—employ FMV or analogous valuation concepts for distinct statutory purposes and under different regulatory standards. Those frameworks have developed through separate statutory authority, regulations, guidance, and case law, and often apply to different business arrangements. Reading the CAA's FMV provisions to alter these existing standards would create unnecessary uncertainty and could disrupt longstanding compliance practices without any indication that Congress intended such a result. Accordingly, CMS should expressly state that the FMV discussion in any forthcoming guidance or regulation is limited to PBM and Affiliate arrangements subject to Section 6224 and should not be construed to interpret or affect FMV determinations under any other federal healthcare program or legal framework.

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HDA welcomes the opportunity to continue working with CMS as a constructive resource on the distinct role of distributors in the pharmaceutical supply chain. Thank you for the opportunity to submit comments in response to the RFI. If you have any questions about these comments, please do not hesitate to contact me at pkelly@hda.org.

Respectfully submitted,

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Healthcare Distribution Alliance